



Master Library Guide

All Courses
June 2019



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Overview

UL PURE™ Learning has partnered with corporate and government clients in the Life Science, Health Care, Energy and General Industry markets for over 30 years.

We currently maintain more than 500 eLearning courses that are written and reviewed by recognized subject matter experts, including the US FDA. In fact, more than 1 million industry professionals, including over 36,000 FDA investigators, have completed over seven million courses since 2003.

Courses are regularly updated to reflect the most current expectations and requirements of regulators and industry groups. Our global quality and compliance management methodology has resulted in measurable performance and compliance improvements. Our eLearning philosophy is based on Mastery Learning, which has been proven to improve retention and change behavior in adult learners through methods that include interaction with dynamic content and built-in assessments.

Should your organization have unique training requirements, you can rely on our Content Solutions team, which develops about 4,000 courses each year for our clients. Our team shares best practices as it relates to instructional design and multi-media, such as incorporating your organization's unique content and branding into our standard courses.

Many courses are mobile-ready and can be translated into 34 languages. Courses can be hosted independently on your own LMS, or take advantage of UL's industry standard LMS for Life Science organizations – ComplianceWire®. Learn more about UL PURE Learning's courses and additional solutions at ulpurelearning.com.

Medical Device - Sales & Marketing

This library, specifically targeted to the Medical Device industry, helps to meet the needs of regulatory, legal, communications, compliance and other Medical Device professionals who engage in marketing, advertising, promotional and communications activities. Incorporating these courses into your vendor credentialing, or Health Care Industry Representative HCIR programs, helps to ensure that sales representatives have the proper training to enter health care facilities.

Clinical: Medical Device

This library, specifically targeted to the Medical Device industry covers underlying Good Clinical Practice (GCP) concepts as well as specific, advanced information for clinical professionals based on their role in the study. The courses are designed for those in clinical development, clinical operations, quality management and regulatory affairs. The global curriculum includes courses describing FDA regulations, ISO 14155, EU directives and ICH guidance; many courses feature content provided by the FDA.

Clinical: Pharmaceutical

The Clinical Pharmaceutical library focuses on the underlying Good Clinical Practice (GCP) concepts as well as specific, advanced information for Pharmaceutical clinical professionals based on their role in the study. The courses are designed for those in clinical development, clinical operations, quality management and regulatory affairs. The global curriculum includes courses describing FDA regulations, ISO 14155, EU directives and ICH guidance; many courses feature content provided by the FDA.

FDA BIMO Course Series

The FDA's BIMO (Bioresearch Monitoring) online training program is designed for FDA Investigators, Supervisors, Compliance Officers and Chief Science Officers (CSOs) from other Centers who have limited experience in the BIMO program and who will conduct inspections or review Establishment Inspection Reports (EIRs) of Clinical Investigators (CIs), Institutional Review Boards (IRBs), Sponsors, Monitors, Contract Research Organizations (CROs) and in vivo Bioequivalence inspections. Using this BIMO training program, clinical professionals can become more familiar with the FDA's expectations and prepare accordingly.

Data Integrity

Since 2014, US FDA and EMA pharmaceutical/medicine GxP enforcement trends have pointed to a concentrated focus on a lack of data integrity. Investigators have cited manufacturers with a number of data integrity observations, such as: failing to document GxP activities at the "time of performance", and failing to have appropriate controls over computer systems to assure only authorized personnel can change GxP records. Both US FDA and EU expect companies to have valid data, spanning all GxP functions: labs, clinical trials, and the manufacturing process. Ensuring data integrity requires a combination of proper quality systems, but also the proper quality culture. UL's Data Integrity program includes several eLearning courses that present real-world case studies on how all employees can raise the culture of quality through the recording of GxP activities. Courses include modules targeted to specific roles, such as QA, Clinical, IT and Lab professionals. In addition, an introductory course can be delivered to all GxP employees. Using this program, companies can not only demonstrate to auditors that GXP personnel are aware of the importance of data integrity issues, they can also raise the overall quality culture of their organization, which leads to greater accuracy of clinical, lab and manufacturing records.

Medical Device GMPs

This library focuses on foundational GMP topics as well as the specialized knowledge needs of individual business functions in Pharmaceutical and Biotechnology companies. Beginning with the core quality and regulatory knowledge typically needed by new hires and reassigned workers, to the more advanced needs of managers and supervisors, courses target the function-specific needs of the entire organization. Many of these courses have been reviewed by the FDA and AdvaMed, the leading advocacy group for Medical Device organizations.

FDA Inspections and Enforcement

UL PURE Learning maintains a unique partnership with the FDA, collaborating to develop courses for the FDA's Investigator training program, which has been

delivered to 36,000+ global, federal, state, and local inspectors to date. Through the partnership, these FDA-authored and/or reviewed courses are available exclusively to UL clients. Your employees within regulatory affairs, auditing, quality assurance and manufacturing areas can gain a better understanding of FDA's activities related to inspection and enforcement, and be better prepared to anticipate FDA enforcement actions. Your company will benefit from a more proactive compliance, audit preparedness and response.

Pharmaceutical GMPs

Courses within this Library focus on the foundational GMP topics as well as the specialized knowledge needs of individuals performing specific functions in Pharmaceutical and Biotechnology companies. Beginning with the core quality and regulatory knowledge typically needed by new hires and reassigned workers, to the more advanced needs of managers and supervisors, courses target the needs of the entire organization. Many of these courses have been written or reviewed – and used by the FDA.

Global Regulatory

This Library (formerly entitled Global Pharmaceutical GMP Library) contains courses that help global Pharmaceutical companies keep pace with both European Union (EU) and ICH guidelines. Courses in this library also help Medical Device companies keep up with global submission requirements of key countries. Finally, this library includes GMP courses that focus on both FDA and EU regulations.

Dietary Supplements GMPs

This library focuses on 21 CFR Part 111 and educates dietary supplement manufacturers on how to maintain proper controls during manufacturing, packaging, labeling and holding operations. By combining these courses with specific policies and procedures, companies that intend to sell products in the US can demonstrate to internal and external auditors that qualified personnel have been trained to meet the necessary regulatory requirements.

Ethics & Corporate Responsibility

This library provides a highly unique approach to Code of Conduct training and focuses on general industry risk areas such as Conflicts of Interest, Accurate Books and Records, Harassment and Discrimination, Intellectual Property, the Foreign Corrupt Practices Act (FCPA) and much more.

HR Compliance & Risk Management

HR Compliance and Risk Management courses use a multi-tiered concept focused on the respective concerns of managers/supervisors, employees and HR professionals. All our courses are designed in accordance with federal regulations and guidelines, as well as HR best practices, and are continually updated to reflect regulatory changes.

Healthcare: General

These courses enable Health Care organizations to meet federal requirements while supporting the need for a consistent corporate message, dependable employee performance and adherence to company policies and procedures.

Pharmaceutical - Sales & Marketing

This library focuses on the Pharmaceutical industry, helping to meet the needs of regulatory, legal, communications, compliance and other Pharmaceutical professionals who engage in marketing, advertising, promotional and communications activities. Incorporating these courses into your vendor credentialing, or Health Care Industry Representative HCIR programs, helps to ensure that sales representatives have the proper training to enter health care facilities.

EHS for Life Science - Basics

The OSHA Standard for General Industry, Title 29 of the Code of Federal Regulations, Part 1910, addresses workplace health and safety requirements for manufacturing and related operations of Pharmaceutical, Life Science, and Medical Device industries. The EPA and DOT impose additional environmental and transportation safety requirements. Smart companies train to address hazard and risk exposures in the absence of regulatory standards because failing to provide training to help workers avoid hazards, civil liability, and humanitarian backlash. Note: each company has slightly different hazard and risk exposures, so companies may need optional title offerings.

HIPAA

The HIPAA Privacy and Security Library consists of three primary components: general training, specialized training for persons interested in greater detail, and training on an organization's own policies and procedures. Our HIPAA curriculum is developed by UL Subject Matter Experts with considerable experience in the practical application of privacy and security laws and regulations, and courses meet the requirements of the Health Insurance Portability and Accountability Act (HIPAA) and applicable state laws. Our staff includes regulatory compliance experts, instructional design professionals, software engineers, and information technology specialists. We also partner with nationally-recognized experts and work closely with federal government regulators.

Medicare Advantage

The Medicare Advantage curriculum fulfills CMS regulatory requirements for MA organization training, education and documentation. The Library focuses on topics such as enrollment, disenrollment, claims, marketing, quality management, administration and management, utilization management, bids, benefits and provider issues. Our internal regulatory compliance attorneys and our nationally-recognized Medicare Advantage subject-matter experts have developed this curriculum that not only fulfills the training requirements, but is also regularly updated to reflect changes in regulations and CMS sub-regulatory guidance. The breadth of our MA Library not only facilitates compliance with CMS regulations, but also provides in-depth training that ensures your employees perform their department-specific functions successfully.

Medicare Part D

Our Medicare Part D Curriculum expressly created for the Managed Care industry is the most comprehensive and detailed curriculum available and fulfills the CMS requirements for training, education and documentation in a cost-effective training method as outlined in Chapter 9 – Part D Program to Control Fraud, Waste and Abuse of the Prescription Drug Benefit Manual. Our curriculum consists of courses on topics such as fraud and abuse, administration and management, appeals and grievances, bid submission, claim and payment processes, enrollment, disenrollment, marketing, pharmacy access and quality management.

Engineering Safety

UL PURE Learning's Engineering Safety Library focuses on the critical ISO and IEC standards that impact the development and approval of medical device products. These standards include IEC 60601, ISO 14971 and others. The library serves to introduce these standards to compliance engineers, product safety engineers, and product designers within medical device and medical technology companies. Clients can combine these eLearning courses with optional, face-to-face workshops that are conducted by UL consultants.

Medicare Broker/Agent Training

UL's five-course training program plus exam for Medicare brokers and agents complies with all Center for Medicare and Medicaid Services (CMS) requirements (excluding plan-specific information) and incorporates the instructional design and knowledge that have made our other Health Care courses so effective. UL has worked with health plans and service providers to address the intersecting challenges of member services and education, regulatory compliance and workforce productivity, resulting in industry-specific solutions for companies that serve the public through group or individual plans, Medicare-eligible enrollees, or individuals who receive government-sponsored coverage.

PPACA

To help your employees understand the impact of PPACA, UL PURE Learning has developed these three eLearning courses. These courses focus on the changing U.S. Health Care system wrought by the Affordable Care Act and the options that individuals will have to purchase health insurance.

Selections:

Libraries: Clinical: Medical Device | Clinical: Pharmaceutical | Data Integrity | Dietary Supplements GMPs | EHS for Life Science - Basics | Engineering Safety | Ethics & Corporate Responsibility | FDA BIMO Course Series | FDA Inspections and Enforcement | Global Regulatory | Healthcare: General | HIPAA | HR Compliance & Risk Management | MDSAP Library | Medical Device - Sales & Marketing | Medical Device GMPs | Medicare Advantage | Medicare Broker/Agent Training | Medicare Part D | Pharmaceutical - Sales & Marketing | Pharmaceutical GMPs | PPACA |

Ionizing Radiation (US)

PS5-01286

Although radiation offers many benefits, exposure to it can also threaten our health and the quality of our environment. We cannot eliminate radiation, but this training shows how we can reduce our risk by controlling our exposure to it.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

A Guide to ISO 13485 - The Quality Management System for Medical Devices

DEV50

This course serves as a guide to ISO 13485 — the international quality management system standard for medical devices. The requirements of the standard apply to the methods used in, and the facilities and controls used for, the design and development, production, installation, and servicing of medical devices. Topics in this course include: Quality Management System, Management's Role, Managing Resources, Planning, Design and Purchasing, Production, Monitoring and Analysis, and Improvement. This course also addresses specific aspects of ISO 13485 as it relates to the European Union (EU). After completing this course, learners will be able to recognize the specific requirements of ISO 13485 and apply them to specific situations.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Medical Device GMPs

Functional Areas:

- ISO Standards

Languages Available:

- Chinese (Simplified) (DEV50)
- Japanese (DEV50)
- Korean (DEV50)
- German (DEV50)
- French (European) (DEV50)
- Spanish (Latin America) (DEV50)

A Guide to ISO 9001:2015 — Quality Management Systems Requirements

DEV61

This course serves as a guide to ISO 9001:2015 — the international quality management system requirements standard. This standard specifies requirements to demonstrate an organization's ability to consistently provide products and services that meet customer satisfaction and applicable statutory and regulatory requirements. Topics in this course include: System and Process, Leadership, Planning, Support, Operation, Performance Evaluation, and Improvement. After completing this course, learners will be able to recognize the specific requirements of ISO 9001:2015 and identify management's role in implementation and maintenance of the standard. Learners will also be able to recognize the requirements for quality management system Clauses 4-10 and recognize how to ensure compliance with the standard.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Medical Device GMPs

Functional Areas:

- ISO Standards

Languages Available:

- Chinese (Simplified)
- French (European)
- German
- Korean
- Spanish (Spain)

A Step-by-Step Approach to Process Validation

PHDV79

Process validation is required by process control regulations for both drugs and medical devices. This course outlines the important tasks performed during each phase of the validation life cycle, as well as the information that should (and should not) be included in validation documents and why processes must be monitored once they are validated. Topics in this course include: Validation Life Cycle, Process Design, Process Qualification including IQ, OQ, PQ, Product Process Qualification, Change Control, and Documentation. After completing this course, you will be able to recognize the validation life cycle, process validation steps, and how the EU regulations differ from FDA requirements. You will also be able to identify validation principles that pertain to the medical device industry.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- GMPs - Process Validation

Languages Available:

- German (PHDV79)
- French (European) (PHDV79)
- Chinese (Simplified) (PHDV79)
- Japanese (PHDV79)
- Korean (PHDV79)
- Spanish (Spain) (PHDV79)

A Tour of FDA

PHDV60

The Food and Drug Administration (FDA) touches the lives of virtually every American, every day. This course outlines the form and function of the FDA, its upper level structure, and its mission and goals. Topics in this course include: History and Scope of FDA, FDA Organization, Program Centers, Center for Food Safety and Applied Nutrition, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, Center for Veterinary Medicine, National Center for Toxicological Research, and Center for Tobacco Products.

Languages Available:
Chinese (Simplified) (PHDV60)
Japanese (PHDV60)
Portuguese (Brazil) (PHDV60)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- Clinical: Medical Device
- Clinical: Pharmaceutical
- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- FDA Inspection Readiness

A Tour of Health Canada

PHDV89

Health Canada touches the lives of virtually every Canadian, every day. This course introduces participants to Health Canada's mission and organization. After a brief introduction, the course will focus on the Health Products and Food Branch (HPFB) of Health Canada, which directly affects pharmaceutical manufacturers. Topics in this course include: Purpose, Organization, HPFB, TPD, BGTD, and HPFBI. After completing this course, learners will be able to identify the major branches of Health Canada, the HPFB, and its directorates. Learners will also be able to identify the unique roles and responsibilities of the three HPFB directorates that most directly affect the pharmaceutical industry.

Languages Available:
French (Canadian)

Format: eLearning - SCORM, eLearning - EduFlex

Libraries:

- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:

- Canada Regulations

A Tour of Health Europe

PHDV90

The system in Europe for ensuring safe, effective, and high-quality health products is composed of national authorities in individual countries as well as bodies in the European Union and the Council of Europe. After completing this course, learners will know the organisations that oversee the health industry in Europe and the bodies in those organisations that affect pharmaceutical companies. Learners will also understand how health products can be approved for sale to the public and the system for reporting and tracking defective products.

Format: eLearning - HIP2

Libraries:

- Clinical: Medical Device
- Clinical: Pharmaceutical
- Global Regulatory

Functional Areas:

- EU Regulations

Access to Medical and Exposure Records for Employees (US)

PS5-100747

The law requires your employer to provide you with access to your medical and exposure records. Why should you care? How do you get access? Take this course to find out! This course is ideal for all employees.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Accurate Company Records

ETHICS24

Companies have a legal obligation to create and retain records that accurately reflect their business transactions. Fraudulent reporting of books, records, or other written communication violates company policy and possibly the law. Topics in this course include: Laws and Regulations, Accurate Timely Records, Accurate Financial Records, and Records Management. After completing this course, learners will be able to recognize their role in recording every company transaction correctly, accurately, and on time. Learners will also be able to recognize the importance of proper management of company records.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Ethics & Corporate Responsibility

Functional Areas:

- Ethics Basics

Active Listening Skills

EHS02

Listening is one of the most important skills for success in life, but it is taken for granted by most people. This course describes how to improve active listening skills and gain an understanding of the significance of listening. Topics in this course include: Communication, Barriers, Benefits, Listening Levels, and Skills. After completing this course, learners will be able to identify the seven listening skills that can help increase productivity as well as improve the ability to work with others.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Functional Areas:

- Professional Development

Languages Available:

- Spanish (Latin America)
- Chinese (Simplified)
- Japanese

Administrative Roles of the Clinical Research Associate

GCP26

This course examines the administrative roles and responsibilities of the Clinical Research Associate (CRA) during specific on-site monitor visits conducted at the principal investigator location on behalf of a sponsor. Topics in this course include: Roles and Responsibilities, Monitoring Plan, PSSV and SIV, Source Documents, and Monitoring Functions. After completing this course, learners will be able to identify the general roles and responsibilities of a CRA, with recommended monitoring tasks to be completed at specified time intervals of an ongoing study.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:

- Clinical: Quality Topics

Administrative Roles of the Clinical Research Coordinator

GCP27

This course describes the administrative roles and responsibilities of the Clinical Research Coordinator (CRC). The CRC is an individual who coordinates many aspects of a clinical trial at the investigative site. The CRC's tasks are formally delegated to them by the principal investigator (PI) and frequently involve both clinical duties (within their professional scope of practice) and coordination activities. Upon completion of this course, you will be able to identify the CRC role throughout a clinical trial, as well as recognize applicable Good Clinical Practice standards.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: **Functional Areas:**

- Clinical: Medical Device
- Clinical: Pharmaceutical
- GCP Basics

Affirmative Action in the Workplace (For Employers)

LAV02

Today, federal laws make it illegal to discriminate against a job applicant or an employee because of the person's race, color, religion, sex, national origin, age, disability, or genetic information. This course addresses the essential features of affirmative action requirements for federal contractors. Topics in this course include discrimination laws, responsibilities of a federal contractor, and the equal opportunity clause. After completing this course, learners will be able to recognize Affirmative Action Plans (AAPs) and their role in aiding compliance with these anti-discrimination laws.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries: **Functional Areas:**

- Ethics & Corporate Responsibility
- HR Compliance & Risk Management
- Corporate Compliance Basics

Age Discrimination

LAV01

Age discrimination can be particularly challenging when an employer is reducing employee numbers or is managing an aging workforce. This course describes the federal legislation that prohibits age discrimination in the workplace. Topics in this course include: Legislation, Prohibited Practices, Claims, and Helpful Strategies. After completing this course, learners will be able to recognize provisions of the Age Discrimination in Employment Act (ADEA).

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: **Functional Areas:**

- Ethics & Corporate Responsibility
- HR Compliance & Risk Management
- Corporate Compliance Basics

Americans with Disabilities Act

LAV07

The course identifies who is classified as a disabled employee and how these employees are protected under the Americans with Disabilities Act (ADA). This course also discusses the concepts of reasonable accommodation and undue hardship as well as coverage for substance abuse. Topics in this course include: Disability, Legislation, Reasonable Accommodation, and Drugs and Alcohol. After completing this course, learners will be able to recognize who is classified as a disabled employee and how the ADA protects these individuals. Learners will also be able to recognize how to comply with the ADA reasonable accommodation requirement.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: **Functional Areas:**

- Ethics & Corporate Responsibility
- HR Compliance & Risk Management
- HR Compliance

An Introduction to ISO 13485 - The Quality Management System for Medical Devices

DEV48

The international standard ISO 13485:2016 specifies the requirements for a quality management system that can be used by an organization in one or more stages of the life-cycle. ISO 13485 can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations. This course is the first of a two part series. Topics in this course include: ISO 13485:2016, Process Approach, Clauses 4-6, Clauses 7 and 8, and Preparation. This course also addresses specific aspects of ISO 13485 as it relates to the European Union (EU). After completing this course, learners will be able to recognize the requirements of ISO 13485.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Medical Device GMPs

Functional Areas:

- FDA QSR Basic Concepts
- ISO Standards

Content Bundles:

- Medical Device - GMP

Languages Available:

- French (European) (DEV48)
- German (DEV48)
- Japanese (DEV48)
- Korean (DEV48)
- Chinese (Simplified) (DEV48)
- Spanish (Latin America) (DEV48)

An Introduction to ISO 9001:2015 — The Quality Management System Requirements

DEV60

This course serves as an introduction to ISO 9001:2015 — the international quality management system requirements standard. This standard specifies requirements to demonstrate an organization's ability to consistently provide products and services which meet customer satisfaction and applicable statutory and regulatory requirements. However, requirements of this standard are generic and are intended to be applicable to any organization regardless of which products and services are provided. **Topics in this course include: Scope, Principles, Certification, Auditing, and Resources.** After completing this course, learners will be able to identify the quality management principles of the standard and be able to recognize considerations for selecting a certification body as well as appropriate preparations for certification audits.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Medical Device GMPs

Functional Areas:

- ISO Standards

Languages Available:

- Chinese (Simplified) (DEV60)
- French (European) (DEV60)
- Spanish (Spain) (DEV60)
- German (DEV60)
- Korean (DEV60)

Antitrust Law and Competitor Relationships

LAV14

Federal antitrust laws are designed to ensure that the basic promise of a free market economy and effective competition is not undermined by unlawful manipulation or collusion between competitors. This course explains how antitrust legislation regulates contact between competitors, and what employers and employees can do to ensure that they are in compliance with US antitrust laws. Topics in this course include: Legislation, Sherman Act, Clayton Act, Federal Trade Commission (FTC), Illegal Agreements, Competitor Interactions, and Helpful Strategies. After completing this course, learners will be able to recognize the antitrust laws that govern competitor interactions as well as their application to everyday business situations.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- HR Compliance & Risk Management

Functional Areas:

- HR Compliance

Application of GMPs to Analytical Laboratories

PHDV78

Compliance with current Good Manufacturing Practices (cGMP) requirements is essential in order to create products that have quality, purity, proper identity, strength, and are safe. All laboratory analysts must follow cGMPs in order to create effective products and comply with all quality standards. Topics in this course include: Laboratory Documents, Laboratory Practices, Raw Data, Method Validation, Calibration, Training, OOS, and Computer Systems. After completing this course, learners will be able to identify cGMP requirements as they apply to analytical laboratory practices.

Languages Available:

French (European)
German
Spanish (Spain)

Format: eLearning - EduFlex, eLearning - SCORM,
eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- GxP Basics

Application of GMPs to Microbiology Laboratories

PHDV72

This course describes the general principles of current Good Manufacturing Practices (cGMPs) and their importance in microbiology laboratories. Topics in this course include: Application, Laboratory Documents, Handling Raw Data, Growth Media, Aseptic Technique, Environmental Monitoring Program, Laboratory Equipment, Training, and OOS Results. After completing this course, learners will be able to identify the importance of handling of raw data and recognize key approaches for ensuring accurate results. This course discusses requirements for both the European Union (EU) and US Food and Drug Administration (FDA).

Languages Available:

French (European) (PHDV72)
German (PHDV72)
Spanish (Spain) (PHDV72)

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- Pharmaceutical GMPs

Functional Areas:

- GxP Basics

Applying Electrical Standards (US)

PS5-00262

Electrical standards do not just help you comply with the law, they keep you safe! You are already familiar with electrical terms and hazards. Take this course to learn about NFPA 70E and what it means for you. Stay compliant and stay safe! Ideal learners are people in all industries, particularly supervisors, electrical workers and safety managers.

Languages Available:

French (Canadian)
Spanish (Latin America)

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Approach to Computerized Systems Validation and Compliance

PHDV103

This course describes an approach to the validation and compliance of computerized systems used in the manufacture of pharmaceuticals, biologicals, and medical devices that are required to meet FDA's regulations. It identifies ways to organize policies and procedures, and plans FDA expects a manufacturing company to establish. This course draws on current industry good practice. Though it also draws on FDA medical device guidance, this course is not intended to describe an approach to developing software that subsequently becomes part of a medical device. This is the second course in a series of four courses. Before taking this course, you should have successfully completed Requirements for Computerized Systems Validation and Compliance.

Languages Available:

German (PHDV103)
French (European) (PHDV103)
Chinese (Simplified) (PHDV103)
Japanese (PHDV103)
Korean (PHDV103)
Spanish (Spain) (PHDV103)

Format: eLearning - EduFlex, eLearning - SCORM,
eLearning (Editable) - CREATE

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- Computer Systems Validation

Content Bundles:

- Computer Systems Validation

Aspects of Regulatory History

GCP22

Regulatory standards for conducting clinical trials are in place to protect those conducting and participating in clinical trials. This course describes the regulatory requirements of the US Department of Health and Human Services (HHS), Food and Drug Administration (FDA), and the guidelines of the International Conference on Harmonisation (ICH) necessary to ensure proper and successful clinical trial execution. Topics in this course include: History, Organizations, Regulations, and Guidelines. After completing this course, learners will be able to recognize the impact of ICH guidelines on the industry from a global perspective.

Languages Available:
Chinese (Simplified) (GCP22)
German (GCP22)
Japanese (GCP22)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: Corexccl

Libraries:

- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:

- GCP - Clinical Management

Auditing of Computer System Validation to Ensure Data Integrity

DATA02

FDA inspectors and corporate auditors must be able to recognize the critical aspects of computerized systems and the documentation needed to demonstrate that they are validated. This course provides an approach to inspecting/auditing these systems and covers the detailed review of systems that automate part of the production process or part of a quality system. Topics in this course include: Data Integrity and Governance, Validation and the SDLC, Key Documentation Deliverables, Requirements, Design and Configuration, Implementation and Verification, and Maintenance. After completing this course, learners will be able to recognize validation activities and the maintenance of the validated state as it relates to data integrity. Prerequisites for this course include Introduction to Data Integrity and either the Computerized Systems Inspections in the Medical Device Industry or the QSIT 5 — The Production and Process Controls Subsystem course.

Languages Available:
Chinese (Simplified) (DATA02)
French (European) (DATA02)
German (DATA02)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Data Integrity

Functional Areas:

- Quality Assurance

Content Bundles:

- Data Integrity

Australian Therapeutic Goods — Medical Device Regulations Overview

PHDV105

This course provides an overview of the regulatory requirements for medical devices and IVD medical devices set forth by the Therapeutic Goods Administration (TGA) of Australia. Topics in this course include: TGA; Essential Principles; Classification of Medical Devices; and Conformity Assessment Procedures. After completing this course, learners will be aware of the structure of the TGA and recognize the role and responsibilities of the TGA. Learners will also be able to identify how medical devices and IVD medical devices are regulated in Australia and the necessary regulatory requirements and deliverables.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Global Regulatory
- Medical Device GMPs

Functional Areas:

- Medical Device
- Global Market Access - Medical Device

Awareness of FDA Inspections for Pharmaceutical Manufacturers

PHA65

This course covers the basics of FDA inspections of drug manufacturing facilities, including authority, purpose, types, and areas/operations typically inspected. The course also discusses how companies and their personnel should generally handle FDA inspections and interact effectively with Investigators. Topics in this course include: Scope, Inspection Types, Initiation, Handling Inspections, Inspection Coverage, FDA Interaction, and Closeout. After completing this course, learners will be able to identify the basics of FDA inspections of drug manufacturing facilities and how firms should handle FDA inspections and interact effectively with Investigators.

Languages Available:

Spanish (Latin America) (PHA65)
French (European) (PHA65)
Chinese (Simplified) (PHA65)
Japanese (PHA65)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Pharmaceutical GMPs

Functional Areas:

- GMP Inspection Readiness
- FDA Inspection Readiness

Content Bundles:

- GMP Inspection Readiness

Basic Radiation Awareness

EHS05

The general public often thinks radiation exposure only occurs in areas displaying "Caution: Radiation," or "Danger: Radiation" signs. Actually, in addition to exposure in certain work places, each of us is exposed to natural radiation each day of the year. Topics in this course include: Effects, Limits, Controls, Assessment, and Regulations. After completing this course, learners will be able to recognize the types of natural and man-made (ionizing) radiation, where radiation originates, its health effects, principles of protection, and the components of an effective Radiation Protection Program.

Languages Available:

German

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- RETIRED - Environmental Health and Safety
- Medical Device - Sales & Marketing

Functional Areas:

- Radiation Awareness

Basics of Business Finance

EHS06

The purpose of corporate financial management is to get everyone pulling together to create value. No company can succeed if its people lack skills in managing its money and assets. This course describes the basics of business finance. Topics in this course include: Funding, Balance Sheet, Income and Cash Flow Statements, Ratios, Forecasting, and Common Language. After completing this course, learners will be able to recognize the fundamentals of corporate finance in simple, easy to understand terms. Learners will also be able to recognize how work activities can and do affect the financial health of an organization.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- HR Compliance & Risk Management

Functional Areas:

- Professional Development

Basics of Inspections: Beginning an Inspection

FDA38

This is the first of two courses designed to inform learners of the basic practices during an inspection of a food establishment. This course explores the preparation needed before an inspection and identifies pre-inspection issues. Topics in this course include: Preparation,

Pre-inspection Issues, HACCP, Product Protection, Hazards, and Corrective Actions. After completing this course, learners will be able to identify the purpose of a Hazard Analysis Critical Control Point (HACCP) plan and recognize the purpose of corrective actions.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE
Partners: FDA

Libraries:
• FDA Inspections and Enforcement

Functional Areas:
• FDA Inspection Readiness

Basics of Inspections: Issues and Observations

FDA39

This is the second of two courses designed to inform the learner of the basic practices during an inspection of a food establishment. This course explores the issues and observations that must be examined during an inspection, including: processing equipment, employee practices, food storage/display, water supply and plumbing, and pest control. Topics in this course include: Employee Practices, Processing Equipment, Food Storage and Display, Cross-contamination, Water Supply, Food Sampling, Inspection Report, and Closing Conference.

After completing this course, learners will be able to identify the unsatisfactory practices that lead to contaminated food. Learners will also be able to recognize proper sampling procedures. Lastly, learners will be able to identify what to include in an inspection report and how to conduct a closing conference at the conclusion of an inspection.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE
Partners: FDA

Libraries:
• FDA Inspections and Enforcement

Functional Areas:
• FDA Inspection Readiness

Basics of PhRMA Code

PHSM01

For members of PhRMA to reaffirm their commitment to following the highest ethical standards as well as all legal requirements while promoting products to the medical community.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:
• Pharmaceutical - Sales & Marketing

Functional Areas:
• Corporate Ethics
• Sales Compliance

Content Bundles:
• Corporate Compliance - Pharmaceutical

Basics of the AdvaMed Code

MDSM01

It is crucial for all Medical Technology companies to understand the guidelines of the Advanced Medical Technology Association (AdvaMed) Code and how they impact interactions with Health Care Professionals (HCPs). This course discusses the Basics of the AdvaMed Code. Topics in this course include: Code, Education and Business Meetings, Consulting, Evaluation and Demonstration Products, and Gifts and Meals. After completing this course, learners will be able to recognize how the AdvaMed Code guides interactions with HCPs.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:
• Medical Device - Sales & Marketing

Functional Areas:
• Vendor Credentialing

Content Bundles:
• Corporate Compliance - Medical Device

Languages Available:

Spanish (Latin America) (MDSM01)
German (MDSM01)
French (European) (MDSM01)
Chinese (Simplified) (MDSM01)
Japanese (MDSM01)

Batch Record Reviews

PHA53

Pharmaceutical batch records are essential to ensure that regulatory and product quality attributes are achieved. This course describes how to properly perform a batch record review. Topics in this course include: Regulations, Manufacturing Records, Packaging Records, Laboratory Records, and Issues and Deviations. After completing this course, learners will be able to identify the GMP and cGMP requirements for batch records and recognize how to maintain GMP and cGMP compliance throughout the review process. The regulatory requirements of FDA are addressed with reference also made to the requirements of the EU.

Languages Available:

French (European) (PHA53)
German (PHA53)
Spanish (Spain) (PHA53)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE
Partners: FDA

Libraries:
• Medical Device GMPs
• Pharmaceutical GMPs

Functional Areas:
• Pharmaceutical GMPs
- Batch Records

Best Practices: Modest Meals

ADVAMED-MINI-02

This course describes the best practices and requirements under the AdvaMed Code for providing modest meals to healthcare professionals as a part of medical device sales presentations.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
• Medical Device - Sales
& Marketing

Functional Areas:
• Corporate Ethics

BIMO: Clinical Investigator

BIM004

This course focuses on the responsibilities of a Clinical Investigator (CI) who participates in clinical research involving unapproved test articles that are under FDA's jurisdiction. Topics in this course include: Purpose, Regulations, Managing Inspections, Develop a Strategy, Critical Elements, and FDA Options. After completing this course, learners will be able to recognize FDA's role in CI compliance and regulatory oversight. Learners will also be able to identify the responsibilities of CIs and recognize the regulations that apply to CIs.

Format: eLearning - EduFlex, eLearning - SCORM
Partners: FDA

Libraries:
• FDA BIMO Course Series

Functional Areas:
• Clinical: Quality Topics

BIMO: General Inspection Assignment Process

BIM002

This is the second in a series of courses that provide an overview of FDA's Bioresearch Monitoring (BIMO) program and the methods and techniques used in conducting and reporting Clinical Investigator, Institutional Review Board (IRB), Sponsor/Monitor, and in vivo Bioequivalence inspections. This course provides an overview of the general inspection assignment process, site selection, background materials used in a BIMO inspection, and regulatory consequences of the BIMO program.

Format: eLearning - HIP2
Partners: FDA

Libraries:
• FDA BIMO Course Series

Functional Areas:
• Clinical: Quality Topics

BIMO: In Vitro Bioequivalence Program Part I

BIM006

This course will introduce some brand name and generic drugs, explain the importance of bioavailability, and describe the underlying concept of bioequivalence for comparison of drug performance. This course will also discuss the implementation of the in vivo bioequivalence compliance program. Topics in this course include: Understanding Drugs, Drug Review Process, Bioavailability, Bioequivalence, Study Endpoints, and Implementation. After completing this course, learners will be able to recognize the distinction between brand name and generic drugs. Learners will also be able to identify the importance of bioavailability and recognize the underlying concept of bioequivalence for comparison of drug performance. In addition, learners will be able to recognize the implementation process of the in vivo bioequivalence compliance program.

Format: eLearning - EduFlex, eLearning - SCORM **Partners:** FDA

Libraries: **Functional Areas:**
• FDA BIMO Course • Clinical: Quality Topics
Series

BIMO: In Vivo Bioequivalence Program Part II

BIM007

This course will introduce learners to the challenges of inspecting clinical and analytical facilities and the various technical terms commonly used in bioavailability and bioequivalence studies. Topics in this course include: Clinical Facility, Clinical Documents, Analytical Facility, Analytical Documents, and Analytical Method Validation. After completing this course, learners will be able to identify the challenges of inspecting clinical and analytical facilities, and recognize the various technical terms commonly used in bioavailability and bioequivalence studies.

Format: eLearning - EduFlex, eLearning - SCORM **Partners:** FDA

Libraries: **Functional Areas:**
• FDA BIMO Course • Clinical: Quality Topics
Series

BIMO: Part 50 & 56 -- Institutional Review Boards (IRBs)

BIM003

This is the third in a series of courses that provide an overview of FDA's Bioresearch Monitoring (BIMO) program and the methods and techniques used in conducting and reporting Clinical Investigator, Institutional Review Board (IRB), Sponsor/Monitor, and in vivo Bioequivalence inspections. This course provides an overview of the regulations applicable to the protection of human subjects who participate in clinical research typically involving test articles which are unapproved for marketing, but approved for research by FDA.

Format: eLearning - HIP2 **Partners:** FDA

Libraries: **Functional Areas:**
• FDA BIMO Course • Clinical: Quality Topics
Series

BIMO: Sponsor/Monitor Responsibilities

BIM005

This course focuses on the responsibilities of sponsors and monitors of clinical research involving unapproved test articles under the jurisdiction of FDA. Topics in this course include: Responsibilities, Applicable Regulations, Compliance Program 7348.810, Strategy, Inspectional Elements, Additional Elements, Potential Outcomes, and Regulatory Actions. After completing this course, learners will be able to recognize the roles and responsibilities of both sponsors and monitors in conducting clinical trials and use that knowledge to conduct inspections successfully in the BIMO program.

Format: eLearning - EduFlex, eLearning - SCORM **Partners:** FDA

Libraries: **Functional Areas:**
• FDA BIMO Course • Clinical: Quality Topics
Series

Biotechnology: An Overview of Compliance Considerations

PHDV68

This course provides an overview of the fundamental compliance issues impacting the biotechnology industry. Topics in this course include: Biotechnology-Derived Products (BDPs), Cell Culture, Antibody Production, Manufacturing Controls, Processing and Filling, BDP Controls, and Testing. After completing this course, learners should recognize what a biotechnology-derived product is, identify how FDA regulates them, and identify various controls for biotechnology-derived products.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE
Partners: FDA

Libraries:
 • Pharmaceutical GMPs

Functional Areas:
 • Biotechnology

Languages Available:
 Spanish (Latin America) (PHDV68)

Bloodborne Pathogens -- Healthcare Workers

EHS09

This course provides an overview of bloodborne pathogens in the healthcare setting. After completing this course, participants will be able to identify bloodborne pathogens in the workplace, and recognize the different ways a person can be exposed to such substances. Participants will also recognize best practices in the management of these substances and effective ways to minimize the risks of exposure.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
 • RETIRED - Environmental Health and Safety
 • Healthcare: General
 • Medical Device - Sales & Marketing
 • Pharmaceutical - Sales & Marketing

Functional Areas:
 • Vendor Credentialing
 • Medical Device EHS Basics

Content Bundles:
 • Vendor Credentialing
 • EHS for Life Science Companies - Basics

Languages Available:
 Spanish (Latin America) (EHS09)
 German (EHS09)
 French (European) (EHS09)
 Chinese (Simplified) (EHS09)
 Japanese (EHS09)

Bloodborne Pathogens (BBP)

PS5-00282

If your job duties include even occasional contact with blood or other infectious materials, you are at risk for contracting potentially deadly, incurable diseases. Take this course to learn what bloodborne pathogens are and how you can protect yourself from them. Ideal learners include anyone who may be exposed to blood or other potentially infectious materials, including healthcare workers, custodians, maintenance staff, research personnel and construction workers.

Format: eLearning - PS5

Libraries:
 • EHS for Life Science - Basics

Languages Available:
 French (Canadian)
 French (European)
 German
 Italian
 Japanese
 Korean
 Portuguese (Brazil)
 Russian
 Spanish (Latin America)
 Chinese (Simplified)

Bloodborne Pathogens Awareness

PS5-102406

Contact with blood or other infectious materials puts you at risk for contracting potentially deadly, incurable diseases. Take this course to learn what bloodborne pathogens are, the risk they present, and general steps you should take to ensure your protection after potential exposure. This course is not intended to teach universal precautions. You need additional information, vaccinations/immunizations, and PPE to provide first aid or handle/clean up BBP and OPIM. Ideal learners include all workers.

Format: eLearning - PS5

Libraries:
 • EHS for Life Science - Basics

Brazil's Technical Regulations for Medical Devices: RDC 16/2013, 67/2009, and 23/2012

DEV63

This course discusses Brazil's technical regulations for medical devices, including RDC 16/2013 for Good Manufacturing Practices (GMPs) of Medical Devices and In Vitro Diagnostic Devices (IVDs), RDC 67/2009 for Technovigilance Requirements for Registration Holders, and RDC 23/2012 for Field Action Requirements. Topics in this course include: Background, Elements, and Applications. After completing this course, learners will be able to identify each of these regulations and recognize the practical actions to use in the normal course of business to ensure that the regulations are adhered to.

Languages Available:
Portuguese (Brazil) (DEV63)

Format: eLearning - EduFlex, eLearning - SCORM

- | | |
|---|--|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• Global Regulatory• Medical Device GMPs | <ul style="list-style-type: none">• Medical Device |

Broker and Agent Training Exam

MSales06

This is the Broker and Agent Training Exam.

Format: eLearning - Exam

- | | |
|--|---|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• Medicare Broker/Agent Training | <ul style="list-style-type: none">• Medicare Plan Broker Training |

Building Customer Loyalty

EHS11

This course teaches the skills needed by employees at all levels of a company to create loyalty, and to impact the company's profitability in a positive way. Topics in this course include: Creating Loyalty, Words, Actions, Leadership, Turnoffs, and Rebuilding. After completing this course, learners will be able to recognize the skills needed to build customer loyalty. Learners will also be able to recognize the importance of customer loyalty to them personally as well as to the company.

Format: eLearning - EduFlex, eLearning - SCORM

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|---|--|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• HR Compliance & Risk Management | <ul style="list-style-type: none">• Professional Development |

Business Practices to Protect Personal Health Information

HIPAA05

This course provides all employees and associates with knowledge of the privacy and security practices for health plans, as required by the Health Insurance Portability and Accountability Act (HIPAA). This course includes updated requirements that were included in the Health Information Technology for Economic and Clinical Health Act (HITECH). Employees will learn the basic principles of health information privacy and security, how they impact the organization, and how they apply to everyday work situations. The course also covers patients' rights under HIPAA, and the consequences for violating privacy and security practices.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

- | | |
|---|---|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• HIPAA | <ul style="list-style-type: none">• Healthcare: HIPAA |

Canadian Medical Device Regulations

DEV64

This course introduces the Canadian medical device regulations. This course identifies the scope and applicability of the Canadian Medical Devices Regulation (CMDR) that was last amended on February 13, 2017. Topics in this course include: Regulatory Agencies, Definition, Medical Device Licensing, Post Approval, and CMDR vs ISO 13485. After completing this course, learners will be able to identify the requirements to market devices in Canada.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Global Regulatory
- Medical Device GMPs

Care and Handling of Drug Product Components, Labeling, Containers, and Closures

PHA41

It is crucial to understand and follow cGMP regulations related to components, labeling, containers, and closures of drug products. This course describes how to implement control handling and testing of drug products while meeting cGMP regulations. Topics in this course include: Receipt and Holding, Sampling, Vendor Certification, and Documentation. After completing this course, learners will be able to identify the proper procedures for the receipt, sampling, storage, testing, and record keeping of drug product components and containers and closures.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- Packaging, Warehousing and Distribution

Languages Available:

- Chinese (Simplified) (PHA41)
- Japanese (PHA41)
- German (PHA41)
- French (European) (PHA41)
- Spanish (Spain) (PHA41)

CE Certification for Medical Devices

MDR03

This course describes information about compliance of medical devices in accordance with the European Medical Device Regulations (MDR). Topics in this course include: Classification and Conformity Routes, General Requirements, Design and Construction, Technical Documentation, Quality Management System (QMS), Device Information and Documentation, and Vigilance. After completing this course, learners will be able to recognize general requirements and harmonized standards for medical devices.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Medical Device GMPs
- Global Regulatory

Functional Areas:

- EU Market Access
- EU MDD
- EU Regulations

Languages Available:

- Chinese (Simplified) (MDR03)
- German (MDR03)
- French (European) (MDR03)
- Japanese (MDR03)
- Korean (MDR03)
- Spanish (Spain) (MDR03)

CFDA Order No. 25 -- Good Clinical Practices for Medical Devices

PHDV104

China Food and Drug Administration (CFDA) Order No. 25 — Good Clinical Practice for Medical Devices was enacted to strengthen the administration, supervision, and management of clinical trials medical devices. Topics in this course include: General Provisions, Preparation Before Clinical Trials, Guarantee of Rights and Interests of Subjects, Clinical Trial Protocol, Responsibilities of Ethics Committee, Responsibilities of Sponsors, Responsibilities of Clinical Trial Institutions and Investigators, Recording and Reporting, and Management of Investigational Medical Devices.

After completing this course, learners will be able to identify participating regulatory agencies. Learners will also be able to identify the rights of clinical trial subjects and the responsibilities of investigators, sponsors, the administrative department, and the ethics committee. Lastly, learners will be able to recognize the documentation and reporting requirements for clinical trials.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:	Functional Areas:
<ul style="list-style-type: none"> • Global Regulatory • Medical Device GMPs 	<ul style="list-style-type: none"> • Medical Device • Global Market Access - Medical Device

Change Control

PHA35

The control of change is very important in the regulated industries of drug products, biologics, and medical devices. Changes to processes, material, equipment, and people can have a direct impact on the quality, effectiveness, and safety of the product. This course presents the concept of change control by placing the learner in the role of a change control manager. Topics include key steps, change indicators, and notification of governing bodies. After completing this course, you will be able to identify what a change control consists of and recognize the basics of the change control model. You will also be able to recognize the importance of a change control. Lastly, you will be able to recognize the key elements of an effective change control system.

Languages Available:
 German (PHA35)
 French (European) (PHA35)
 Spanish (Spain) (PHA35)
 Chinese (Simplified) (PHA35)
 Japanese (PHA35)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE
Partners: FDA

Libraries:	Functional Areas:
<ul style="list-style-type: none"> • Medical Device GMPs • Pharmaceutical GMPs • Global Regulatory 	<ul style="list-style-type: none"> • Pharmaceutical GMP Basics

Clinical Trial Audits and Consequences of Non-Compliance

GCP21

Sponsors can put measures in place in an attempt to dissuade researchers from being noncompliant, but those measures are only as effective as the personnel applying them. This course will provide a description of the clinical trial audit process and how audits help to ensure trials are conducted in accordance with regulatory requirements. Topics in this course include: Clinical Trial Audit, FDA Inspection, and Noncompliance. After completing this course, learners will be able to identify FDA standards for conducting and reporting clinical site inspections, as well as recognize FDA's system for classifying inspections and taking corrective action.

Languages Available:
 Chinese (Simplified) (GCP21)
 German (GCP21)
 Japanese (GCP21)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE
Partners: Corexcel

Libraries:	Functional Areas:	Content Bundles:
<ul style="list-style-type: none"> • Clinical: Medical Device • Clinical: Pharmaceutical 	<ul style="list-style-type: none"> • GCP - Clinical Management 	<ul style="list-style-type: none"> • Global Clinical Operations

Code of Business Conduct

LAV15

All employees need to be aware of their companies Code of Business Conduct. This course describes the Code of Business Conduct and basic ethical principles and guidelines for conducting business with our partners, clients, and competitors. Topics in this course include: Obeying the Law, Conflicts of Interest, Gift Policies, Protected Information, and Ethical Conduct. After completing this course, learners will be able to identify the basic principles that make up the Code of Business Conduct.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

- | | |
|---|---|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none"> • Ethics & Corporate Responsibility | <ul style="list-style-type: none"> • HR Compliance |

Code of Conduct

GHC05

Trust is the cornerstone of any long-term business relationship. Our responsibility is to earn that trust every day by acting in an ethically and legally responsible manner that is beyond reproach. This course addresses the standards of conduct outlined in our Company's Code of Conduct. Topics in this course include: Compliance with the Code, Protecting Information, Conflicts of Interest, Government Contracts, and Reporting Violations. After completing this course, learners will be able to identify our Company's standards which must be applied to activities they perform on a daily basis and help build the crucial foundation of trust that our customers and members rely on every day.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

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|---|---|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none"> • Healthcare: General | <ul style="list-style-type: none"> • Healthcare: Compliance Topics |

Collecting Samples and Establishing Limits for Cleaning Validation

PHA54

GMP regulations require that equipment used in the manufacturing of a drug, medical device, or biologic product be cleaned in such a way as to ensure that the quality, purity, and safety of a product will not be adversely affected. This course explains methods in which to collect samples and the need for establishing limits of cleanliness in cleaning validation. Topics in this course include: Locations, Methods, Pros and Cons, Approaches, Influencing Factors, and Documentation. After completing this course, you will be able to identify the advantages and disadvantages of common sampling methods. You will also be able to recognize the need for established limits of cleanliness in cleaning validation, as well as be able to utilize formulas to derive safe, practical cleaning limits.

Languages Available:
 French (European)
 German
 Spanish (Spain)

Format: eLearning - EduFlex, eLearning - SCORM **Partners:** FDA

- | | |
|---|--|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none"> • Pharmaceutical GMPs | <ul style="list-style-type: none"> • Pharmaceutical GMPs - Cleaning Validation • GMPs - Process Validation |

Combination Products – cGMP Requirements

PHDV93

FDA has issued a regulation on the current good manufacturing practice (cGMP) requirements applicable to combination products in an effort to improve the consistency of the regulatory requirements and implementation. This course discusses cGMP requirements and FDA rules that relate to combination products. Topics in this course include: Background, Final Rule, Compliance, The Office of Combination Products, and Post-Approval Modifications. After completing this course, learners will be able to recognize the four different types of combination products and the scope of the regulation in 21 CFR Part 4. They will also be able to identify how to comply with each of the drug, device, and biological product provisions and handle post-marketing events.

Languages Available:
 Chinese (Simplified) (PHDV93)
 Japanese (PHDV93)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

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|--|--|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none"> • Medical Device GMPs • Pharmaceutical GMPs | <ul style="list-style-type: none"> • GMP - Combination Products |

Complaint Management for Medical Device Manufacturers

DEV46

It is very important for manufacturers to properly respond to reports of alleged medical device problems. This course covers the FDA regulations for reporting these problems. Topics include: Definition, System Elements, Complaint File, Investigation, MDR, and Complaint Analysis. After completing this course, you will be able to identify the primary elements in an effective complaint handling system; recognize how to document, evaluate, and investigate complaints; recognize complaints that must be reported under FDA regulations; and identify the importance of statistical techniques in analyzing complaint trends.

Languages Available:
 German (DEV46)
 French (European) (DEV46)
 Chinese (Simplified) (DEV46)
 Japanese (DEV46)
 Korean (DEV46)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE
Partners: FDA

Libraries:
 • Medical Device GMPs

Functional Areas:
 • Complaint Management

Complaint Management for Pharmaceutical Manufacturers

PHA71

There are specific requirements regarding how companies must receive, investigate, document, file, and report customer complaints. This course identifies the primary elements in an effective pharmaceutical complaint handling system. Topics in this course include: System Elements, Complaint File, Investigation, Adverse Drug Experiences, and Complaint Analysis. After completing this course, learners will be able to identify the key elements in building an effective pharmaceutical complaint handling system.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
 • Pharmaceutical GMPs

Functional Areas:
 • Pharmaceutical GMPs
 - Basics

Computer Workstation Safety

EHS14

Computer workstations can be a source of nagging and debilitating Repetitive Stress Injuries (RSIs). This course addresses causes and symptoms of RSIs at computer workstations and ways to prevent those injuries. Topics in this course include: RSIs, Symptoms, Prevention, Exercises, and Laptop Safety. After completing this course, learners will be able to identify the symptoms of RSIs and find ways to stay healthy and prevent these injuries while working at a computer workstation.

Languages Available:
 Spanish (Latin America) (EHS14)

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
 • RETIRED - Environmental Health and Safety
 • Ethics & Corporate Responsibility
 • HR Compliance & Risk Management

Functional Areas:
 • EHS - Ergonomics

Computerized Systems Inspections in the Medical Device Industry

DEV59

This course has been designed to assist FDA inspectors in recognizing the critical aspects of computerized systems in the medical device industry. This course explains how computerized systems are used in the medical device manufacturing process and provides an approach to inspecting these systems. This course does not cover the detailed review of software that forms part of a medical device; it covers only inspection of systems that automate part of the device production process or part of the quality system.

Languages Available:
 German (DEV59)
 French (European) (DEV59)
 Chinese (Simplified) (DEV59)
 Japanese (DEV59)
 Korean (DEV59)
 Spanish (Spain) (DEV59)

Before taking this course, users should complete *Requirements for Computerized Systems Validation and Compliance and Approach to Computerized Systems Validation and Compliance*.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
 • FDA Inspections and Enforcement
 • Medical Device GMPs

Functional Areas:
 • Computer Systems Validation

Content Bundles:
 • Computer Systems Validation

Computerized Systems Inspections in the Pharmaceutical Industry

PHA81

This course explores how FDA personnel recognize the critical aspects of computerized systems in the pharmaceutical industry during Pre-Approval and routine current Good Manufacturing Practices (cGMP) inspections. The course explains how computerized systems are used in the pharmaceutical manufacturing process and provides an approach to inspecting these systems. Topics in this course include: Use, Inspectional Approach, Focus, and Regulations and Guidelines. After completing this course, learners will be able to recognize where computerized systems are used in the pharmaceutical manufacturing process. Learners will also be able to recognize FDA's approach to inspecting computerized systems. Learners will also be able to identify the levels of review that may be used and what comprises each level.

Languages Available:

German
 French (European)
 Chinese (Simplified)
 Japanese
 Korean
 Spanish (Spain)

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- Computer Systems Validation

Content Bundles:

- Computer Systems Validation

Conducting Annual Product Reviews

PHA45

This course identifies regulations for manufacturers conducting annual reviews of pharmaceutical products. Topics in this course include: APR Requirements, Benefits of APRs, APR Organization and Content, and Quality Metrics. After completing this course, learners will be able to recognize the benefits of conducting an Annual Product Report (APR), and how to organize an APR.

Languages Available:

German
 French (European)
 Spanish (Spain)

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- Pharmaceutical GMP Basics

Confidentiality, Intellectual Property Protection, and Information Security

LAV19

Every day, employees may come into contact with information that must be protected. In order to preserve the confidentiality, integrity, and availability of this information, each employee must recognize information that is considered sensitive and be able to protect it. This course defines sensitive information, including intellectual property and trade secrets, and teaches employees how to protect it. Topics in this course include: Legal Protection, Company Protection, and Responses. After completing this course, learners will be able to identify what information is considered sensitive and how they can protect sensitive information and intellectual property, including how to respond to a request by a third party for this information.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Functional Areas:

- Corporate Compliance Basics

Confined Space Hazards Awareness

PS5-102385

If one of your co-workers passed out in a confined space, would you go in to rescue him? Can you be sure the air in the space is safe? This training will help you understand the risks associated with confined spaces. Do not take this information lightly. It can mean the difference between life and death! Ideal learners are all employees.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Confined Spaces: Permit-Required

PS5-101280

You may be able to enter an enclosed space, but could you get back out safely? If it is a permit-required confined space, you know there is a risk of a flammable, asphyxiating, corrosive or toxic atmosphere. This training will help you understand the hazards associated with confined spaces and the procedures your employer has in place to protect you and those around you. Do not take this information lightly. It can make the difference between life and death! Ideal learners are anyone who works in or around confined spaces.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Languages Available:

Czech
Dutch
French (European)
German
Italian
Japanese
Korean
Polish
Portuguese (Brazil)
Russian
Spanish (Latin America)
Thai

Corrective and Preventive Actions

PHA70

Corrective and preventive actions (CAPA) can prevent continuing production problems, high scrap rates, product failures, customer dissatisfaction, and harm to a user or patient. This course describes the regulatory requirements for the corrective and preventive actions procedures. Topics in this course include: Quality System, CAPA Program, Nonconformities, Root Cause Analysis, and Change Control. After completing this course, learners will be able to recognize the applicable regulatory requirements of implementing an effective CAPA procedure.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Pharmaceutical GMPs

Functional Areas:

- Pharmaceutical GMPs - CAPA

Languages Available:

German (PHA70)
Japanese (PHA70)
Chinese (Simplified) (PHA70)

Courtroom Testimony

FDA46

This course will introduce you to your role if you are called as an FDA witness, including grand jury, deposition, declaration, and courtroom testimony. Topics in this course include: Types of Testimony, Preparation, Conduct, On the Stand, and After Testimony. After completing this course, learners will be able to recognize the types of testimony, ways to prepare for testimony, the fundamental characteristics of appropriate courtroom conduct, and the components of effective testimony.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- FDA Inspection Readiness

Data Integrity for Clinical Research Staff

DATA05

Clinical research staff must be aware of the potential and inherent risks to data integrity. Topics in this course include: FDA Directions, Roles, and Errors. After completing this course, learners will be able to identify the role of clinical staff in maintaining data integrity, and identify various challenges to data integrity.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Languages Available:

Chinese (Simplified) (DATA05)
German (DATA05)
French (European) (DATA05)
Spanish (Spain) (DATA05)

Libraries:

- Data Integrity

Functional Areas:

- Quality Assurance

Content Bundles:

- Data Integrity

Data Integrity for Quality Control Laboratories

DATA04

To ensure the quality of raw materials, in-process materials, and finished goods, laboratory data integrity is of great importance in current Good Manufacturing Practices (cGMP) for the US Food and Drug Administration (FDA)-regulated industry. This course focuses on data integrity in the Quality Control (QC) laboratory. Topics in this course include: History, Strategies for Control, and Ethics. After completing this course, learners will be able to recognize potential strategies for maintaining data integrity and the consequences of noncompliance, and identify the types of data integrity issues found by FDA.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Data Integrity

Content Bundles:

- Data Integrity

Languages Available:

- Chinese (Simplified) (DATA04)
- German (DATA04)
- French (European) (DATA04)
- Spanish (Spain) (DATA04)

Data Integrity: The Role of Quality Assurance for Data Integrity

DATA03

Clinical trial data integrity has traditionally been an integral part of quality assurance. This course describes quality assurance in the light of new data collection methods and procedures. Topics in this course include: Overall Approach to Quality, Quality Activities, and Documentation. After completing this course, learners will be able to identify the role of Quality Assurance in data integrity, and recognize regulatory compliance auditing and QMS auditing.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Data Integrity

Content Bundles:

- Data Integrity

Languages Available:

- French (European) (DATA03)
- German (DATA03)
- Spanish (Spain) (DATA03)
- Chinese (Simplified) (DATA03)

DEA Compliance

PHA40

Today, many organizations use regulations for controlled substances to keep their facilities, production processes, and employees safe. This course explains the regulations found in 21 CFR Chapter 2 governing the manufacture and distribution of drugs classified as controlled substances by the Controlled Substances Act (CSA), and as enforced by the Drug Enforcement Agency (DEA). Topics in this course include: DEA's Role, Classifications, Registration, Facility Controls, Production Controls, Employee Controls, and Recordkeeping. After completing this course, learners will be able to identify how the DEA enforces the laws and associated regulations under the CSA.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Pharmaceutical GMPs

Functional Areas:

- Pharmaceutical GMP Basics

Languages Available:

- Chinese (Simplified) (PHA40)

Defensive Driving - Small Vehicles

PS5-00264

A split-second decision can change your life, especially when you are behind the wheel of a fast-moving, heavy vehicle. Take this course to refresh your memory about safe driving practices, particularly what you need to do before you drive, while you drive and in the event of an accident. Ideal learners are anyone who drives cars or small vehicles.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Languages Available:

- French (Canadian)
- Dutch
- French (European)
- German
- Italian
- Japanese
- Korean
- Polish
- Portuguese (Brazil)
- Russian
- Spanish (Latin America)
- Chinese (Simplified)

Deficit Reduction Act: False Claims and Employee Protections Training

GHC01

This course covers the Deficit Reduction Act of 2005 (DRA) and provides awareness of the mandates and provisions that must be provided to employees of a healthcare entity. The course also includes information on the Fraud Enforcement and Recovery Act (FERA) that was signed into law by the President on May 20, 2009 and the Affordable Care Act (ACA) signed into law on March 23, 2010. Topics in this course include: Definitions, State Acts, Whistleblowers, and Compliance. After completing this course, learners will be able to recognize both federal and state laws enacted to reduce the amount of fraud and abuse within the Medicare reimbursement system.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

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|---|---|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">Healthcare: General | <ul style="list-style-type: none">Healthcare: Compliance Topics |

Design Control Regulations for Medical Device Manufacturers

DEV40

Manufacturers of medical devices are responsible for ensuring that the products they create follow the rules for design control. This course describes FDA design control regulations by providing basic information about the key procedures followed during the design and development of a product. Topics in this course include: Design and Development Plan, Design Input, Design Output, Design Review, Verification, Validation, Design Transfer, and Change Control. The design plan requires documentation of training, planning validation, design transfer and changes, formal review, a design history file, and human factors. After completing this course, learners will be able to recognize the purpose and scope of design control regulations and will also be able to identify the eight main aspects of design control and how they affect medical device manufacturers.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

- | | |
|---|---|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">Medical Device GMPs | <ul style="list-style-type: none">Quality Assurance |

Languages Available:
German (DEV40)
French (European) (DEV40)
Chinese (Simplified) (DEV40)
Japanese (DEV40)
Spanish (Spain) (DEV40)

Destruction and Reconditioning

FDA33

This course discusses procedures and methods for destroying, reconditioning, and/or denaturing products that are in violation of the FD&C Act. Topics in this course include: Seized Articles, Detained Products, Voluntary Correction, Procedures, and Damage. After completing this course, learners will be able to identify the circumstances and procedures under which articles may be destroyed or reconditioned.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

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|---|--|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">FDA Inspections and Enforcement | <ul style="list-style-type: none">FDA Inspection Readiness |

Detecting and Preventing Fraud

ETHICS13

This course will identify what constitutes fraud, how to recognize and report potential or actual fraud, and when and how you should report it. After completing this course, you will also be able to recognize internal fraud, computer fraud, social engineering, and money laundering.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

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|---|--|--|
| Libraries: | Functional Areas: | Content Bundles: |
| <ul style="list-style-type: none">Ethics & Corporate Responsibility | <ul style="list-style-type: none">Corporate Ethics | <ul style="list-style-type: none">Corporate Compliance - Plan SponsorsCorporate Compliance - General Industry |

Languages Available:
Spanish (Latin America) (ETHICS13)
Italian (ETHICS13)
French (European) (ETHICS13)
Chinese (Simplified) (ETHICS13)
Japanese (ETHICS13)

Dietary Supplements -- cGMP Requirements for Quality Control

Dietary05

This course provides information about regulatory requirements for Dietary Supplement manufacturers, holders, packagers and labelers during Quality Control operations. Topics in this course include: Laboratory Operations, Material Reviews, Returned Products, Packaging and Labeling, and Records. After completing this course, learners will be able to identify regulatory requirements for Quality Control operations, including material reviews and dispositions.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Dietary Supplements GMPs

Functional Areas:

- Dietary Supplement GMPs

Content Bundles:

- cGMPs for Dietary Supplements

Dietary Supplements -- cGMPS for Manufacturing Plants and Equipment

Dietary03

The Final Rule (21 CFR Part 111) defines the current Good Manufacturing Practices (cGMPs) for the Dietary Supplement industry, including specific requirements for facilities and equipment. This course outlines current FDA requirements for facilities that manufacture, package, label, hold, and distribute dietary supplements. Topics in this course include: Physical Plant, Plant Design, Equipment and Utensils, and Records. After completing this course, learners will be able to identify FDA requirements for manufacturing plants and equipment that manufactures dietary supplements.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Dietary Supplements GMPs

Functional Areas:

- Dietary Supplement GMPs

Content Bundles:

- cGMPs for Dietary Supplements

Dietary Supplements -- Introduction to Part 111 cGMPs

Dietary02

The popularity of dietary supplements and the size of the global industry are increasing rapidly, and product safety has grown into a main concern. Current good manufacturing practices (cGMPs) for dietary supplements have been issued by FDA to address this concern. Topics in this course include: History, Jurisdiction of cGMP Requirements, Basic Terminology, Basic Requirements of the Final Rule, and Personnel Requirements. After completing this course, learners will be able to recognize the origin and scope of cGMPs for dietary supplements. Learners will also be able to identify the purpose of general provisions and personnel subparts, as well as the 16 basic subparts of the 21 CFR Part 111 Final Rule. This course is the second in a series of courses on dietary supplement regulations.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Dietary Supplements GMPs

Functional Areas:

- Dietary Supplement GMPs

Content Bundles:

- cGMPs for Dietary Supplements

Dietary Supplements -- Packaging, Labeling, Holding, and Distribution

Dietary01

This course discusses the requirements for dietary supplement product packaging, labeling, holding, and distribution.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Dietary Supplements GMPs

Functional Areas:

- Dietary Supplement GMPs

Content Bundles:

- cGMPs for Dietary Supplements

Dietary Supplements -- Production and Process Control System for Manufacturing Operations

Dietary04

This course is designed to help learners understand and recognize the principles and practices of process control and the role they play in ensuring quality dietary supplement product manufacturing. Topics in this course include: Basic Requirements, Specifications, Contamination, Samples, Evaluation, Testing, Rejections, and Documentation. After completing this course, learners will be able to identify the cGMP process control requirements for manufacturing operations, including sanitation, contamination, rejected products, specifications, in-process adjustments, reserve sampling, and records.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Dietary Supplements GMPs

Functional Areas:

- Dietary Supplement GMPs

Content Bundles:

- cGMPs for Dietary Supplements

Dietary Supplements -- Requirements for Records and Recordkeeping

Dietary06

This course explains how GMP records and associated procedures remain effective and essential elements of maintaining product quality. Topics in this course include: Master Manufacturing Records, Batch Records, Best Practices, Record Retention, and 21 CFR Part 11. After completing this course, learners will be able to recognize the importance of the Master Manufacturing Record (MMR) and Batch Production Records.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Dietary Supplements GMPs

Functional Areas:

- Dietary Supplement GMPs

Content Bundles:

- cGMPs for Dietary Supplements

Discrimination and Harassment Free Workplace

ETHICS19

Each of us is responsible for our working environment. Every employee needs to understand the kind of behavior that fosters a positive and productive climate and the unacceptable behavior, such as discrimination and harassment which can negatively affect our workplace. This course addresses the laws and our company's policies related to discrimination, harassment, and diversity, and why they are important. Topics in this course include: Importance, Laws and Policies, Harassment, and Reporting Complaints. After completing this course, learners will be able to recognize how diversity is important to our company's success, the laws and policies that define discrimination and harassment, acceptable and unacceptable behavior, and the proper response to situations of discrimination and harassment.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Ethics & Corporate Responsibility

Functional Areas:

- Harassment Topics

Diversity in the Workplace

LAV05

The increasing diversity of today's workforce means that employees and supervisors are part of a dynamic and ever-changing environment. This course explains how culture influences values, assumptions, thought processes, and work relationships. Topics in this course include Importance, Change, Laws, and Stereotypes. After completing this course, learners will be able to recognize the changing work environment and identify how to improve their working relationships with people from different backgrounds.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Functional Areas:

- HR Compliance

Content Bundles:

- HR Compliance

Documenting the Drug Development Process — ICH Q8(R2)

ICHreg03

FDA issued the International Conference on Harmonization (ICH) guidance Q8(R2) Pharmaceutical Development. This guidance addresses documenting the drug development process via the Common Technical Document (CTD). Topics in this course include: CTD, Pharmaceutical Development, Drug Components, Drug Product, Manufacturing Process, Container Closure System, and Microbial Attributes. After completing this course, learners will be able to recognize the FDA guidance on pharmaceutical development and be able to identify how it can be used to design and manufacture safe and effective pharmaceutical or biological products that are of consistent quality.

Format: eLearning - EduFlex, eLearning - SCORM

- | | |
|---|---|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• Global Regulatory | <ul style="list-style-type: none">• ICH: Quality Management |

Documenting Validation Activities

PHA55

The process of validation in FDA-regulated industry is important to gain FDA acceptance. The key to successful validation is the understanding that validation must be documented. This course illustrates the process of documenting validation activities for FDA acceptance. Topics in this course include: Validation, Documents, Equipment, Materials, Process, and People. After completing this course, learners will be able to recognize FDA's definition of validation and identify the required components of the validation process.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE **Partners:** FDA

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|---|---|---|
| Libraries: | Functional Areas: | Content Bundles: |
| <ul style="list-style-type: none">• Medical Device GMPs• Pharmaceutical GMPs | <ul style="list-style-type: none">• Design Controls• Computer Systems Validation• QC Laboratories | <ul style="list-style-type: none">• Computer Systems Validation |

Doing Business with the US Government

ETHICS26

This course is designed to help learners understand how laws and company policies are applicable to your job. Topics in this course include: Obeying the Law; US Laws and Regulations; Employee Activities; Relationships with US Government Customers; Lobbying Activities; Relationships with Subcontractors, Suppliers, and Vendors; and Responsibilities and Reporting. After completing this course, learners will be able to identify potential violations of laws and policies that apply to US government contracts and recognize ways to find help.

Format: eLearning - EduFlex, eLearning - SCORM

- Libraries:**
- Ethics & Corporate Responsibility

Doing the Right Thing for Customers and Business Partners

ETHICS03

Businesses must be able to demonstrate that they can run their business with integrity and keep their promises. This course explores how to build strong relationships with our customers and business partners through trust, quality and service, privacy protection, and fair treatment. Topics in this course include: Earning Trust, Quality and Service, Protecting Privacy, and Fair Treatment. After completing this course, learners will be able to recognize how to build strong relationships with our customers and business partners.

Format: eLearning - EduFlex, eLearning - SCORM

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| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• Ethics & Corporate Responsibility | <ul style="list-style-type: none">• Corporate Ethics |

Doing the Right Thing: Anti-bribery

ETHICS09

This course provides basic training on complying with laws prohibiting bribery, including the US Foreign Corrupt Practices Act (FCPA). Because of the special circumstances facing employees in the healthcare field, this course is focused on issues faced in interactions with healthcare professionals as well as government officials. Topics in this course include: Legal Foundation, Laws, and FCPA in Action. After completing this course, learners will be able to identify and navigate situations that may be perceived as bribery. Learners will also be able to recognize requirements of the FCPA.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Ethics & Corporate Responsibility

Functional Areas:

- Corporate Ethics

Drug Safety & Adverse Event Reporting

GCP15

This course explains the regulatory requirements in the clinical trial and post-marketing environments, while also describing the international drug safety monitoring efforts. Topics in this course include: History, Pre-clinical Safety Data, Sponsor Responsibilities, and Postmarketing Reports. After completing this course, learners will be able to recognize terminology associated with drug safety monitoring during clinical trials, identify sponsor's responsibilities regarding safety reporting, and recognize the importance of drug safety and adverse event reporting.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: Corexcel

Libraries:

- Clinical: Pharmaceutical

Functional Areas:

- GCP - Clinical Management

Content Bundles:

- Good Clinical Practices (GCP)

Languages Available:

- Chinese (Simplified) (GCP15)
- German (GCP15)
- Japanese (GCP15)

Effectively Responding to FDA 483s and Warning Letters

PHDV70

No company wants to receive an FDA 483 or Warning Letter for adverse findings after an FDA inspection, but it does happen. This course explains the basic principles of FDA 483s and the use of Warning Letters to provide feedback on compliance concerns. Topics in this course include: FDA 483, Response, Warning Letter, Response Process, and Avoiding Mistakes. After completing this course, learners will be able to describe key aspects of written responses to both FDA 483s and Warning Letters, and recognize the importance of both of these documents.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- FDA Inspection Readiness

Languages Available:

- Spanish (Spain)
- Chinese (Simplified)
- Japanese

Egress and Emergency Action Plans Awareness

PS5-01423

Each year, more than 200 deaths and 5,000 injuries result from fires and explosions in the workplace. The National Fire Protection Association reported over 115,000 non-residential structural fires in a recent year, accounting for \$2.4 billion in direct property damage. Those are the losses due to fires, but there are other hazardous situations that can threaten a worker's life and limb. These include severe weather, medical emergencies, chemical release, and bomb threats. We can't completely eliminate dangerous workplace situations, but we can reduce the number of associated injuries and deaths attributable to these incidents. This course will focus on two important aspects of this effort: egress and emergency action plans.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

E-Mail and Corporate Communications

ETHICS20

E-mail remains the predominant form of communication in the business world, with estimates ranging in excess of 100 billion e-mails sent and received daily. This course illustrates the use of e-mail in the workplace, including several hot-button issues, such as an employee's expectation of privacy, and electronically transmitted computer viruses. Topics in this course include: How E-mail Works, E-mail Use, and Privacy and Security. After completing this course, learners will be able to recognize the consequences of sending or forwarding an inappropriate e-mail attachment or message.

Format: eLearning - EduFlex, eLearning - SCORM

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|---|--|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none"> • Ethics & Corporate Responsibility | <ul style="list-style-type: none"> • Corporate Ethics |

Enforcement of the Postmarketing Adverse Drug Experience Reporting Regulations

FDA64

This course provides an overview of Postmarketing Adverse Drug Experience (PADE) regulations, guidance, inspectional candidate selection, inspectional techniques, and regulatory actions to enhance the field investigator's knowledge. Topics in this course include: Reporting, FAERS, Types of ADE Reports, ADE Team, Inspecting, and Compliance. After completing this course, learners will be able to recognize how to perform the inspectional activities necessary to monitor industry's surveillance, receipt, evaluation, and submission of adverse drug experience information to FDA.

Format: eLearning - EduFlex, eLearning - SCORM **Partners:** FDA

- | | |
|---|--|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none"> • FDA Inspections and Enforcement | <ul style="list-style-type: none"> • FDA Inspection Readiness |

Environmental Control and Monitoring

PHDV87

It is important for all personnel involved in the manufacturing of sterile products and medical devices to understand how to maintain the quality of the cleanroom environment through environmental control and monitoring. This course examines regulatory requirements for environmental control and monitoring and how to prevent particulate and microbiological contamination of sterile products and devices. Topics in this course include: Purpose, Control, Monitoring, Documentation, and Prevention. After completing this course, learners will be able to recognize the methods of environmental control and monitoring, and identify how to prevent contamination.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE **Partners:** FDA

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|--|---|---|
| Libraries: | Functional Areas: | Content Bundles: |
| <ul style="list-style-type: none"> • Medical Device GMPs • Pharmaceutical GMPs | <ul style="list-style-type: none"> • Maintenance and Facilities • QC Laboratories | <ul style="list-style-type: none"> • Maintenance and Facilities - Basics • Basics of Aseptic Processing |

Languages Available:
 German (PHDV87)
 French (European) (PHDV87)
 Chinese (Simplified) (PHDV87)
 Japanese (PHDV87)
 Korean (PHDV87)
 Spanish (Spain) (PHDV87)

Essentials of an Effective Calibration Program

PHDV75

Injuries, fatalities, or major class action suits filed against the manufacturer can result when products are produced with out-of-calibration equipment. This course identifies the essentials of an effective calibration program. This course contains references to both U.S. and EU regulations. Topics in this course include the four aspects of calibration, calibration standards, regulatory requirements, and calibration procedures. After completing this course, learners will be able to recognize the reasons for calibration and the requirements and standards of effective calibration programs.

Format: eLearning - EduFlex, eLearning - SCORM **Partners:** FDA

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| Libraries: | Functional Areas: | Content Bundles: |
| <ul style="list-style-type: none"> • Medical Device GMPs • Pharmaceutical GMPs | <ul style="list-style-type: none"> • Maintenance and Facilities | <ul style="list-style-type: none"> • Maintenance and Facilities - Basics |

Languages Available:
 Chinese (Simplified)
 Japanese
 Korean
 Spanish (Spain)

Ethical Review Boards

GCP14

This course addresses the role, responsibilities, and regulatory requirements of Institutional Review Boards (IRBs)/Independent Ethics Committees (IECs) in protecting the rights and welfare of human research subjects. Topics in this course include: Development, Membership/Procedures, Review and Approval, Post-Approval Responsibilities, Vulnerable Subjects, Noncompliance, and Compliance Resources. After completing this course, learners will be able to recognize their obligations in relation to the IRB/IEC and the policies and procedures that were developed to protect and safeguard research subjects.

Format: eLearning - EduFlex, eLearning - SCORM

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|--|---|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none"> • Clinical: Medical Device • Clinical: Pharmaceutical | <ul style="list-style-type: none"> • GCP - Clinical Management |

Ethical Third Party Sales and Marketing Intermediary (“SMI”) Relationships

MDSM06

This course explores third party sales and marketing intermediary relationships. It discusses the key regulatory risks associated with sales and marketing with third parties, depicts how an effective compliance program can assist a company in mitigating regulatory risks, and describes essential elements of an effective compliance program.

Format: eLearning - Magazine

- | | |
|--|---|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none"> • Medical Device - Sales & Marketing • Medical Device - Sales & Marketing | <ul style="list-style-type: none"> • Corporate Compliance Basics • Corporate Ethics • Medical Device Sales Compliance • Pharmaceutical Sales Compliance |

Ethics as the Foundation to Clinical Research

GCP10

All clinical research personnel confront ethical decisions. This course reviews the principles and methods that exist to ensure that the rights and welfare of human subjects are protected. Topics in this course include: Ethical Documents, Decision-Making Process, Emerging Trends, and Considering the Ethical Dilemma. After completing this course, learners will be able to recognize the ethical components of historical clinical research guidelines, the definition of clinical equipoise and its importance in clinical trials, and one systematic approach to ethical decision-making.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: Corexcel

- | | |
|--|---|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none"> • Clinical: Medical Device • Clinical: Pharmaceutical | <ul style="list-style-type: none"> • GCP - Clinical Management |

Languages Available:
 French (European)
 German
 Spanish (Spain)

EU Directives and Inspection Readiness

PHDV96

The EU has strict requirements for the manufacture and supply of medicinal products, which are defined in EU directives and GMP guides. To confirm that these requirements are being complied with, manufactures and suppliers are regularly inspected. If significant deficiencies are identified during inspections, the company may face sanctions and could even be barred from supplying product. Upon completion of this course, you will be able to identify the regulatory background regarding EU inspections, the expectations inspectors may have, and how to prepare for inspections.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- EU Regulations
- FDA Inspection Readiness

Content Bundles:

- GMP Inspection Readiness

Languages Available:

- German (PHDV96)
- French (European) (PHDV96)
- Spanish (Spain) (PHDV96)

EU In Vitro Diagnostic Regulations (IVDR)

MDR02

This course describes information about the compliance of the in vitro diagnostic medical devices in accordance with the European In Vitro Diagnostic Medical Device Regulations (IVDR). Topics in this course include: Definitions, Regulatory Requirements, Conformity Assessments and Performance Studies, and EU Portal and Surveillance. After completing this course, learners will be able to recognize essential requirements and harmonized standards for in vitro diagnostic medical devices.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Medical Device GMPs
- Global Regulatory

Functional Areas:

- EU Market Access
- EU Regulations
- EU MDD

Languages Available:

- Chinese (Simplified)
- Japanese
- Korean

EU Medical Device Regulation (MDR)

MDR01

This course describes basic information concerning the European Medical Device Regulation and the CE marking of medical devices. Topics in this course include: History, Definitions, Approach, Quality System, and General Classifications and Rules. After completing this course, learners will be able to identify the basic components of the EU Medical Device Regulation (MDR).

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Medical Device GMPs
- Global Regulatory

Functional Areas:

- EU Market Access
- EU Regulations
- EU MDD

Languages Available:

- Chinese (Simplified)
- Japanese
- Korean

European Union Clinical Trials Directive

GCP16

The European Union (EU) Clinical Trials Regulation covers clinical trials in the EU and sets forth requirements of investigators, sponsors, EU Member States' Competent Authorities, and others responsible for clinical trial regulation. Topics in this course include: Requirements and Responsibilities, Overall Authorization, Modifications and Amendments, IMPs, and Adverse Events. After completing this course, learners will be able to identify the principal elements of the EU Clinical Trials and Good Clinical Practice Directives.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:

- GCP - Clinical Management

Languages Available:

- French (European)
- German
- Spanish (Spain)

European Union GMP Requirements

PHA78

If you are involved with the manufacture of medicinal products you must comply with Good Manufacturing Practice (GMP) requirements. This course explains the European Union's (EU) GMP regulations and guidelines. Topics in this course include: Pharmaceutical Quality Systems, Staff, Premises and Equipment, Documentation, Production, Quality Control Department, and Controls. After completing this course, learners will be able to identify the EU's basic GMP regulations and recognize how to comply with these requirements.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Pharmaceutical GMPs

Functional Areas:

- EU Regulations
- GMP Pharmaceuticals
 - EU Regulations
- Pharmaceutical GMPs
 - Basics

Languages Available:

- Spanish (Spain) (PHA78)
- French (European) (PHA78)
- German (PHA78)
- Chinese (Simplified) (PHA78)
- Japanese (PHA78)

European Union GMP Requirements for Computerised Systems

PHDV95

This course introduces the European Union's GMP requirements for computerised systems that are associated with the manufacture of medicinal products. Reference is also made to FDA expectations. This course covers requirements that govern the use of computerised systems as specified in regulations and guidance documents issued by the European Union.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- GMP - EU Regulations

Languages Available:

- German (PHDV95)
- French (European) (PHDV95)
- Spanish (Spain) (PHDV95)

European Union Good Distribution Practices for Medicinal Products

PHA77

This course describes the Good Distribution Practices required by the European Union (EU). The EU's recommended practices are similar to requirements in the US and many other countries. The controls to maintain the quality and integrity of medicinal products as they are distributed from manufacturer to patient are explained in this course. Because modern supply chains are often complex, the responsibilities of all organisations involved with wholesale activities — including storage, transport, purchase, and supply — are detailed. The controls required to prevent falsified or fake products entering the supply chain are also addressed.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Pharmaceutical GMPs
- Global Regulatory

Functional Areas:

- GMP Pharmaceuticals
 - EU Regulations

Languages Available:

- German (PHA77)
- French (European) (PHA77)
- Spanish (Spain) (PHA77)

Evidence and Proof

FDA22

FDA takes action based on information collected and developed by investigational and analytical personnel. FDA's ability to perform its function is based on the quality and care used in collecting and preserving information. Information is evidence; obtaining it properly is a vital portion of FDA's law enforcement work. This course explores forms of evidence and proof. Topics in this course include: Physical Evidence, Photographic Evidence, Written Evidence, Testimony, Elements of Proof, and FDA Actions. After completing this course, learners will be able to recognize the processes involved in gathering evidence and proof, and identify the circumstances under which both can be used.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- FDA Inspection Readiness

Failure Investigations for Medical Device Manufacturers

DEV45

Handling medical device failures can be significant in a company's ability to maintain a state of control in operations and prevent future failures. This course will explore what a failure is, the regulatory and practical aspects of investigations, and the elements that make these investigations effective. Topics in this course include: Product Failure, Investigations, Root Cause, CAPA, Follow-up, and Documentation. After completing this course, learners should be able to recognize the basic definition of failures, identify when a failure investigation should occur, and the documentation required.

Languages Available:
Chinese (Simplified) (DEV45)
Japanese (DEV45)
Korean (DEV45)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE
Partners: FDA

Libraries:

- FDA Inspections and Enforcement
- Medical Device GMPs

Functional Areas:

- Root Cause

Failure Investigations for Pharmaceutical Manufacturers

PHA59

An effective system for conducting failure investigations can provide a means for preventing recurrences. This course will familiarize the learner with GMP regulations regarding failure investigations and the key components of a good investigation. Topics include: Failures, Root Cause, Corrective Actions, Follow-Up, and Investigation Reports. After completing this course, you will be able to identify the failure investigation process. You will be able to recognize how GMP regulations address failure investigations and the key components of a good investigation. You will also be able to identify how to determine the root cause of a failure and recognize the importance of corrective actions and follow-ups to failure investigations.

Languages Available:
German (PHA59)
French (European) (PHA59)
Japanese (PHA59)
Spanish (Spain) (PHA59)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE
Partners: FDA

Libraries:

- Pharmaceutical GMPs

Functional Areas:

- Pharmaceutical GMPs - Root Cause Analysis

Fair Labor Standards Act (FLSA) and Equal Pay Act (EPA)

LAV03

The Fair Labor Standards Act (FLSA) is a federal law that establishes minimum wage, overtime pay, recordkeeping, and youth employment standards. The Equal Pay Act (EPA) is a federal law that requires men and women in the same workplace to receive equal pay for equal work.

This course provides an overview of the FLSA and EPA with a concentration on employer concerns. It also covers important distinctions between exempt and non-exempt employees and between employees and independent contractors. Topics in this course include: FLSA, Minimum Wage, Overtime, Exempt Employees, Contractors, Compensatory Time, Child Labor, Nursing Mothers, and Equal Pay Act (EPA). After completing this course, learners will be able to recognize the significant aspects and exemptions of both the FLSA and EPA.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Functional Areas:

- Corporate Compliance Basics

Fall Protection

PS5-00556

Each year, many workers are hurt or killed as a result of falls in the workplace. Falls are usually complex events that involve a variety of factors. This training will cover systems and procedures designed to prevent falls off, onto or through working levels and to protect workers from being struck by falling objects.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Languages Available:

Czech
 French (European)
 German
 Hungarian
 Italian
 Japanese
 Korean
 Polish
 Portuguese (Brazil)
 Russian
 Spanish (Latin America)
 Thai
 Dutch

Family and Medical Leave Act (FMLA)

LAV06

Managers and supervisors in the workplace must fully understand the federal Family and Medical Leave Act (FMLA). This course explains who is covered by the FMLA and what leave and other benefits must be provided to eligible employees. Topics in this course include: Eligibility, Types of Leave, Conditions and Coverage, Notices, Job Restoration, Non Discrimination/No Retaliation Policy. After completing this course, learners will be able to understand the provisions of the FMLA.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- HR Compliance & Risk Management

Functional Areas:

- HR Compliance

Content Bundles:

- HR Compliance

Languages Available:

Spanish (Latin America) (LAV06)

FDA 483s: Inspectional Observations

FDA30

This course is designed to familiarize FDA staff with the important aspects of the FDA 483. Topics in this course include: FDA 483, Objectionable Conditions, Reportable Conditions, Essentials, and Annotation. After completing this course, you will recognize the purpose of issuing an FDA 483. You will be able to identify what kinds of inspectional observations are included on an FDA 483, when that form is issued to the inspected firm, and how to annotate it during the discussion with management.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- FDA Inspection Readiness

Languages Available:

Chinese (Simplified)
 German
 Japanese

FDA Establishment Inspection (EI)

FDA32

FDA performs approximately 15,000 establishment inspections (EIs) per year. Topics in this course include: FDA Authority, Preparation, Initiating Inspection, Refusals, Observation, Evidence, and Concluding an Inspection. After completing this course, learners will be able to recognize the procedures to prepare for, conduct, and conclude inspections.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- FDA Inspection Readiness

Languages Available:

Chinese (Simplified) (FDA32)

FDA Establishment Inspection Report Writing

FDA26

Establishment inspection reports (EIRs) are written reports that create a record of an inspection of a regulated firm. This course illustrates the purpose of the establishment inspection report (EIR), and what should be included in an EIR. Topics in this course include: FDA Required Standards, Parts of an EIR, Readability, and Additional Formats. After completing this course, learners will be able to identify the purpose and multiple uses of the EIR, recognize the items to be included in the EIR, recognize ways to make the report more readable, and identify multiple formats of the EIR.

Languages Available:
Chinese (Simplified)

Format: eLearning - EduFlex, eLearning - SCORM **Partners:** FDA

Libraries:
• FDA Inspections and Enforcement

Functional Areas:
• FDA Inspection Readiness

FDA Good Guidance Practices (GGPs)

FDA21

This course on FDA Good Guidance Practices (GGPs) explains which Agency documents are considered guidance documents. It also explains why we have GGPs, their legal effect, how they are developed, and GGP implementation. Topics in this course include: Purpose and Scope, Implementation, Issuing Guidance, and Legal Effects. After completing this course, learners will be able to describe the history, development, issuance, and use of Agency guidance. Learners will also be able to recognize how and why GGPs were established.

Languages Available:
French (European) (FDA21)

Format: eLearning - EduFlex, eLearning - SCORM **Partners:** FDA

Libraries:
• FDA Inspections and Enforcement

Functional Areas:
• FDA Inspection Readiness

FDA Training and Qualification Requirements

PHA67

Effective personnel training and qualification can produce a competent workforce, which can lead to a reduction of errors/deviations, customer complaints, regulatory risk, and operational costs. This course addresses the measures required to stay in compliance with FDA regulations, and the requirements needed to implement an effective training and qualification program. This course also discusses specific responsibilities of personnel, records that need to be maintained, and how to measure training and qualification. Topics in this course include: Responsibilities, System Requirements, Training Specifics, Qualification Specifics, and Metrics. After completing this course, learners will be able to identify FDA's requirements for personnel training and qualification, responsibilities of personnel, and how to measure training and qualification.

Languages Available:
Chinese (Simplified) (PHA67)
Japanese (PHA67)
Korean (PHA67)

Format: eLearning - EduFlex, eLearning - SCORM,
eLearning (Editable) - CREATE

Libraries:
• Medical Device GMPs
• Pharmaceutical GMPs

Functional Areas:
• Pharmaceutical GMPs - Training

Field Examinations

FDA28

Field examinations help to ensure the safety, purity, and compliance of products released for public use. For imported products, field exams help to determine legal admissibility. This course is designed to familiarize individuals with the "what, why, and when" of conducting examinations of products while performing inspections, sample collections, or surveillance activities. Topics in this course include: Scope, Indicators, Equipment, and Conduct. After completing this course, learners will be able to recognize the basics of field examinations. In addition, learners will also be able to identify the types of field examinations, the equipment commonly used during field examinations, and ways to conduct these examinations.

Format: eLearning - EduFlex, eLearning - SCORM **Partners:** FDA

Libraries:
• FDA Inspections and Enforcement

Functional Areas:
• FDA Inspection Readiness

Financial Disclosure by Clinical Investigators

GCP24

This course provides a summary of Title 21 of the Code of Federal Regulations (CFR) Part 54 entitled "Financial Disclosure by Clinical Investigators." This course discusses which financial arrangements must be disclosed, as well as investigator and sponsor responsibilities when disclosing financial information. Topics in this course include: Requirements, Responsibilities, and FDA Evaluation. After completing this course, learners will be able to identify the types of financial arrangements that must be disclosed and recognize how FDA evaluates the submitted financial information and the actions they may take if it is inadequate.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:

- GCP - Clinical Management

Content Bundles:

- Good Clinical Practices (GCP)

Fire Extinguisher Safety

PS5-00246

If you were confronted with a fire in your workplace, would you know whether to fight or flee? If you decide to fight the fire, do you know what to do? Take this course to learn when to fight or flee a fire and how to choose and use fire extinguishers. Knowing what to do can save lives! Ideal learners include all employees.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Languages Available:

French (Canadian)
Czech
Dutch
French (European)
German
Italian
Japanese
Korean
Polish
Portuguese (Brazil)
Russian
Spanish (Latin America)
Thai

Fire Prevention

PS5-00271

Fire is a terrible way to die or be injured. You cannot assume that having a fire department keeps you safe. Most workplace fires are completely preventable. Take this course to find out how to reduce the risk of fires in your workplace. Ideal learners are all employees.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Languages Available:

Czech
Dutch
German
Japanese
Polish
Portuguese (Brazil)

Fire Safety for Healthcare Workers

EHS31

Fire safety in healthcare facilities is especially crucial because employees are not just keeping themselves safe. They're responsible for the safety of patients as well. This course identifies measures specifically designed to keep workers and patients in a healthcare facility safe. Topics in this course include: Ingredients, Fire Classes, Safe Practices, Regulatory Requirements, and Response and Plan. After completing this course, learners will be able to recognize the sources of heat, oxygen, and fuel that can help start a fire.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- RETIRED - Environmental Health and Safety
- Healthcare: General

Functional Areas:

- EHS - Fire Prevention

Languages Available:

Spanish (Latin America) (EHS31)

First Aid - Basics

PS5-100989

Incidents requiring first aid can happen anywhere and at any time. The first response to such an incident is the most important. First aid given at the scene can improve the chances of survival and recovery of a victim. This course presents ways to respond to basic first aid situations until the emergency medical services (EMS) personnel arrive. Ideal learners are all employees.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Languages Available:

Czech
Dutch
French (European)
German
Italian
Japanese
Korean
Polish
Portuguese (Brazil)
Russian
Spanish (Latin America)
Thai

First Aid - Medical Emergencies

PS5-100991

Injuries, both on and off the job, represent a significant health problem. The outcome of injuries depends on not only the severity of the injury, but also on the rendering of first aid care. Prompt, properly administered first aid care can mean the difference between life and death. This course will cover a variety of emergency scenarios and the appropriate first aid care. Ideal learners are all employees.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Languages Available:

Czech
Dutch
French (European)
German
Japanese
Polish
Portuguese (Brazil)
Spanish (Latin America)
Thai

Food and Drug Law: Criminal Acts Violations

FDA04

This course will describe several felony criminal statutes available for use by FDA that are not part of Title 21 of the USC. These are statutes that have been used in the past and are most likely to be used for felony violations associated with Title 21 criminal prosecutions. Topics in this course include: Definition, False Statements, Mail and Wire Fraud, Justice Obstruction, Conspiracy, Aiding and Abetting, and Intent. After completing this course, learners will be able to recognize what constitutes as criminal felony behavior and the means by which FDA proves criminal intent. Learners will also be able to identify specific elements of proof for the statutes covered in this course.

This is the fourth course in a series of courses on FDA's Food and Drug Law.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- Food and Drug Law

Food and Drug Law: FDA Jurisdictions

FDA01

This course introduces the legal jurisdiction of FDA and the responsibilities and limits assigned by Congress to FDA. Topics in this course include: Jurisdiction History, Responsibilities, Foods, Drugs, Devices, Cosmetics, and Jurisdiction Limits. After completing this course, learners will be able to recognize the scope and limits of FDA jurisdiction. Learners will also recognize how products are regulated within the different industries.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- Food and Drug Law

Food and Drug Law: Imports and Exports

FDA05

This course is a general introduction to Chapter 8 of the Federal Food, Drug, and Cosmetic (FD&C) Act, which addresses Imports and Exports. Topics in this course include: Imports, Exports, Primary Agencies, Other Agencies, Importers, Samples, Violative Samples, and Preventing Violations. After completing this course, learners will be able to recognize the definition of imports and exports and recognize various imported and exported products. Learners will also be able to identify the roles agencies play in the import and export of FDA regulated products, as well as non-government parties involved in the import process. Finally, learners will be able to recognize how FDA determines that a sample is in violation of the FD&C Act and prevents violative products from entering the US. Before taking this course, employees should have completed *FDA01 — Food and Drug Law: FDA Jurisdictions* and *FDA03 — Food and Drug Law: Prohibited Actions* in the online “Food and Drug Law” series. This course is not intended to provide detailed legal guidance to any party.

Format: eLearning - SCORM, eLearning - EduFlex

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- Food and Drug Law

Food and Drug Law: Judicial Actions

FDA03

This course will address the types of judicial actions, both criminal and civil, that are available to FDA as part of its law enforcement armory in the event it encounters suspected violations of the Food, Drug, and Cosmetic (FD&C) Act. Topics in this course include: Judicial System, Law Enforcement, The Laws, Criminal Penalties, and Civil Penalties. After completing this course, learners will be able to identify how FDA is empowered to take judicial action, identify the laws enforced by FDA, identify the entities that enforce federal law, and recognize what criminal and civil penalties may be imposed for violations of the FD&C Act and related laws. Prerequisites for this course are *FDA01 — Food and Drug Law: FDA Jurisdictions* and *FDA02 — Food and Drug Law: Prohibited Actions*.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- Food and Drug Law

Food and Drug Law: Prohibited Actions

FDA02

The FD&C Act specifically describes what actions are violations and who will be held accountable for those actions. This course discusses prohibited actions under that law. Topics in this course include: Common Violations, Consequences, Responsibility, and Defining Cases. After completing this course, learners will be able to recognize the specific acts that are prohibited under the FD&C Act. Learners will also be able to identify the most commonly violated acts and recognize how FDA determines who is responsible. Finally, learners will be able to identify major cases that establish consequences for violating prohibited acts, and recognize what these consequences may be.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- Food and Drug Law

Foreign Corrupt Practices Act (FCPA)

ETHICS16

This course explores the Foreign Corrupt Practices Act (FCPA) and anti-bribery. It discusses the laws, regulations, and policies associated with anti-bribery and anti-corruption.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Ethics & Corporate Responsibility

Functional Areas:

- Corporate Ethics

Content Bundles:

- Corporate Compliance - General Industry

Languages Available:

- German (ETHICS16)
- Italian (ETHICS16)
- French (European) (ETHICS16)
- Dutch (ETHICS16)
- Japanese (ETHICS16)
- Chinese (Traditional) (ETHICS16)
- Portuguese (Brazil) (ETHICS16)
- Spanish (Spain) (ETHICS16)
- Turkish (ETHICS16)

Fraud and Abuse Awareness

GHC04

Fighting fraud and abuse within a health plan is important, and associates are valuable assets in anti-fraud efforts. This course describes how an increased awareness of fraud and abuse will help in the prevention and detection of fraud and abuse. Topics in this course include: The Fight against Fraud, Problem Providers, Suspect Subscribers, Victims, Fighting Back, and Responding. After completing this course, learners will be able to identify how to report common types of fraud and abuse. In addition, learners will be able to recognize the negative effects fraud and abuse have on business and our customers.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

- Libraries:**
- Healthcare: General
- Functional Areas:**
- Healthcare: Fraud and Abuse

GCP/ICH Obligations of Sponsors and Monitors

GCP04

This course describes sponsor and monitor requirements and responsibilities for the conduct of clinical trials in support of new drug and biologics applications. Topics in this course include: Sponsor's Role, Research Team, Investigators, Prestudy Site Visit (PSV), Other Visits, and Monitoring Activities. After completing this course, learners will be able to recognize the roles and responsibilities of sponsors and monitors during clinical trials.

Languages Available:
Chinese (Simplified)
German
Japanese

Format: eLearning - EduFlex, eLearning - SCORM **Partners:** FDA

- Libraries:**
- Clinical: Medical Device
 - Clinical: Pharmaceutical
- Functional Areas:**
- GCP Basics

GCP/ICH Obligations of Sponsors, Monitors, and Investigators

GCP01

This course addresses the GCP obligations of sponsors, monitors, and investigators as described in the ICH GCP Guideline. Topics in this course include: Definitions, Protecting Subjects, Sponsor, Monitor, Investigator, and Overall Responsibilities. After completing this course, learners will be able to identify the specific obligations of sponsors, monitors, investigators, and their staff for executing clinical trials.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE **Partners:** FDA Corexcel

- Libraries:**
- Clinical: Medical Device
 - Clinical: Pharmaceutical
- Functional Areas:**
- GCP Basics
- Content Bundles:**
- Good Clinical Practices (GCP)

General Overview and Philosophy of IEC 60601

MDSafety_03

Build a foundational understanding of how the IEC 60601-1 standard mitigates shock, mechanical, radiation, fire and other hazards and learn how the risk of each of the identified hazards is determined and reduced..

Format:

- Libraries:**
- Engineering Safety
- Functional Areas:**
- IEC 60601

Global Anti-Bribery

ETHICS14

This course introduces global anti-bribery laws and provides basic principles and specific guidelines for complying with anti-bribery laws around the world.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Ethics & Corporate Responsibility

Functional Areas:

- Anti-Corruption

Content Bundles:

- Corporate Compliance - Pharmaceutical
- Corporate Compliance - Medical Device
- Corporate Compliance - General Industry

Languages Available:

- Spanish (Latin America) (ETHICS14)
- German (ETHICS14)
- Italian (ETHICS14)
- French (European) (ETHICS14)
- Chinese (Simplified) (ETHICS14)
- Japanese (ETHICS14)
- Polish (ETHICS14)
- Portuguese (Brazil) (ETHICS14)
- Russian (ETHICS14)
- Spanish (Spain) (ETHICS14)
- Turkish (ETHICS14)

Global Fair Competition Laws

ETHICS22

Fair competition laws help to preserve a level competitive playing field for companies. This course covers the basic principles and laws governing fair competition. Topics in this course include: Definitions, Horizontal Agreements, Vertical Agreements, Other Key Considerations, Laws, EU Law — General Considerations, and EU Law — Specific Considerations. After completing this course, learners will be able to recognize the principles and laws that ensure fair competition globally.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Ethics & Corporate Responsibility

Functional Areas:

- Corporate Compliance Basics
- Ethics Basics

Languages Available:

- German
- French (European)
- Chinese (Simplified)
- Spanish (Spain)
- Japanese

Global Regulatory Strategy and Planning Process

DEV54

This course discusses creating the strategy and planning documents that help companies align the development of new products with the regulatory submission process for those products. Along with the regulatory plan, a company's regulatory strategy describes the overall regulatory approach and the specific tactical steps required to meet regulatory objectives for the product. Topics in this course include: Purpose, Strategy Elements, and Plan Elements. After completing this course, learners will be able to identify the elements of a regulatory strategy and plan that can meet your company's development needs while meeting regulatory submission requirements for a variety of regulatory environments.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Medical Device GMPs
- Global Regulatory

Functional Areas:

- Medical Device Market Entry

Languages Available:

- Chinese (Simplified) (DEV54_SCH)
- Japanese (DEV54_JP)
- Korean (DEV54_KOR)

GMP Principles for Batch Records

PHA60

This course explains the Good Manufacturing Practices associated with batch records. Topics in this course include: Record Requirements, Manufacturing Records, Packaging Records, Deviations, and Batch Record Review. After completing this course, learners will be able to identify the regulatory requirements for batch records and recognize how to properly create and maintain batch records.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- Pharmaceutical GMPs - Batch Records

Languages Available:

- Spanish (Latin America) (PHA60)
- German (PHA60)
- French (European) (PHA60)
- Dutch (PHA60)
- Chinese (Simplified) (PHA60)
- Japanese (PHA60)

GMP Principles of SOPs

PHA64

Working within SOPs is critical to making high-quality products that comply with FDA regulations. This course describes the basic GMP principles involved in creating SOPs. Topics include the contents of an SOP, the proper procedure for changing an SOP, and appropriate use of an SOP. After completing this course, you will be able to identify what SOPs are, what their purpose is, and how they are structured. You will be able to recognize how to handle changes to SOPs, as well as how SOPs are used in the workplace.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- Pharmaceutical GMP Basics

Languages Available:

- Spanish (Latin America) (PHA64)
- German (PHA64)
- French (European) (PHA64)
- Chinese (Simplified) (PHA64)
- Japanese (PHA64)
- Korean (PHA64)

GMP Updates: Supply Chain Quality and Emerging Compliance Concerns

PHDV92

Supply chain activities provide the natural resources and raw materials that manufacturers transform into a finished product. This course describes why supply chain quality has evolved as a critical concern in the medical device and pharmaceutical industries and what manufacturers can do to better manage supply chain quality. Topics in this course include: Challenges, Responses, and Company Improvements. After completing this course, learners will be able to recognize how regulators are responding to supplier quality concerns and identify what manufacturers can do to better manage supply chain quality.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- GMPs - Suppliers

Languages Available:

- Chinese (Simplified)
- Japanese
- German

Good Clinical Practices (GCPs) for New Product Investigations

PHA36

This course describes the general requirements of Good Clinical Practice (GCP) for new product investigations for the protection of human subjects, as well as information regarding the concepts, individuals, and groups involved with them. Topics in this course include: Clinical Trial Process, Clinical Trial Team, Specific GCP Requirements, and Documentation Requirements. After completing this course, learners will be able to recognize the basic concepts and key elements of GCP, including documentation, purpose, subject protection, and regulatory authority requirements.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:

- GCP - Clinical Management

Languages Available:

- Chinese (Simplified)
- German
- Japanese

Good Documentation Practices for Medical Device Manufacturers

DEV56

This course presents the critical importance of creating and maintaining good documents for medical device manufacturers. Learners will identify the stages of the Documentation Life Cycle, recognize important types of documents, recognize how documentation is controlled, identify the important requirements of electronic recordkeeping, and recognize best practices for recording and correcting data.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Medical Device GMPs
- Global Regulatory

Functional Areas:

- GMP Basic Concepts

Content Bundles:

- Medical Device - GMP

Languages Available:

- Spanish (Latin America) (DEV56)
- German (DEV56)
- French (European) (DEV56)
- Chinese (Simplified) (DEV56)
- Japanese (DEV56)

Good Laboratory Practices (GLPs)

PHDV62

Nonclinical laboratory studies are one of the first steps taken in bringing a new drug, device, or biologic to the marketplace, so it is important that practices are in place to ensure the reliability of the study and the safety and efficacy of the product. This course gives the learner an introduction to Good Laboratory Practice (GLP) Regulations and their application to nonclinical animal safety and toxicology studies. Topics in this course include: GLP Guidance, Personnel, Protocol, Documentation, and Inspections. After completing this course, learners will be able to recognize the general characteristics of GLPs and identify how they apply to nonclinical studies.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE
Partners: FDA

Libraries:
• Clinical: Pharmaceutical

Functional Areas:
• GxP Basics

Gowning for Sterile Manufacturing

PHA63

Because of the importance of preventing contamination in finished sterilized pharmaceuticals or medical devices, anyone involved in the production of these products must have a basic knowledge of sanitization and sterilization, the microbiological principles involved, and the importance of proper gowning and working in cleanrooms. This course covers requirements of the European Union (EU) and FDA. Topics in this course include Regulations, Contaminants, and Gowning Procedures. After completing this course, you will be able to identify the sources and types of contamination in a manufacturing environment, recognize the importance of health issues and personal hygiene, and identify the staged entry and use of cleanrooms. You will also be able to recognize important practices and procedures for proper gowning. Before taking this course, make sure you have completed Principles of Aseptic Processing and Principles of Sterilization.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
• Medical Device GMPs
• Pharmaceutical GMPs
• Global Regulatory

Functional Areas:
• Maintenance and Facilities

Content Bundles:
• Maintenance and Facilities - Basics
• Basics of Aseptic Processing

Languages Available:

German
French (European)
Spanish (Spain)
Chinese (Simplified)
Japanese

Guidelines of Workplace Safety

EHS53

This course explains how both employees and employers uphold safety in the workplace. Topics in this course include: Causes of Accidents, Accidents and Prevention, Hazards in the Workplace, Employer Role, and Your Role. After completing this course, learners will be able to recognize potential workplace accidents and hazards that may be prevented in order to maintain workplace safety.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
• RETIRED - Environmental Health and Safety
• Ethics & Corporate Responsibility
• HR Compliance & Risk Management

Functional Areas:
• Workplace Safety

Languages Available:

Spanish (Latin America) (EHS53)

GxPs

PHDV61

Regulated Good Practices (GxPs) apply to the development, clinical testing and manufacture of drugs, biological products and medical devices to ensure their safety, efficacy, and security. This course discusses the manner in which regulatory authorities oversee the drug, biologic, and device development and manufacturing processes using GxP regulations. Topics in this course include: GLPs, GCPs, and GMPs. After completing this course, you will be able to identify what practices comprise the GxP regulations. You will also recognize how these practices relate to each step in the development and manufacture of new drugs, biologics, and medical devices.

Languages Available:
 French (European) (PHDV61)
 Chinese (Simplified) (PHDV61)
 Japanese (PHDV61)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE
Partners: FDA

- | | |
|---|--|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none"> • Clinical: Medical Device • Clinical: Pharmaceutical • Pharmaceutical GMPs | <ul style="list-style-type: none"> • GxP Basics |

Handling a Product Recall

PHDV64

This course defines product recalls and explains their impact on the manufacturer, FDA's requirements and enforcement when dealing with a product recall, and the basic steps for handling a recall. Topics include: Procedures, Roles, Effects, and Communication. After completing this course, learners will be able to recognize the definition of "product recall", the impact of a product recall on a manufacturer, and FDA's requirements and enforcement authorities when dealing with a product recall. Learners will also be able to identify the basic steps for handling a recall.

Languages Available:
 Chinese (Simplified) (PHDV64_SCH)
 Japanese (PHDV64_JP)
 Korean (PHDV64_KOR)

Format: eLearning - EduFlex, eLearning - SCORM
Partners: FDA

- | | |
|--|--|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none"> • Medical Device GMPs • Pharmaceutical GMPs | <ul style="list-style-type: none"> • GMPs - Recalls |

Handling an FDA Inspection

PHDV74

This course addresses the roles and responsibilities of personnel during an FDA inspection. Topics in this course include Personnel Conduct, Inspection Types, Process, Records, Photos and Samples, Concluding an Inspection, and Enforcement. After completing this course, learners will be able to identify the basics of handling an FDA Good Manufacturing Practice (GMP) inspection.

Languages Available:
 German (PHDV74)
 French (European) (PHDV74)
 Chinese (Simplified) (PHDV74)
 Japanese (PHDV74)
 Korean (PHDV74)
 Spanish (Spain) (PHDV74)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE
Partners: FDA

- | | | |
|---|--|--|
| Libraries: | Functional Areas: | Content Bundles: |
| <ul style="list-style-type: none"> • FDA Inspections and Enforcement • Medical Device GMPs • Pharmaceutical GMPs | <ul style="list-style-type: none"> • GMP Inspection Readiness • FDA Inspection Readiness | <ul style="list-style-type: none"> • GMP Inspection Readiness |

Handling Confidential Information

ETHICS10

This course explores the importance of protecting confidential information in order to preserve privacy and maintain a competitive edge. After completing this course you will be able to recognize the definition of confidential information, identify ways that information is made vulnerable in the workplace, and recognize specific policies, laws, and examples that relate to confidentiality.

Languages Available:
 Italian (ETHICS10)
 French (European) (ETHICS10)
 Chinese (Simplified) (ETHICS10)
 Japanese (ETHICS10)
 Spanish (Spain) (ETHICS10)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

- | | | |
|---|--|--|
| Libraries: | Functional Areas: | Content Bundles: |
| <ul style="list-style-type: none"> • Ethics & Corporate Responsibility | <ul style="list-style-type: none"> • Corporate Ethics | <ul style="list-style-type: none"> • Corporate Compliance - Plan Sponsors |

Harassment Avoidance Training for California

LAV22

Supervisors and managers must take all complaints and incidents of sexual harassment seriously and should respond quickly and appropriately. This course describes the different types of sexual harassment that can occur in the workplace and how to prevent, monitor, and report these events if they occur. Topics in this course include: Laws and Policies, Types of Sexual Harassment, Prevention and Monitoring, Enforcement, Reporting Harassment, Investigating Harassment, and Retaliation. After completing this course, learners will be able to recognize what actions constitute harassment in the workplace.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Functional Areas:

- Harassment Topics

Harassment in the Workplace

LAV21

Harassment is a serious issue facing companies today. This course identifies what constitutes harassment and outlines the best practices for addressing and preventing harassment in the workplace. Topics in this course include: Definition, Sexual Harassment, Laws, Prevention, and Reporting. After completing this course, learners will be able to identify harassing behavior, avoid harassing behavior, and properly address harassing behavior in the workplace.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- HR Compliance & Risk Management
- Ethics & Corporate Responsibility

Functional Areas:

- HR Compliance

Content Bundles:

- HR Compliance

Hazard Communication (US)

PS5-00206

Workers are exposed to hazardous chemical products every day. This poses serious problems for exposed workers and their employers. Hazard Communication (HazCom) training is designed to provide workers with the information they need to recognize and avoid hazardous chemicals. This course will introduce learners to everything from the content of the HazCom Standard to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) to how to use Safety Data Sheets (SDSs) and chemical labels to prepare for hazards or react to exposures.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Languages Available:
Spanish (Latin America)

HazMat Transportation - Part 1 - The Hazardous Materials Table (US)

PS5-00576

Because of the risks and dangers associated with shipping hazardous materials, the U.S. Department of Transportation Pipeline and Hazardous Materials Safety Administration and its supporting agencies regulate the transport of these materials within the US and ensure we comply with the Hazardous Materials Regulations (or the HMR).

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

HazMat Transportation - Part 2 - Shipping Papers (US)

PS5-00250

Shippers are responsible for documenting information about hazardous materials before offering them for transport. This module covers the components of a properly prepared shipping paper.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

HazMat Transportation - Part 3 - Packaging (US)

PS5-00578

If given the task of packaging or inspecting and accepting hazardous materials for transportation, could you do so in compliance with the HMR's (Hazardous Materials Regulations) packaging requirements? Your employer wants to make sure you can, since the U.S. Department of Transportation (or DOT) and its designated agencies regulate the packaging and transportation of hazardous materials. These agencies also have the authority to inspect hazardous materials, or HAZMAT, packages and fine or penalize you as well as your employer for any HMR violations. Therefore, this module focuses on the various actions shippers and carriers must take to ensure that hazardous materials meet the general packaging requirements.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

HazMat Transportation - Part 4 - Marking (US)

PS5-00580

This series of Hazardous Materials Transportation e-Lessons provides general awareness training for the U.S. Department of Transportation (USDOT) Hazardous Materials Regulations. Module 4 covers the marking and labeling of hazardous materials.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

HazMat Transportation - Part 5 - Labeling and Placarding (US)

PS5-00581

This series of Hazardous Materials Transportation e-Lessons provides general awareness training for the U.S. Department of Transportation (USDOT) Hazardous Materials Regulations. Module 5 covers Placarding.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

HazMat Transportation - Part 6a - Carrier Requirements - Highway (US)

PS5-00582

This series of Hazardous Materials Transportation e-Lessons provides general awareness training for the U.S. Department of Transportation's (USDOT) Hazardous Materials Regulations. Module 6 is composed of four parts: Module 6a covers Highway Carrier Requirements.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

HazMat Transportation - Part 6b - Carrier Requirements - Air (US)

PS5-00583

When it comes to transporting hazardous materials by air, Part 175 of the Hazardous Materials Regulations or HMR provides air carriers with the specific requirements they need to accept, handle and transport hazardous materials.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

HazMat Transportation - Part 6c - Carrier Requirements - Rail (US)

PS5-00584

The DOT (Department of Transportation) identifies requirements for transporting hazardous materials by rail in Part 174 of the HMR (Hazardous Materials Regulations).

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

HazMat Transportation - Part 6d - Carrier Requirements - Water (IMDG) (US)

PS5-00585

In this module, we will focus on the actions we can take to protect our waters and marine life when transporting hazardous materials by any type of vessel or ship.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

HazMat Transportation - Part 7 - Security Awareness (US)

PS5-00223

Hazardous materials are vulnerable when they are in transit. Imagine what would happen if criminals or terrorists were able to obtain dangerous chemicals and materials! Take this course to find out what you can do to prevent that from happening. Ideal learners include people who work at companies involved in the packaging, shipment, transportation and distribution of hazardous materials.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

HAZMAT Transportation Awareness (US)

PS5-00575

In the United States, we ship millions of tons of hazardous materials (HAZMAT) every day. These materials can be poisonous, toxic, flammable, explosive or corrosive by nature. Take this course to learn basic information about how to identify and safely handle hazardous materials, all while complying with federal laws and regulations. This course is ideal for employees who are involved in shipping, packaging or transporting hazardous materials in the United States.

Languages Available:
Spanish (Latin America)

Format:

Libraries:

- EHS for Life Science - Basics

Hearing Conservation

PS5-00267

Did you know that most noise-related hearing loss is completely preventable? In this course you will learn about the noise risks in your workplace and what you need to do to protect your hearing. Ideal learners include all employees who work with noisy tools or equipment or in loud environments.

Languages Available:
Czech
Dutch
French (European)
German
Italian
Japanese
Korean
Polish
Portuguese (Brazil)
Russian
Spanish (Latin America)
Thai

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

High Purity Water Systems

PHDV82

Because water quality can directly impact product quality, GMP regulations require that water receive the same scrutiny, monitoring, and control as any other critical raw material used in manufacturing processes. This course describes the typical uses of water in pharmaceutical and medical device manufacturing. Topics in this course include: Types of Water, Quality Determination, WFI System, Monitoring Process, Monitoring Approaches, System Problems, and Solutions. After completing this course, learners will be able to recognize water types used in manufacturing, monitoring processes, and solutions to problems within high purity water systems.

Format: eLearning - EduFlex, eLearning - SCORM **Partners:** FDA

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- GMP Basic Concepts

HIPAA -- The Impact On Clinical Research

GCP05

Congress enacted the Health Insurance Portability and Accountability Act (HIPAA) to protect patient privacy and confidentiality. This course explains the history of HIPAA implementation, legal entities involved in HIPAA oversight and compliance, and the impact HIPAA has on clinical research in the United States. Topics in this course include: Privacy Requirements, PHI, Waivers, Current Regulations, Limited Data Sets, Exceptions and Enforcement, and Future Clinical Research. After completing this course, learners will be able to identify penalties for violations of HIPAA Privacy requirements.

Languages Available:
Chinese (Simplified) (GCP05)
German (GCP05)
Japanese (GCP05)
French (European) (GCP05)
Spanish (Spain) (GCP05)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:

- GCP Basics

HIPAA and Privacy Guidelines for Medical Device Sales Representatives

PRIVACY01

It is important for Medical Device Sales representatives to know how our sensitivity to customers' privacy concerns is critical to maintaining their trust. This course outlines the HIPAA Privacy Rule and how it affects daily business activities in the healthcare environment. Topics in this course include: Federal Regulations, Effects of HIPAA, Products and Software, Assistance and Training, and Patient Privacy. After completing this course, learners will be able to recognize the basic provisions of the HIPAA Privacy Rule and how HIPAA affects detailing and customer support activities.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

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| Libraries: | Functional Areas: | Content Bundles: |
| <ul style="list-style-type: none">• Medical Device - Sales & Marketing | <ul style="list-style-type: none">• Vendor Credentialing | <ul style="list-style-type: none">• Vendor Credentialing |

HIPAA and Privacy Guidelines for Pharmaceutical Sales Representatives

PRIVACY02

It is important for Pharmaceutical Sales Representatives to know how our sensitivity to customers' privacy concerns is critical to maintaining their trust. This course outlines the HIPAA Privacy Rule and how it affects daily activities. Topics in this course include: Effects of HIPAA, Products and Software, and Patient Issues. After completing this course, learners will be able to recognize the basic provisions of the HIPAA Privacy Rule and how HIPAA affects detailing and customer support activities.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

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| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• Pharmaceutical - Sales & Marketing | <ul style="list-style-type: none">• Pharmaceutical Sales Compliance |

HIPAA Privacy: Role-Based Training I (Incidental PHI Contact)

HIPAA06

This course is designed for employees who do not access PHI as part of their regular duties, but need to know what they should do when they do come into contact with PHI. Topics in this course include: PHI Encounters and Compliance. After completing this course, learners will be able to recognize how to apply HIPAA's privacy requirements to situations they encounter every day.

Format: eLearning - SCORM, eLearning - EduFlex, eLearning (Editable) - CREATE

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|---|---|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• HIPAA | <ul style="list-style-type: none">• Healthcare: HIPAA |

HIPAA Privacy: Role-Based Training II (Internal Uses of PHI)

HIPAA07

This course is designed for employees who are authorized to use protected health information (PHI) as part of their regular duties. Topics in this course include: Handling PHI and Compliance. After completing this course, learners will be able to recognize how to apply HIPAA's privacy requirements to situations they encounter every day.

Format: eLearning - EduFlex, eLearning - SCORM

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| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• HIPAA | <ul style="list-style-type: none">• Healthcare: HIPAA |

HIPAA Privacy: Role-Based Training III (Uses and Disclosures of PHI)

HIPAA08

This course is designed for employees who are authorized to use, disclose, and request PHI as part of their regular duties. After completing this course, learners will be able to apply HIPAA's privacy requirements to situations they encounter every day. Before taking this course, learners must complete one or more of the following: Business Practices for Protecting PHI HIPAA: General Awareness HIPAA: Privacy Standards

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries: **Functional Areas:**
• HIPAA • HIPAA

HIPAA Privacy: Role-Based Training IV (Managers, Supervisors, and Compliance Staff)

HIPAA09

This course is designed for HIPAA privacy officials, supporting HIPAA compliance staff, and managers, including those who have additional compliance responsibilities, such as ownership of PHI sources or information application and system purchases. After completing this course, learners will be able to apply HIPAA's privacy requirements to situations they encounter every day. Before taking this course, learners must complete one or more of the following: Business Practices for Protecting PHI HIPAA: General Awareness HIPAA: Privacy Standards Learners must also complete HIPAA Privacy: Role-Based Training III (Uses and Disclosures of PHI)

Format: eLearning - SCORM, eLearning - EduFlex

Libraries: **Functional Areas:**
• HIPAA • Healthcare: HIPAA

HIPAA: General Awareness

HIPAA01

This course is designed to provide all employees and associates with an in-depth overview of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy, security, and data standardization requirements from a health plan perspective. This course describes the updated requirements that were included in the Health Information Technology for Economic and Clinical Health Act (HITECH), which was signed into law February 2009. Topics in this course include: Privacy Standards, Security Standards, Data Standardization, and Enforcement. After completing this course, learners will be able to identify HIPAA regulations and ways to keep members' PHI secure.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries: **Functional Areas:**
• HIPAA • Healthcare: HIPAA
• Medical Device - Sales & Marketing
• Pharmaceutical - Sales & Marketing
• Ethics & Corporate Responsibility

HIPAA: Privacy Standards

HIPAA02

Health plan members must be able to trust that shared information will be protected and remain confidential. This course provides an in-depth look at the Privacy Standards included in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the requirements of the Health Information Technology for Economic and Clinical Health Act (HITECH). Topics in this course include: Permitted Uses and Disclosures, Authorized Uses and Disclosures, Minimum Necessary, Individual Rights, and Breach Disclosures. After completing this course, learners will be able to recognize the rules governing the use and disclosure of a member's protected health information.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries: **Functional Areas:**
• HIPAA • Healthcare: HIPAA

Hiring and Firing

LAV04

Hiring is an important factor in creating a solid workforce, and firing is a tool to ensure productivity. This course provides techniques for making good hiring decisions, terminating employees in a consistent and fair manner, and avoiding lawsuits resulting from the hiring and firing process. Topics in this course include: Regulations, Hiring, Interviewing, Testing, and Firing. After completing this course, learners should recognize several tools that will assist in the hiring and firing processes. Learners will also identify how to handle difficult employee situations.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: **Functional Areas:**

- Ethics & Corporate Responsibility
- HR Compliance & Risk Management
- HR Compliance

How to Meet Drug Retention and Stability Testing Requirements

PHA43

This course is designed to provide the learner with an understanding of the principles of drug stability testing and requirements for maintaining reserve samples. The goal of this lesson is for the learner to gain an understanding of shelf life and product expiration dating, and respect for the expiration and product storage labeling information, based on its effect on product safety and effectiveness.

Format: eLearning - EduFlex, eLearning - SCORM **Partners:** FDA

- Libraries:** **Functional Areas:**
- Pharmaceutical GMPs
 - Pharmaceutical GMP Basics

HP: Compliance Program General Session

GHC02

The Office of Inspector General (OIG) guidance promotes Compliance Programs for all healthcare organizations. This course is designed to fulfill the OIG and Centers for Medicare and Medicaid Services (CMS) requirement for a general training session on effective Compliance Programs. Topics in this course include: Definitions, Core Elements, Standards and Leadership, Training, Communication, Disciplinary Standards, and Monitoring and Responding to Compliance Issues. After completing this course, learners will be able to recognize the elements of an effective Compliance Program, FWA laws, and the resources available for compliance with government regulations.

Format: eLearning - EduFlex, eLearning - SCORM,
eLearning (Editable) - CREATE

- Libraries:** **Functional Areas:**
- Healthcare: General
 - Healthcare: Compliance Topics

ICH GCP Obligations of Investigators Conducting Clinical Trials

GCP02

This course addresses the obligations of investigators as described by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). It focuses on the investigator's responsibilities to protect the rights and welfare of human subjects and ensure data integrity. By extension, these responsibilities also apply to other investigation site staff involved in the planning, conduct, recording, and reporting of clinical trials.

Format: eLearning - EduFlex, eLearning - SCORM, **Partners:** Corexcel
eLearning (Editable) - CREATE

- Libraries:** **Functional Areas:**
- Clinical: Pharmaceutical
 - GCP Basics

ICH Q7: Resources and Materials Management

ICHreg02

This is the second in a series of courses designed to instruct on Good Manufacturing Practices (GMPs) for Active Pharmaceutical Ingredients (APIs), as set out by the ICH Q7 Guideline. This course covers qualifications for personnel, requirements for buildings used in API manufacturing, considerations for API manufacturing equipment, and materials management. Learners should have a working knowledge of current GMPs for drug products as set out in CFR 21 Parts 210 and 211. Learners should also have a basic understanding of chemical and biological processes used in the manufacture of Active Pharmaceutical Ingredients. Learners should have completed the course ICH Q7: Introduction and Quality Management.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:	Functional Areas:
<ul style="list-style-type: none"> Pharmaceutical GMPs Global Regulatory 	<ul style="list-style-type: none"> ICH: Quality Management

ICH Q7A: Introduction and Quality Management

ICHreg01

This is the first in a series of courses designed to instruct on current good manufacturing practices (GMPs) for active pharmaceutical ingredients (APIs), as set out by the ICH Q7 Guideline. This course covers the Introduction to ICH Q7 and Quality Management for API manufacture. The learner should have a working knowledge of current GMPs for drug products as set out in the Code of Federal Regulations, CFR 21 Parts 210 and 211, as well as a basic understanding of chemical and biological processes used in the manufacture of Active Pharmaceutical Ingredients.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:	Functional Areas:	Content Bundles:
<ul style="list-style-type: none"> Pharmaceutical GMPs Global Regulatory 	<ul style="list-style-type: none"> ICH: Quality Management 	<ul style="list-style-type: none"> Pharmaceutical - Risk Management

IEC 61010 — Measurement, Control, and Laboratory Use Equipment

MDSafety_07

Because measurement, control, and laboratory equipment is crucial to the quality and consistency of medical products, IEC 61010 exists to ensure those types of equipment meet certain standards and create safe, consistent products. This course covers the IEC 61010 standard for measurement, control, and laboratory use equipment. Topics in this course include: Structure, Testing Conditions, Markings and Documentation, Insulation Factors, Hazard Testing, and Risk Assessment. After completing this course, you will recognize the basic standards that are utilized in evaluating measurement, control, and laboratory equipment.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:	Functional Areas:
<ul style="list-style-type: none"> Engineering Safety 	<ul style="list-style-type: none"> IEC 61010 IEC 61010

Languages Available:
 Chinese (Simplified)
 Japanese
 Korean

IEC 61010-1: Measurement, Control, and Laboratory Use Equipment — Standards and Application

MDSafety_08

Because measurement, control, and laboratory equipment is crucial to the quality and consistency of medical devices, IEC 61010-1 exists to ensure those types of equipment meet certain standards and create safe, consistent products. This course covers the IEC 61010-1 standard for measurement, control, and laboratory use equipment as well as application methods. Topics in this course include: Insulation Factors, Hazard Testing, and Risk Assessment. After completing this course, learners will be able to recognize standards and application methods that are utilized in evaluating measurement, control, and laboratory equipment.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:	Functional Areas:
<ul style="list-style-type: none"> Engineering Safety 	<ul style="list-style-type: none"> IEC 61010

Languages Available:
 Chinese (Simplified)
 French (European)
 German
 Japanese
 Spanish (Spain)

IEC 62304: Medical Device Software Development Process and Risk Management

MDSafety_10

This course describes IEC 62304's requirements for any software development process involving medical devices. Topics in this course include: Software Development Process; Software Maintenance; Software Risk Management; Software Configuration Management; and Problem Resolution. After completing this course, learners will be able to recognize IEC 62304's software development requirements throughout the software's life cycle.

Languages Available:
Japanese

Format: eLearning - EduFlex, eLearning - SCORM

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| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• Engineering Safety | <ul style="list-style-type: none">• Medical Device• Risk Management |

IEC 62304: Medical Device Software Life Cycle Processes and Requirements

MDSafety_09

This course introduces IEC 62304, the standard that contains the requirements for the medical device software life cycle process, and explains the key processes for the software life cycle. Topics in this course include: General Requirements, Safety Classifications, Legacy Software, and Implementation. After completing this course, learners will be able to recognize the purpose of the IEC 62304 standard, recognize its basic requirements, identify safety classifications under the standard, recognize implications of legacy software, and identify implementation considerations.

Languages Available:
Japanese

Format: eLearning - EduFlex, eLearning - SCORM

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| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• Engineering Safety | <ul style="list-style-type: none">• Risk Management• Medical Device |

Implementing an Equipment Qualification Program

PHDV88

A well-developed and established equipment qualification program allows a company to meet current GMP requirements and save operational costs at the same time. This course provides an overview of the equipment qualification requirements, for the US and European Union, that apply to the pharmaceutical, biotechnology, and medical device industries. Topics in this course include: Protocol, Design, Installation, Operation, Performance, and Legacy Equipment. After completing this course, learners will be able to identify the steps in successful implementation of an equipment qualification program.

Languages Available:
Chinese (Simplified) (PHDV88)
Japanese (PHDV88)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

- | | |
|---|--|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• Medical Device GMPs• Pharmaceutical GMPs | <ul style="list-style-type: none">• GMP Basic Concepts |

Import Operations 1: Background

FDA37

The first in a series of three courses, this course introduces FDA's import program and the laws applied to products offered for entry into the US and products intended for export from the US. Topics in this course include: Enforcement Approaches, Importers vs. Domestic, FD&C Act, 21 CFR, 19 CFR, 18 USC, and Resources. After completing this course, learners will be able to recognize how FDA ensures that imported products meet US public health standards. Learners will also be able to identify the differences between the regulation of domestic and imported products, the regulations that apply to imported products, and how the FD&C Act, the Code of Federal Regulations, and the United States Code address imports.

Languages Available:
Chinese (Simplified) (FDA37_SCH)
Japanese (FDA37_JP)
Korean (FDA37_KOR)

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

- | | |
|---|---|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• FDA Inspections and Enforcement | <ul style="list-style-type: none">• FDA Import Operations |

Import Operations 2: The Process

FDA42

The second in a series of three, this course addresses FDA import and export programs, procedures, and policies and introduces the process followed during import proceedings. This course concentrates on how FDA regulates products pre-entry, types of entries, how FDA makes decisions about entries, and the resources available to assist with entry decisions. Topics in this course include: Pre-Entry, Food Safety, Entries, Entry Decisions, Resources, Examination, Analysis, Admissibility, and Enforcement. After completing this course, learners will be able to recognize the approaches and processes FDA uses to determine whether or not an import entry is in compliance with current import regulations.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- FDA Import Operations

Languages Available:

- Chinese (Simplified) (FDA42_SCH)
- Japanese (FDA42_JP)
- Korean (FDA42_KOR)

Import Operations 3: Other Activities

FDA43

This course continues discussion on import operations. Topics in this course include: Filers, Sharing Information, Exports, Export Certificates, and Shared Responsibility. After completing this course, learners will be able to recognize how import filers participate in OASIS; how FDA identifies and removes violative imports from the US market; how FDA regulates exports; and what other agencies share responsibilities for imports with FDA. Learners will also be able to recognize the different types of export certificates and their significance.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- FDA Import Operations

Languages Available:

- Chinese (Simplified) (FDA43_SCH)
- Japanese (FDA43_JP)
- Korean (FDA43_KOR)

Improving Productivity

EHS49

Mastering productivity skills will make employees more valuable, and their work more satisfying. This course identifies basic skills for setting goals, prioritizing tasks, and managing time. This course also illustrates how to avoid time-wasters, delegate appropriately, and make efficient decisions. Topics in this course include: Productivity, Values, Becoming a Goal Getter, Planning, Time Wasters, Delegating, Individual Decisions, Group Decisions, Networking, and Teamwork. After completing this course, learners will be able to recognize the basic skills for setting goals, prioritizing tasks, and managing time.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- HR Compliance & Risk Management

Functional Areas:

- Professional Development

Languages Available:

- Spanish (Spain)

Industrial Ergonomics

PS5-00291

Jobs in an industrial environment can be physically demanding. Preventing work-related musculoskeletal problems rests on an ergonomically sound work environment, good work practices and employee awareness. This course will introduce common risk factors and methods to prevent musculoskeletal injury. Ideal learners include all industrial employees.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Languages Available:

- French (Canadian)
- Czech
- Dutch
- French (European)
- German
- Japanese
- Polish
- Portuguese (Brazil)
- Spanish (Latin America)
- Thai
- Chinese (Simplified)

Infection Prevention and Control

EHS50

In the United States, there are an estimated 8.8 million persons who work in healthcare professions. Healthcare workers may acquire infections from patients or other personnel, household members, or other community contacts, and transmit infections to them as well. Studies indicate that well-organized infection control programs can prevent one-third of infections acquired at healthcare facilities, yet only 6-9% are actually prevented because specific safe work practices are not followed. This course presents information about how infections are transmitted and methods for infection control.

Format: eLearning - HIP2

Libraries:

- RETIRED - Environmental Health and Safety
- EHS for Life Science - Basics

Functional Areas:

- EHS Basics for HealthCare Workers

Information Security

HIPAA10

Information security is critical for any business, and it is the law for healthcare organizations. This course addresses training on the HIPAA Security Standard for all management and staff and presents healthcare industry current practices as outlined by the HIPAA regulations. Topics in this course include Security Roles, Security Controls, Administrative Safeguards, Physical Safeguards, and Technical Safeguards. After completing this course, learners will be able to recognize the security policies, procedures, and controls that are part of our daily business routine. Learners will also be able to identify suspected security breaches and how to respond to them.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- HIPAA

Functional Areas:

- Healthcare: HIPAA

Informed Consent

GCP13

The informed consent document and process are designed to serve as an ethical framework for safeguarding the rights and well-being of research participants. This course explains informed consent regulations and guidelines, the informed consent process, and the roles and responsibilities of clinical research professionals. Topics in this course include: Foundational Documents, Consent Document, Types, Exceptions, Pediatric Research, Managing Consent, and Verifying. After completing this course, learners will be able to identify key historical events that led to the current informed consent regulations and guidelines and will also be able to recognize the informed consent process as well as its documentation requirements.

Languages Available:

- Chinese (Simplified)
- German
- Japanese

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: Corexcel

Libraries:

- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:

- GCP Basics

Content Bundles:

- Good Clinical Practices (GCP)

Interactions with Healthcare Professionals - Field

PHSM07

This course covers the guidelines, rules, and regulations that govern interactions between field sales representatives and healthcare professionals.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Pharmaceutical - Sales & Marketing

Functional Areas:

- Pharmaceutical Sales Compliance

Interactions with Healthcare Professionals - In-House

PHSM06

Pharmaceutical company interactions with healthcare professionals are subject to extensive regulatory scrutiny and should be conducted in compliance with internal and external guidelines, policies, rules, and regulations. This course covers the guidelines, rules, and regulations that govern interactions with healthcare professionals as well as the appropriate manner in which to conduct such interactions. Topics in this course include: Regulations and Guidance, Speaker Programs, Drug Adherence Programs, Patient Assistance Programs and Support for Independent Third Party Charities, Investigator Initiated Research Studies, Gifts, Meals and Entertainment, Professional Services, and Education. After completing this course, learners will be able to identify the guidelines, policies, rules, and regulations that govern interactions with healthcare professionals. Learners will also be able to identify the appropriate manner in which to conduct these interactions.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:
• Pharmaceutical - Sales & Marketing

Functional Areas:
• Pharmaceutical Sales Compliance

Interviewing Techniques

FDA27

Interviews are an important part of virtually every operation performed by FDA investigators and analysts. This course identifies effective interviewing techniques and traits of an effective interviewer. Topics in this course include: FDA Interviewers, Preparation, Interviewees, Interviewer Traits, Effective Questions, and Nonverbal Behavior. After completing this course, learners will be able to recognize the fundamentals of conducting an effective interview. Learners will be able to identify the traits of a successful interviewer and the importance of appropriate interpersonal skills. Learners will also be able to identify appropriate questioning techniques to use in an interview.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:
• FDA Inspections and Enforcement
• Pharmaceutical GMPs

Functional Areas:
• FDA Inspection Readiness

Introduction to CFDA and CFDA Registration

PHDV97

This course introduces the basic structure of the China Food and Drug Administration (CFDA) and the process for approving medical devices in China.

Languages Available:
Chinese (Simplified) (PHDV97)

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
• Global Regulatory

Functional Areas:
• Medical Device Market Entry

Introduction to Data Integrity

DATA01

This course provides foundational knowledge of the concepts of data integrity and quality. Topics in this course include: Regulatory Requirements, International Standards, Ensuring Data Integrity, and Evaluation and Review. After completing this course, learners will be able to identify requirements that help maintain data integrity and quality.

Languages Available:
Chinese (Simplified) (DATA01)
German (DATA01)
French (European) (DATA01)
Spanish (Spain) (DATA01)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:
• Data Integrity

Functional Areas:
• Quality Assurance

Content Bundles:
• Data Integrity

Introduction to GMPs

PHA38

Current Good Manufacturing Practices (cGMPs) are specific requirements that ensure safe manufacturing of pharmaceutical products and medical devices. This course describes the importance, purpose, and enforcement of cGMPs by FDA. Topics in this course include: History, Procedures, Documentation, Pharmaceutical Quality System, Responsibilities, and FDA Inspections. After completing this course, learners will be able to recognize basic cGMP requirements and identify the roles and responsibilities of pharmaceutical and medical device manufacturing employees.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Languages Available:

French (European) (PHA38)
Portuguese (Brazil) (PHA38)
Spanish (Spain) (PHA38)
Hebrew (PHA38)
German (PHA38)
Japanese (PHA38)
Chinese (Simplified) (PHA38)

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- GMP Basic Concepts

Content Bundles:

- Pharmaceutical - GMP

Introduction to Medicaid

PPACA03

This course discusses the many challenges state governors and legislators face in managing their Medicaid programs and provides a foundation of knowledge for health plans to make required changes to business and information system processes as a result of the Patient Protection and Affordable Care Act (ACA). With the passing of this landmark reform, the management of Medicaid programs has changed and is continuing to evolve with expanded Medicaid coverage and eligibility.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- PPACA

Functional Areas:

- Healthcare: Affordable Care Act

Introduction to Medical Device Health Care Compliance

MDSM05

This course provides an introduction regarding the compliance of pertinent laws, regulations, and guidance that regulate the medical device industry. Topics in this course include: FDA Regulations, OIG, AdvaMed Code of Ethics, FCPA and False Claims Act, State Legislation and Sunshine Act Provisions. After completing this course, learners will be able to recognize the various laws, regulations, and guidance that regulate the medical device industry.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Medical Device - Sales & Marketing

Functional Areas:

- Vendor Credentialing

Content Bundles:

- Vendor Credentialing

Introduction to Pharmaceutical Compliance

PHSM09

This course introduces the agencies that govern standards of behavior in the pharmaceutical industry as well as the key requirements for compliant behavior.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Pharmaceutical - Sales & Marketing

Functional Areas:

- Corporate Ethics
- Sales Compliance

Content Bundles:

- Corporate Compliance - Pharmaceutical

Introduction to Risk Management

MDSafety_05

Understand the role ISO 14971 plays within the IEC 60601 standards to demonstrate compliance with risk management requirements worldwide, including its use in the CB Scheme Test Report Form in order to document compliance.

Format:

- Libraries:**
- Engineering Safety
- Functional Areas:**
- IEC 60601

Introduction to the Medical Device Single Audit Program (MDSAP)

DEV62

This course covers the Medical Device Single Audit Program, which conducts audits of medical device manufacturers that satisfy the relevant requirements of five regulatory authorities participating in the program as well as those of ISO 13485:2016. Topics in this course include: Program, Audit Types, Structure, and Nonconformity Grading and Audit Responses. After completing this course, learners will be able to recognize the structure of the MDSAP as well as grading and follow-up requirements.

Languages Available:
Portuguese (Brazil) (DEV62)
French (European) (DEV62)
Spanish (Spain) (DEV62)
German (DEV62)
Japanese (DEV62)
French (Canadian) (DEV62)

Format: eLearning - EduFlex, eLearning - SCORM

- Libraries:**
- Medical Device GMPs
 - Global Regulatory
- Functional Areas:**
- Medical Device

Introduction to the Quality System Regulation (QSR)

DEV43

Good Manufacturing Practices (GMPs) help protect medical devices and medical device users. This course describes the GMPs for medical devices as specified in the Quality System Regulation (QSR). Topics in this course include: Quality System, Design Control, Software Validation, and Responsibility. After completing this course, learners will be able to identify the components of a quality system, design controls, and software validation.

Languages Available:
German (DEV43)
French (European) (DEV43)
Chinese (Simplified) (DEV43)
Japanese (DEV43)
Korean (DEV43)
Spanish (Spain) (DEV43)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

- Libraries:**
- FDA Inspections and Enforcement
 - Medical Device GMPs
- Functional Areas:**
- FDA QSR Basic Concepts
- Content Bundles:**
- Medical Device - GMP

Introduction to the Regulation of Prescription Drug and Biologic Promotions

PHSM10

Promotional messages for prescription drugs are different from most commercial campaigns because the drugs, and the claims pharmaceutical companies make regarding their benefits, directly affect public health. The federal government regulates prescription drug and biologic promotions through organizations within the U.S. Food and Drug Administration (FDA). Topics in this course include: Regulation, Package Insert, General Requirements, Review Process, and Enforcement Actions. After completing this course, learners will be able to recognize how FDA defines promotional materials for prescription drugs and biologics. Learners will also be able to identify the organizations responsible for reviewing those materials as well as the general regulatory requirements with which promotional materials must comply.

Format: eLearning - EduFlex, eLearning - SCORM

- Libraries:**
- Pharmaceutical - Sales & Marketing
- Functional Areas:**
- Pharmaceutical Sales Compliance

Investigational Product Development

GCP23

This course provides an overview and summary of the investigational product development process. The course includes information on the different phases of clinical research necessary to file an Investigational New Drug Application (IND) and a New Drug Application (NDA). Topics in this course include: Stages, Trial Phases, Medical Devices, FDA Approval, and Post-marketing. After completing this course, learners will be able to recognize drug development phases and the main purpose of each phase as well as other elements of the investigational product development.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:	Functional Areas:
<ul style="list-style-type: none">• Clinical: Pharmaceutical	<ul style="list-style-type: none">• GCP - Clinical Management

ISO 14155: Obligations of Sponsors and Monitors for Medical Device Trials

GCP20

ISO 14155 is intended to be applied worldwide to clinical investigations of medical devices in order to fulfill the various national, regional, and international regulatory requirements. Topics in this course include: Ethics, CIP, Investigator's Brochure, Informed Consent, Other Documents, Sponsors, and Monitors. After completing this course, the learner will be able to identify the specific requirements of ISO 14155. The learner will also be able to recognize the roles and responsibilities of sponsors and monitors in clinical investigations of medical devices.

Languages Available:
Chinese (Simplified) (GCP20_SCH)
Japanese (GCP20_JP)
Korean (GCP20_KOR)

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:	Functional Areas:
<ul style="list-style-type: none">• Clinical: Medical Device	<ul style="list-style-type: none">• Clinical: Medical Device Topics

ISO 14971: Risk Management for Medical Devices

DEV55

This course illustrates the application of risk management activities for medical device product safety through implementing the ISO 14971 International Standard for Risk Management. Topics in this course include: Overview, Definitions, General Requirements, Risk Assessment, Risk Control, Risk in Context, Risk Management File, and Tools. After completing this course, learners will be able to recognize how to apply risk management activities for medical device product safety.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:	Functional Areas:
<ul style="list-style-type: none">• Medical Device GMPs	<ul style="list-style-type: none">• ISO Standards

Japanese Medical Device and Pharmaceutical Regulations

PHDV94

The course introduces the Japanese medical device regulations. This course explores the scope and applicability of Japan's new Act on Medical Devices (PMD Act). Topics in this course include: History, Agencies, Approval Process, PMD vs ISO 13485, and Labeling. After completing this course, learners will be able to recognize the general structure of PMD and its requirements for the manufacture and distribution of medical devices to the Japanese market.

Languages Available:
Japanese

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:	Functional Areas:
<ul style="list-style-type: none">• Global Regulatory	<ul style="list-style-type: none">• Medical Device Market Entry

Key Concepts of Process Validation

PHDV77

Production problems can result in high scrap rates, product failures, customer dissatisfaction, and even death of a user. This course identifies the key concepts in the regulatory requirements for the validation of manufacturing processes. Topics in this course include: Requirements and Procedures, Process Design, Verification and Validation, Installation and Operational Qualification, and Continued Verification and Revalidation. After completing this course, learners will be able to identify recognize important aspects of process validation and identify the components of the validation life cycle.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Languages Available:

German (PHDV77)
French (European) (PHDV77)
Chinese (Simplified) (PHDV77)
Japanese (PHDV77)
Korean (PHDV77)
Spanish (Spain) (PHDV77)

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- GMPs - Process Validation

Lab Safety

PS5-100555

A laboratory safety program depends on participation and cooperation from every employee. This course describes common hazards associated with laboratory environments and introduces ways to control and limit chemical exposure. Ideal learners are any employees who work in a laboratory environment.

Format: eLearning - PS5

Languages Available:

Japanese
Portuguese (Brazil)

Libraries:

- EHS for Life Science - Basics

Laboratory Specimens for Clinical Research

GCP25

This course will introduce you to regulations and guidelines that oversee the process of laboratory sample collection and shipping of human specimens for clinical research use in the United States. Topics in this course include: Clinical Laboratories, CLIA Certification, Site Responsibility and Documentation, Medical Waste Disposal, and Packaging and Transport of Specimens. After completing this course, learners will be able to identify the rules and regulations that apply to laboratory samples. In addition, learners will also be able to recognize how a sponsor utilizes the services of a central laboratory and how a principal investigator utilizes a local laboratory. Finally, learners will be able to identify the sponsor and investigator site responsibilities for collection of specimens, as well as specimen packaging for shipping.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:

- GCP - Clinical Management

Lockout/Tagout (LOTO)

PS5-101282

Would you stick your hand into a machine and hope no one turns it on? You can guarantee the machine stays off by locking and tagging it out. Failure to lock out machinery before servicing it is a major cause of injury and death. These deaths and injuries can be prevented by establishing and following an effective lockout/tagout program. Ideal learners are all employees.

Format: eLearning - PS5

Languages Available:

French (Canadian)
French (European)
Hungarian
Italian
Japanese
Korean
Portuguese (Brazil)
Russian
Spanish (Latin America)

Libraries:

- EHS for Life Science - Basics

Lockout/Tagout (LOTO) Awareness

PS5-102281

Energy powers machines and industrial systems. Lockout/tagout procedures neutralize hazardous energy and prevent equipment startup during servicing, maintenance and installation activities. Take this course to learn how lockout/tagout helps ensure workplace safety. Ideal learners are personnel working where lockout/tagout occurs. Those who work under lockout protections also benefit from refresher information provided in this course.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Maintenance and Cleaning of Drug Manufacturing Equipment

PHA44

Properly designed, constructed, cleaned, and maintained equipment lies at the core of the process control necessary to consistently manufacture pure, high quality drug products. In this course, you will learn about equipment selection, installation, qualification, and maintenance. After completing this course, you will be able to identify cleaning and maintenance practices for equipment used in manufacturing, as well as how a pharmaceutical company incorporates this equipment in their manufacturing. Additionally, you will be able to identify the necessary documentation and records for equipment used in the manufacture of prescription and over-the-counter drugs.

Languages Available:

- French (European) (PHA44)
- Japanese (PHA44)
- Spanish (Spain) (PHA44)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- Pharmaceutical GMPs

Functional Areas:

- Maintenance and Facilities

Content Bundles:

- Pharmaceutical - GMP
- Maintenance and Facilities - Basics

Making Ethical Decisions

ETHICS17

The purpose of this training is to help you become a better decision maker when faced with ethics situations. You will recognize how to identify and resolve ethics issues and concerns, and you will identify how to get help when you are unsure as to the best course of action.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Ethics & Corporate Responsibility

Functional Areas:

- Professional Development

Content Bundles:

- Corporate Compliance - Plan Sponsors

Making Meetings Work I: Purpose and Preparation

EHS60

This course explores ways to assess the effectiveness of meetings and skills to enhance the meeting process. Topics in this course include: Purpose, Meeting Costs, Key Steps, and Prepare. After completing this course, learners will be able to recognize how to lead meetings, accomplish goals, and follow up to ensure success.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- HR Compliance & Risk Management

Functional Areas:

- Professional Development

Making Meetings Work II: Leadership

EHS61

The success of any meeting is largely determined by the leadership skills of the key participants. This course discusses the leadership skills necessary to conduct successful meetings. Topics in this course include: Start, Lead, Goals, Common Problems, Conflict, and Finish. After completing this course, learners will be able to recognize how to effectively set up, kickoff, conclude, and follow up a meeting. Learners should take *Making Meetings Work I: Purpose and Preparation* prior to taking this training.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- HR Compliance & Risk Management

Functional Areas:

- Professional Development

Management Responsibility for Quality: What FDA Expects

PHDV101

Under FDA law and regulations, an effective and compliant Quality System literally begins and ends with management. This course explains who is considered management by FDA, what are management's responsibilities under FDA Good Manufacturing Practices, how FDA inspectors decide if management is meeting its obligations, and what are possible consequences if it is not. Topics in this course include: Authority, Quality System, Management Role, Quality Audits, Training, Outsourcing, and FDA Inspections. After completing the course, learners will be able to recognize how and why a successful Quality System depends on active management support and involvement to ensure safe and effective products reach patients and customers.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Pharmaceutical GMPs
- Medical Device GMPs

Languages Available:

- Chinese (Simplified) (PHDV101)
- French (European) (PHDV101)
- German (PHDV101)
- Japanese (PHDV101)

Managing Conflict

EHS62

As workforce numbers shrink, and individuals are called to interact more intensely with fewer people, the ability to manage conflict effectively becomes more important. This course identifies appropriate responses to conflict. Topics in this course include: Conflict Resolution Styles, Selecting Styles, Collaboration Guidelines, and Application. After completing this course, learners will be able to successfully approach and resolve conflict in the workplace.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Functional Areas:

- Professional Development

Managing Job Stress

EHS63

Stress is a major factor in employee attendance, work performance, and Equal Employment Opportunity Commission (EEOC) claims. This course provides participants with an opportunity to assess their stress level at work and learn strategies for coping with that stress. Topics in this course include: Definition, Stressors, Positive Stress, Hassles, Outlook, and Visualization. After completing this course, learners will be able to identify their stress level at work. Learners will also be able to recognize strategies for coping with different problems in the workplace.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- HR Compliance & Risk Management

Functional Areas:

- Professional Development

Managing Transition to Teams

EHS64

This course will help team leaders and team members to understand the process of moving from a hierarchical structure and mindset to a more team-oriented approach. Topics in this course include: Differences, Model, Transition, Vision, Coaching, and Example. After completing this course, learners will be able to recognize how to transition successfully from a top-down management approach to one in which team members work together to achieve greater results than could be achieved individually.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
• HR Compliance & Risk Management

Functional Areas:
• Professional Development

MAO/PDP: Compliance Program Guidelines

MAPD04

Effective compliance programs are a requirement for Medicare Advantage Organizations (MAO) and Medicare Prescription Drug Plans (PDP) that contract to do business with the Centers for Medicare and Medicaid Services (CMS). This course describes how to properly design and implement an effective compliance program. Topics in this course include: General Requirements; Written Policies, Procedures, and Standards of Conduct; Compliance Officer, Committee, and High Level Oversight; Training and Education; Communication; Disciplinary Standards; Routine Auditing and Monitoring; and Prompt Response. After completing this course, learners will be able to recognize the requirements of an effective compliance program.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
• Medicare Advantage
• Medicare Part D

Functional Areas:
• Medicare Advantage

MAPD/PDP: Communications and Marketing

MAPD03

This course examines what types of communication materials are regulated, what must be included in the materials and what is prohibited, how the CMS approval process works, the parameters of promotional marketing to beneficiaries, and what role providers and pharmacies are permitted to play in marketing a sponsor's plan. Topics in this course include: Definitions; Marketing Review Process and Required Documents; General Communication Requirements; General Marketing Requirements; Outreach Activities; Websites and Social/Electronic Media; Call Center Requirements; and Marketing and Sales Oversight. After completing this course, learners will be able to identify the communication materials that are regulated by CMS, the information that must be included in the materials, and how the CMS approval process works. Learners will also be able to identify what role providers and pharmacies are permitted to play in marketing a sponsor's plan.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:
• Medicare Advantage
• Medicare Part D

Functional Areas:
• Medicare Advantage

MAPD: Disenrollment

MAPD06

To ensure proper member disenrollment, specific standards must be maintained. This course describes processes and procedures for disenrollment from Medicare Advantage (MA) and Medicare Advantage-Prescription Drug (MAPD) health plans. Topics in this course include: Voluntary and Required Involuntary Disenrollments, Optional Involuntary Disenrollments: Non-Payment of Premiums, Optional Involuntary Disenrollment: Behavior, Post Enrollment Activities, and System Reports. After completing this course, learners will be able to identify the key concepts, principles, and the MA plan's responsibility in the disenrollment process.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
• Medicare Advantage
• Medicare Part D

Functional Areas:
• Medicare Advantage
• Medicare Part D

MAPD: Enrollment

MAPD02

To ensure proper member enrollment, specific standards must be maintained. This course describes processes and procedures for enrollment of beneficiaries into a Medicare Advantage (MA) and Medicare Advantage Prescription Drug (MAPD) health plans. Topics in this course include: Member Eligibility, Election Periods, Enrollment Mechanisms, Enrollment Process, and Auto and Facilitated Enrollments. After completing this course, learners will be able to identify the key concepts, principles, and the MA plan's responsibility in the enrollment process, as well as identify requirements for submitting enrollment data.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

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| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• Medicare Advantage• Medicare Part D | <ul style="list-style-type: none">• Medicare Advantage |

MAPD: Risk Adjustment and Data Validation

MA35

This course identifies the principles and motivation for risk adjustment of capitation payments that the Centers for Medicare & Medicaid Services (CMS) makes to Medicare Advantage (MA) plans. Topics in this course include: History, Goals, Hierarchical Condition Category (HCC), Documentation and Coding Requirements, Data Flow, and Data Validation. After completing this course, learners will be able to identify the components of the risk adjustment process, the requirements for data collection, and the process for submitting data to CMS.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

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| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• Medicare Advantage | <ul style="list-style-type: none">• Medicare Advantage |

Markings and Accompanying Documents

MDSafety_06

Gain an understanding of the requirements of Clause 7 within IEC 60601-1 for markings, which address durability and legibility, markings on the outside of the equipment, markings on the inside of the equipment, markings of controls, safety signs, symbols, color of insulation, and indicator lights and controls.

Format:

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|--|---|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• Engineering Safety | <ul style="list-style-type: none">• IEC 60601 |

Massachusetts Pharmaceutical and Medical Device Manufacturer Conduct Regulation (Mass. Code) and Similar State-Level Requirements

MDSM03

The Massachusetts Pharmaceutical and Medical Device Manufacturer Conduct Regulation (Mass. Code) imposes a number of restrictions on pharmaceutical and medical device manufacturing companies' (including distributors') interactions with healthcare practitioners. The Mass. Code is intended to benefit patients, enhance the practice of medicine, and ensure that the relationship between pharmaceutical or medical device manufacturers and healthcare practitioners does not interfere with the independent judgment of healthcare practitioners. This course provides an introduction to the Mass. Code. Topics in this course include: Scope; Data; Contracts, Audits, and Meals; Education, Conferences, and Meetings; Other Payments, and Disclosure of Payments. After completing this course, learners will be able to recognize the provisions of the Mass. Code, 105 CMR 970.000, how to comply with new restrictions, and what some of the critical differences are between the Mass. Code and the AdvaMed and PhRMA Codes of Ethics.

Format: eLearning - EduFlex, eLearning - SCORM

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| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• Medical Device - Sales & Marketing | <ul style="list-style-type: none">• Vendor Credentialing |

MDR Regulation 1: Overview and General Provisions

FDA63

FDA Investigators, compliance officers, medical device manufacturers, user facilities, and importers need to be aware of the Medical Device Reporting (MDR) regulation and its provisions. This course describes the key characteristics of the MDR regulation and its preamble as well as the key terms used in the MDR regulation. Topics in this course include: Origin, Device and Modernization Amendments, Characteristics, , and Application. After completing this course, learners will be able to identify the key characteristics of the MDR regulation and its preamble as well as the key terms used in the MDR regulation. Also, you will be able recognize to whom the MDR regulation applies and who is exempt from the regulation.

Languages Available:

Chinese (Simplified)
Japanese
Korean

Format: eLearning - EduFlex, eLearning - SCORM**Partners:** FDA**Libraries:**

- FDA Inspections and Enforcement

Functional Areas:

- FDA MDR

MDR Regulation 2: Device User Facility, Importer, and Manufacturer Reporting Requirements

FDA65

Medical device manufacturers, user facilities, and importers need to identify and monitor significant adverse events involving medical devices. This course describes important terms crucial to understanding the Medical Device Reporting (MDR) regulation and its requirements as they relate to user facilities, importers, and manufacturers. Topics in this course include: User Facilities, Importers, Manufacturers, and Event Files. After completing this course, learners will be able to identify the requirements for electronic MDR submission, MDR procedures, and event files.

Languages Available:

Chinese (Simplified)
Japanese
Korean

Format: eLearning - EduFlex, eLearning - SCORM**Partners:** FDA**Libraries:**

- FDA Inspections and Enforcement

Functional Areas:

- FDA MDR

MDR Regulation 3: Requirements for Individual Adverse Event Reports

FDA66

FDA investigators, compliance officers, medical device manufacturers, user facilities and importers need to know how to document and submit adverse event reports in a timely fashion. This course identifies the proper forms and timelines for reporting adverse events. Topics in this course include: Reporting, MEDWATCH, Deadlines, Codes, and Exceptions. After completing this course, learners will be able to recognize the proper forms and timeframes necessary for adverse event reporting and identify when it is not necessary to file a report.

Languages Available:

Chinese (Simplified)
Japanese
Korean

Format: eLearning - EduFlex, eLearning - SCORM**Partners:** FDA**Libraries:**

- FDA Inspections and Enforcement

Functional Areas:

- FDA MDR

Medical Device Filings: 510(k), PMA, and IDE

DEV53

This course describes the premarket approval and notification processes for medical devices in the US. Topics in this course include: FDA Authority, Classification, Premarket Notification, Premarket Approval, IDE, and Compliance. After completing this course, learners will be able to identify the essential elements of the 510(k), premarket approval (PMA), and Investigational Device Exemption (IDE) filing processes for medical devices under FDA.

Format: eLearning - EduFlex, eLearning - SCORM**Libraries:**

- Medical Device GMPs
- Global Regulatory

Functional Areas:

- Medical Device Market Entry

Medical Device Packaging, Labeling, and Distribution

DEV41

Mistakes or mix-ups in the critical areas of product packaging, labeling, and distribution can pose a danger to the consumer. This course provides you with information on current packaging and labeling requirements specified by the Quality System Regulation. A basic understanding of quality system regulations for medical device and equipment manufacturers (21 CFR 820), quality control procedures, and quality principles are prerequisites for this course. Topics in this course include: Importance of Labeling, Packaging, Label Control, and Distribution. After completing this course, learners will be able to recognize the requirements for packaging, labeling, and distribution of medical devices 21 CFR 820.120-160.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: **Functional Areas:**
• Medical Device GMPs • Quality Assurance

Languages Available:

French (European)
Dutch
Chinese (Simplified)
Japanese

Medical Device Safety Reporting

GCP19

This course explores the process by which US and European regulatory agencies ensure the safety of medical devices used in medical facilities and homes every day by following up on adverse events. Topics in this course include: Adverse Events, Premarket Reporting, Marketed Devices, and Reports. After completing this course, learners will be able to identify the regulatory requirements in the medical device clinical trial and postmarketing environments as well as recognize device safety monitoring and reporting efforts in the US and Europe.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: **Functional Areas:**
• Clinical: Medical • Clinical: Medical
 Device Device Topics

Languages Available:

French (European)
German
Spanish (Spain)

Medical Education for Healthcare Professionals

PHSM03

Pharmaceutical companies contract with healthcare professionals to provide them with services and insights by participating in market research and advisory boards, performing clinical trials, endorsing a product, and conducting peer-to-peer training for other healthcare professionals, among other services. The pharmaceutical industry set forth certain guidelines that must be followed when engaging and providing medical education for healthcare professionals. This course discusses consulting arrangements and medical education programs for healthcare professionals. Topics in this course include: General Guidelines, Consulting Arrangements, Medical Education Programs, Supporting Medical Education, and FDA and OIG Guidance on Medical Education. After completing this course, learners will be able to identify various types of consulting arrangements that exist between a pharmaceutical company and healthcare professionals and the guidelines that govern these arrangements. Learners will also be able to recognize the guidelines that impact medical education programs for healthcare professionals.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: **Functional Areas:**
• Pharmaceutical - Sales • Pharmaceutical Sales
 & Marketing Compliance

Medicare Advantage: Administration and Management

MA27

This course provides information on the administrative infrastructure and management capabilities required of all Medicare Advantage Organizations (MAOs). Topics in this course include: Basic Responsibilities, Basic Requirements, Specific Requirements, Infrastructure, and Documentation. After completing this course, learners will be able to recognize the critical role of management in operating an MAO, identify the basic administrative infrastructure necessary to do business with CMS in the Medicare Advantage (MA) program, and identify the areas where management must ensure compliance in the MAO.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: **Functional Areas:**
• Medicare Advantage • Medicare Advantage

Medicare Advantage: Claims Processing

MA38

This course explores the Centers for Medicare and Medicaid Services (CMS) regulations and instructions for the processing of Part C medical claims for Medicare Advantage (MA). Topics in this course include: Rules and Requirements, Benefits and Services, Payment (Claim) Organization Determinations, Claims Processing, and Enrollee Financial Caps. After completing this course, learners will be able to identify the MA plan's responsibilities in monitoring delegated claims processing.

Format: eLearning - EduFlex, eLearning - SCORM,
eLearning (Editable) - CREATE

Libraries: Medicare Advantage
Functional Areas: Medicare Advantage

Medicare Advantage: Grievances, Organization Determinations, and Appeals

MA37

The Medicare Part C program provides coverage for medical benefits for eligible Medicare beneficiaries. This course describes the grievance, organization determination, and appeal processes that are required in order to protect the rights of Medicare Part C enrollees. Topics in this course include: Representatives, Grievance Process, Organization Determinations, Reconsiderations, Discharge Appeals, Exceptions, Documentation and Reporting, and Education and Training. After completing this course, learners will be able to identify the definitions and regulatory requirements for processing grievances, organization determinations, and appeals including time limits, documentation, follow-up, and reporting procedures.

Instructions for handling Part D grievances, coverage determinations, and appeals are found in the course *Medicare Part D: Grievances, Coverage Determinations, and Appeals*.

Format: eLearning - EduFlex, eLearning - SCORM,
eLearning (Editable) - CREATE

Libraries: Medicare Advantage
Functional Areas: Medicare Advantage

Medicare Advantage: Membership Services

MA28

This course discusses the obligations of a Medicare Advantage Organization (MAO) and of the Centers for Medicare and Medicaid Services (CMS) regarding Member Services. Topics in this course include: Operations; MAO Operational Functions; Classification of Complaints, Appeals, and Grievances; Required Skills; and CMS Call Center Monitoring and Required Disclosures. After completing this course, learners will be able to identify an MAO's Member Services functions, recognize CMS' regulatory requirements related to Member Services, recognize the importance of classification of member complaints, and be aware of CMS' call center monitoring process and member disclosure requirements.

Format: eLearning - EduFlex, eLearning - SCORM,
eLearning (Editable) - CREATE

Libraries: Medicare Advantage
Functional Areas: Medicare Advantage

Medicare Advantage: Overview of the Medicare Program

MA29

This course provides an overview of the Medicare Program including what it is, how it is implemented, and how government regulations influence it. This course also describes the Centers for Medicare and Medicaid Services (CMS), which is the agency responsible for developing and implementing Medicare policy. Topics in this course include: Medicare Population, Role of the Federal Government, CMS Structure and Function, Medicare Categories and Options, Medicare Advantage Plan, Payment Process, and Fraud and Abuse. After completing this course, learners will be able to recognize the Medicare coverage options and their eligibility requirements, the role of the Federal government in regulating Medicare, and the penalties for violating healthcare fraud and abuse laws.

Format: eLearning - EduFlex, eLearning - SCORM,
eLearning (Editable) - CREATE

Libraries: Medicare Advantage
Functional Areas: Medicare Advantage

Medicare Advantage: Plan Benefit Package and Bid Pricing Tool

MA36

This course covers benefits, plan benefit packages (PBPs), and tools for submitting bids. Topics in this course include: Benefits, PBP Design, PBP Tool, Bid Requirements, and Bid Pricing Tool. After completing this course, you will be able to identify how CMS defines a benefit, recognize how these benefits should be designed to create a PBP, recognize how to use the CMS system for submitting a PBP to CMS, identify who is required to submit a bid, identify what components are required for each bid, and recognize the elements of the Bid Pricing Tool.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries: Medicare Advantage
Functional Areas: Medicare Advantage

Medicare Advantage: Provider Compliance

MA34

This course reviews requirements every provider must adhere to, including specific rights and responsibilities, and elements contained in their contract with the Medicare Advantage Organizations. Topics in this course include: Regulatory Requirements and Contract Provisions, Beneficiary Access to Care, Beneficiary Protections, Payment and Government Funds, Compliance Program, and Provider Rights. After completing this course, learners will be able to recognize the responsibilities of providers who contract with Medicare Advantage Organizations in order to be compliant with CMS' regulatory requirements.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries: Medicare Advantage
Functional Areas: Medicare Advantage

Medicare Advantage: Provider Networks

MA40

This course examines provider networks and the tools associated with their development. It includes an in-depth look at tools that are used in the development and validation of provider networks, critical terms used by the Centers for Medicare and Medicaid Services (CMS), and the usefulness of template contracts and checklists, and credentialing and verification requirements. Topics in this course include: Provider Contracting, MAO Responsibilities, Network Adequacy, Qualification and Selection, and Credentialing Facilities. After completing this course, learners will be able to recognize CMS' requirements for MA plans to provide adequate provider networks.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Medicare Advantage
Functional Areas: Medicare Advantage

Medicare Advantage: Quality Management and Utilization Management

MA41

This course describes the Quality Improvement (QI) regulatory requirements for a Medicare Advantage Organization (MAO). Topics in this course include: QI Program, CCIP Projects, QI Program Effectiveness, and Utilization Management (UM). After completing this course, learners will be able to identify the basics of implementing a QI program.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries: Medicare Advantage
Functional Areas: Medicare Advantage

Medicare Health Plan and PDP: Fraud, Waste, and Abuse

MAPD01

Healthcare fraud, waste, and abuse are considered a top priority to the US government, second only to terrorism and violent crime. This course addresses fraud, waste, and abuse laws, regulations, and guidelines that apply to Medicare health plans and Prescription Drug Plans (PDP) also referred to as plan sponsors. Topics in this course include: Background, Definitions, and Government Oversight. After completing this course, learners will be able to recognize the increased government interest in managed care fraud and abuse including areas of concern and how to combat fraud, waste, and abuse.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

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| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• Medicare Advantage• Medicare Part D | <ul style="list-style-type: none">• Medicare Advantage |

Medicare Part D: Administration and Management

PARTD01

This course describes the Medicare Part D program and details the requirements that companies must meet in order to become Medicare Part D sponsor organizations. This course examines the respective roles of CMS, state governments, the sponsor, and the sponsor's contractors. You will learn how sponsors can meet their regulatory obligation to demonstrate compliance with certain licensure and insurance-related provisions of state law in the states in which the sponsor plans to offer coverage.

Format: eLearning - EduFlex, eLearning - SCORM

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|---|---|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• Medicare Part D | <ul style="list-style-type: none">• Medicare Part D |

Medicare Part D: Bid and Benefit Package

PARTD03

This course explains the benefits available to individuals who are eligible for Part D and presents the requirements for bidding to become a sponsor. Topics in this course include: Standard Coverage, Alternative Coverage, Bid Requirements, Actuarial Requirements, and Bid Review Process. After completing this course, learners will be able to identify the requirements for successful bidding and recognize what CMS examines during the bid review process.

Format: eLearning - EduFlex, eLearning - SCORM

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|---|---|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• Medicare Part D | <ul style="list-style-type: none">• Medicare Part D |

Medicare Part D: Coordination of Benefits and True Out-of-Pocket Facilitation

PARTD10

This course examines the procedures required by the Centers for Medicare and Medicaid Services (CMS) that Part D sponsors (MAPDs and PDPs) must follow when coordinating benefits with other providers of prescription drug coverage. The course also discusses the Part D true out-of-pocket (TrOOP) facilitation process. Topics in this course include: Purpose, Sponsor Responsibilities, TrOOP Balances, and Claims Processing. After completing this course, learners will be able to recognize CMS' process for coordinating prescription drug benefits among payers and the requirement for calculating and maintaining accurate TrOOP information.

Format: eLearning - EduFlex, eLearning - SCORM

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|---|---|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• Medicare Part D | <ul style="list-style-type: none">• Medicare Part D |

Medicare Part D: Grievances, Coverage Determinations & Appeals

PARTD02

This course outlines the Centers for Medicare & Medicaid Services' (CMS) requirements for the grievances, coverage determinations, and appeals processes. Topics in this course include: Enrollee Protections, Grievances, Coverage Determinations, Exceptions, and Appeals. After completing this course, learners will be able to recognize the sponsors' obligations during the grievances, coverage determinations, and appeals processes. Learners will also be able to identify the components of the grievance and appeals processes.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:
● Medicare Part D

Functional Areas:
● Medicare Part D

Medicare Part D: Medication Therapy Management and Quality Improvement Program

PARTD08

This course identifies primary cost control provisions in detail, including drug utilization management (UM) and medication therapy management programs (MTMPs). Topics in this course include: Utilization Management, Formularies, MTMP: Services, MTMP: Beneficiaries, Quality Assurance, and Quality Improvement. After completing this course, learners will be able to identify primary cost control provisions, quality assurance requirements, and the processes CMS has implemented to conduct oversight of the primary cost control and quality provisions.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:
● Medicare Part D

Functional Areas:
● Medicare Part D

Medicare Part D: PDP Disenrollment and Transaction Processing

PARTD11

The Medicare Part D program provides prescription drug coverage for eligible Medicare beneficiaries. This course describes processes and procedures for disenrollment from a Medicare Prescription Drug Plan (PDP). Topics in this course include: Disenrollment, Mistaken Enrollment/Disenrollment, and MARx System. After completing this course, learners will be able to identify the procedures we must follow to disenroll members from our PDP. Learners will also be able to recognize the features of the processing system for PDP enrollment and disenrollment.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
● Medicare Part D

Functional Areas:
● Medicare Part D

Medicare Part D: PDP Enrollment

PARTD05

The Medicare Part D program provides prescription drug coverage for eligible Medicare beneficiaries. This course describes processes and procedures for enrollment in a Medicare Prescription Drug Plan (PDP). Topics in this course include: Member Eligibility, Enrollment Periods, Enrollment Mechanisms, Enrollment Process, and Auto and Facilitated Enrollment. After completing this course, learners will be able to identify the eligibility requirements individuals must meet in order to enroll in a PDP. Learners will also be able to recognize when people may enroll in PDPs, and what information our organization must collect and distribute prior to enrollment.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
● Medicare Part D

Functional Areas:
● Medicare Part D

Medicare Part D: Pharmacy Network

PARTD07

Part D sponsors must develop a network of pharmacies so beneficiaries have “convenient” access to drugs covered under Part D. Topics in this course include: Pharmacy Types, Access Requirements, and Contract Requirements. After completing this course, learners will be able to identify the types of pharmacies that can be included in a network as well as the requirements Part D sponsors must meet to contract with pharmacies and create a pharmacy network.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Medicare Part D
Functional Areas: Medicare Part D

Medicare Plan: Broker and Agent Training - Beneficiary Protections

MSales04

This is course four in the required series of courses that must be taken by brokers and agents who are interested in marketing Medicare Part C and Part D products and Section 1876 Cost Contracts. This course describes the rights and protections of Medicare plan enrollees in Medicare Advantage Health Plans and Prescription Drug Plans (collectively referred to as Medicare plans in this course) as required by the Centers of Medicare and Medicaid Services (CMS), and the grievance, coverage determination and appeal processes that are required in order to protect the rights of Medicare plan enrollees. Topics in this course include: Basic Rights, Grievance Process, Organization Determinations and Appeals, Part D Determinations and Appeals, and Aggressive Marketing. After completing this course, learners will be able to identify the rights and protections available to Medicare beneficiaries in the Medicare Advantage (MA) and Part D programs. Learners will also be able to identify the grievance process and recognize the appeals process for Part C and Part D.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Medicare Broker/Agent Training
Functional Areas: Medicare Plan Broker Training

Medicare Plan: Broker and Agent Training - Broker/Agent Requirements

MSales01

This course is the first of a series covering brokers and agents marketing and selling Medicare Part C and Part D products and Section 1876 Cost Contracts (collectively referred to as Medicare plans. Topics in this course include: Training, HIPAA, Compliance Program, and FWA. After completing this course, learners will be able to recognize specific requirements related to brokers/agents who want to sell Medicare plan products.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Medicare Broker/Agent Training
Functional Areas: Medicare Plan Broker Training

Medicare Plan: Broker and Agent Training - Marketing

MSales05

This is course five in the required series of courses that must be taken by brokers and agents who are interested in marketing Medicare Part C and Part D products and Section 1876 Cost Contracts (collectively referred to as Medicare plans in this course). This module provides the rules related to marketing Medicare plan products as required by the Centers of Medicare and Medicaid Services (CMS).

Format: eLearning - EduFlex, eLearning - SCORM

Libraries: Medicare Broker/Agent Training
Functional Areas: Medicare Plan Broker Training

Medicare Plan: Broker and Agent Training - Medicare Basics

MSales02

This is course two in the required series of courses that must be taken by brokers and agents who are interested in marketing Medicare Part C and Part D products and Section 1876 Cost contracts (collectively referred to as Medicare plans in this course). Topics in this course include: Medicare, MA Health Plans, Other Plan Types, Prescription Drug Coverage Plans, and Part D Utilization Management. After completing this course, learners will be able to identify the differences between Original Medicare, Medicare Advantage, and Medicare Prescription Drug options. Learners will also be able to recognize a few key attributes of the various product options. Lastly, learners will be able to identify who is eligible for various Medicare coverage options.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Medicare Broker/Agent Training

Functional Areas:

- Medicare Plan Broker Training

Medicare Plan: Broker and Agent Training - Medicare Part C and Part D Enrollment & Disenrollment

MSales03

This is course three in the required series of courses that must be taken by brokers and agents who are interested in marketing Medicare Advantage Part D (MA-PD) plans, Prescription Drug Plans (PDPs), and Section 1876 Cost Plans. This module describes processes and procedures for enrollment and disenrollment from Medicare Advantage Health Plans and Prescription Drug Plans (collectively referred to as Sponsors in this course). Topics in this course include: Election Periods, Disenrollment, Enrollment Process, Processing the Enrollment Request, and Non-discrimination Requirements. After completing this course, learners will be able to recognize the responsibilities that the brokers and agents working with MA-PD plans, PDPs, and Cost Plans must meet when enrolling and disenrolling Medicare Advantage and Part D plan members.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Medicare Broker/Agent Training

Functional Areas:

- Medicare Plan Broker Training

MedTech Europe Code of Ethical Business Practice

MDSM04

This course describes the MedTech Europe Code of Ethical Business Practice (the Code). Topics in this course include: General Criteria for Events, Specific Event Guidelines, Grants and Charitable Donations, Arrangements with Consultants, and Research. After completing this course, learners will be able to recognize the guidelines that apply to the many types of interactions between MedTech Europe members (Members or MedTech Members) and healthcare professionals (HCPs) and/or healthcare organizations (HCOs).

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Medical Device - Sales & Marketing

Functional Areas:

- Vendor Credentialing

Content Bundles:

- Corporate Compliance - Medical Device

Languages Available:

- German (MDSM04)
- French (European) (MDSM04)
- Spanish (Spain) (MDSM04)
- Dutch (MDSM04)
- Italian (MDSM04)
- Japanese (MDSM04)
- Chinese (Simplified)

Meeting GMP Training Requirements

PHDV76

In order to produce products that are pure, safe, effective, and in compliance with FDA regulations, it is necessary to understand the nature of GMP Training Requirements. GMP regulations are very clear as to what training is required. This interactive program introduces you to these training requirements and asks you to apply them to actual FDA-regulated industry situations. Upon completion of this course, you will be able to discuss the requirements and different types of training specified in GMPs. You will also be able to discuss several varied approaches to training and understand the advantages and disadvantages of each. Finally, you will understand the more technical aspects of training, why each is important to GMP compliance, and identify examples of achieving training compliance.

Languages Available:

French (European) (PHDV76)
Chinese (Simplified) (PHDV76)
Japanese (PHDV76)

Format: eLearning - EduFlex, eLearning - SCORM,
eLearning (Editable) - CREATE

- | | |
|---|--|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• Medical Device GMPs• Pharmaceutical GMPs | <ul style="list-style-type: none">• Pharmaceutical GMPs- Training |

Meeting Process Requirements for Returned and Salvaged Drug Products

PHA42

Like any other product, pharmaceuticals may be returned from the marketplace for a variety of reasons, including overstock, mislabeling, or product defects. This course explains the unique principles and practices involved in proper handling and processing of returned and salvaged products. Topics in this course include: Definitions, GMP Regulations, Inspection, Harmful Conditions, and Product Details. After completing this course, learners will be able to recognize the procedures for correct handling of returned and salvaged pharmaceutical products.

Format: eLearning - EduFlex, eLearning - SCORM **Partners:** FDA

- | | |
|---|---|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• Pharmaceutical GMPs | <ul style="list-style-type: none">• Packaging,
Warehousing and
Distribution |

National Patient Safety Goals: HCIR Credentialing

MDSM07

This course focuses on best practices and safety goals for healthcare industry representatives (HCIRs). Topics in this course include: Definition, HCIR Program, What to Know, and Policies and Procedures. After completing this course, learners will be able to recognize the role and value of standardized credentialing training for HCIRs and the five substantive training areas recommended for HCIRs. Learners will also be able to recognize how this training advances the goals of safety, quality of care, confidentiality, and compliance with applicable regulatory guidelines.

Format: eLearning - EduFlex, eLearning - SCORM

- | | |
|--|--|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• Medical Device - Sales
& Marketing | <ul style="list-style-type: none">• Vendor Credentialing |

Obligations of Investigators in Conducting Medical Device Trials

GCP03

This course addresses the requirements for conducting clinical trials for investigational premarket medical devices. It provides an overview of the clinical investigator's general and specific obligations to protect human subjects while providing valid data that sponsors may submit to regulatory authorities for approval. This course also introduces documentation and reporting requirements, the inspection process, and the consequences for failure to comply with good clinical practice. It concludes with suggestions for improving compliance.

Format: eLearning - EduFlex, eLearning - SCORM,
eLearning (Editable) - CREATE

- | | |
|--|--|
| Libraries: | Functional Areas: |
| <ul style="list-style-type: none">• Clinical: Medical
Device | <ul style="list-style-type: none">• GCP Basics |

Office Safety

EHS65

Hidden dangers lurk in every corner of a workplace. With potential hazards ranging from fire to personal injury, knowing how to identify hazards and avoid accidents can keep everyone safe in the office. This course identifies common hazards that may be present in your office and how to avoid such hazards. Topics in this course include: Emergency Action Plan, Hazard Identification, Safe Work Practices, Office Equipment, Walking Surfaces, Good Housekeeping, and Workplace Violence. After completing this course, learners will be able to describe an action plan, identify potential hazards in the workplace, and recognize methods of hazard avoidance.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- RETIRED - Environmental Health and Safety
- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Functional Areas:

- Workplace Safety

Languages Available:

Spanish (Latin America)

Office Safety

PS5-00290

Although accidents involving office personnel generally occur less frequently than mishaps to industrial workers, they do still occur and can result in serious injuries and even death. Office safety is the responsibility of everyone. You must understand what you can do to stay safe on the job, and you need to be aware of how to correct unsafe conditions. This course provides the information you need to work safer in your office environment. Ideal learners include office workers.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Languages Available:

Chinese (Simplified)
Czech
Dutch
French (Canadian)
German
Polish
Portuguese (Brazil)
Spanish (Latin America)
Thai

OIG Compliance Program Guidance for Medical Device Manufacturers -- Field Force

OIG03

This course identifies practices that present a potential risk of liability for medical device manufacturers under the three major risk areas identified in the OIG Compliance Program Guidance for Pharmaceutical Manufacturers. Topics in this course include: Risk Areas, Problematic Areas, Consulting Agreements, Truthful and Non-Misleading Product Promotion, and Discounting Arrangements. After completing this course, learners will be able to identify risk areas in medical device promotion as well as OIG Guidance for navigating these risks successfully.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Medical Device - Sales & Marketing

Functional Areas:

- Medical Device Sales Compliance

Operating Room Conduct

PHA68

In your job, you may be asked to visit an operating room (OR) and assist with the setup or use of a medical device. This course addresses all aspects of operating room (OR) conduct and covers important, general information about the hospital environment and staff, proper behavior prior to and upon arrival at the hospital, and proper dress for the OR. Topics include: General Information, Protocols, Check-In Process, Attire, OR Setting, Representative Tasks, Considerations in the OR, and Hazards. After completing this course, learners will be able to identify proper operating room conduct.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: AORN

Libraries:

- Medical Device - Sales & Marketing

Functional Areas:

- Vendor Credentialing

Content Bundles:

- Vendor Credentialing

Languages Available:

- Spanish (Latin America) (PHA68)
- German (PHA68)
- French (European) (PHA68)
- Chinese (Simplified) (PHA68)
- Japanese (PHA68)

Orientation to GMP Compliance

PHDV73

Because FDA GMP regulations have a direct impact on how you do your job, you need insight on how they are applied and interpreted. This course illustrates how the Food, Drug, and Cosmetic Act is tied to Title 21 of the Code of Federal Regulations and how Good Manufacturing Practices (GMPs) are key elements in those regulations. Topics include key definitions, GMP focus areas, interpretation of GMPs, and enforcement actions. After completing this course, you will be able to recognize GMP regulations, basic GMP requirements, your roles and responsibilities for compliance, and the ways FDA enforces GMP regulations.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- GMP Basic Concepts

Content Bundles:

- Pharmaceutical - GMP
- Medical Device - GMP

Languages Available:

- Spanish (Latin America) (PHDV73)
- German (PHDV73)
- French (European) (PHDV73)
- Dutch (PHDV73)
- Chinese (Simplified) (PHDV73)
- Japanese (PHDV73)

Overcoming Negativity in the Workplace

EHS95

This course is designed to help learners manage and solve interpersonal conflicts at work or away from work. Topics in this course include: Viewpoints and Approaches, Evaluation, Changing Thoughts, Listening, and Application. After completing this course, learners will be able to identify the approaches and skills required to solve problems. Learners will also be able to recognize how to overcome negativity in the workplace.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Functional Areas:

- Professional Development

Overhead and Gantry Crane Safety

PS5-00953

Anyone who works with cranes knows not to underestimate the daily risk of collapse, electrical accidents, falls and other serious incidents. The power that makes overhead, gantry and similar cranes so useful also makes them dangerous. By properly maintaining and operating the cranes with which you work, you can protect yourself and your co-workers. Ideal learners are crane operators and their supervisors.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Languages Available:

- Czech
- Dutch
- German
- Japanese
- Polish
- Spanish (Latin America)
- Thai

Overview of FDA's Bioresearch Monitoring Program

BIMO01

This is the first in a series of courses that provide an overview of FDA's Bioresearch Monitoring (BIMO) program and the methods and techniques used in conducting and reporting Nonclinical Laboratory, Clinical Investigator, Institutional Review Board (IRB), Sponsor/Monitor, and in vivo Bioequivalence inspections. This course provides an overview and historical perspective of FDA's BIMO program. Topics in this course include: Purpose and History, BIMO Terminology, Research and Marketing Permits, Regulatory Expectation, and Implementation. After completing this course, learners will be able to recognize the historical perspective and regulatory basis of the BIMO program. Learners will also be able to identify the definitions of common BIMO terms and recognize how FDA implements the BIMO program.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- Clinical: Medical Device
- Clinical: Pharmaceutical
- FDA BIMO Course Series

Functional Areas:

- Clinical: Quality Topics

Overview of the Clinical Research Process

GCP11

Clinical research is the testing of experimental drugs, biologics, and medical devices in humans. This course describes the clinical research process for those who are involved in any aspect of the development, research, marketing, or sales of new drugs, biologics, and devices. Topics in this course include: Regulations, GCP, Documents, Phases, Timelines and Costs, and Final Stages. After completing this course, learners will be able to recognize the nonclinical and clinical components of new product development.

Languages Available:

- Chinese (Simplified) (GCP11)
- German (GCP11)
- Japanese (GCP11)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:

- GCP - Clinical Management

Content Bundles:

- Global Clinical Operations

Overview of the Preparation Requirements for the ICH Common Technical Document

GCP06

This course is an overview of how completed research studies are organized and summarized to be in compliance with the International Conference on Harmonisation (ICH) Common Technical Document (CTD - M4) guideline. Topics in this course include: Organization, QOS, Nonclinical Sections, Clinical Sections, and Modules 3, 4, and 5. After completing this course, learners will be able to identify the purpose of the CTD and ICH recommendations for summarizing and reporting data for completed research studies. Learners will also be able to recognize where to find more detailed information about the recommended CTD format for the three primary scientific areas (Quality, Safety, and Efficacy) that are part of a CTD.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Clinical: Pharmaceutical

Functional Areas:

- ICH Common Technical Document

Packaging and Labeling of Finished Pharmaceuticals

PHA39

Proper packaging and labeling of pharmaceuticals insures safe and sufficient products for consumers. This course describes the packaging and labeling of pharmaceutical products. Topics in this course include: GMP Principles, Packaging, Consumer Protection, Precautions, Labeling, Label Control, and On-Line Controls. After completing this course, learners will be able to recognize GMP requirements for packaging and labeling and the systems and procedures that prevent mix-ups.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- Pharmaceutical GMPs

Functional Areas:

- Pharmaceutical GMP Basics

Languages Available:

- French (European)
- Spanish (Spain)
- German
- Japanese
- Chinese (Simplified)

Part 11: Electronic Records and Signatures -- Application

FDA61

In many organizations today, electronic records and electronic signatures are becoming more common. This course identifies how to implement Part 11 and what it means in terms of FDA's enforcement policy for 21 CFR Part 11, Electronic Records; Electronic Signatures. Topics in this course include: Meeting Expectations, Records, Security, Electronic Signatures, System Documentation, and Audit Trails. After completing this course, learners will be able to recognize how to apply Part 11 regulations to your company's systems and records in accordance with FDA's expectations.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- 21 CFR Part 11

Languages Available:

- French (European) (FDA61)
- Chinese (Simplified) (FDA61)
- Japanese (FDA61)
- Korean (FDA61)

Part 11: Electronic Records and Signatures -- Changes in Enforcement Policy

FDA57

Since the inception of Part11, FDA has issued changes to the enforcement policy for electronic records and signatures. This course describes how to implement the new changes of Part 11 enforcement. Topics in this course include: Key Changes, FDA Enforcement, and Unaffected Provisions. After completing this course, learners will be able to recognize FDA expectations for compliance with all applicable predicate rules.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Pharmaceutical GMPs

Functional Areas:

- 21 CFR Part 11

Languages Available:

- French (European) (FDA57)
- Chinese (Simplified) (FDA57)
- Japanese (FDA57)
- Korean (FDA57)

Part 11: Electronic Records; Electronic Signatures

FDA31

In many industries today, the use of electronic records and signatures is becoming more common. This course explains the purpose of 21 CFR Part 11. Topics in this course include: Records Requirements, Records Security, Electronic Signatures, Signature Controls, and FDA Enforcement. After completing this course, learners will be able to recognize how to properly implement and use an electronic record or signature. FDA requirements for computerized systems that generate electronic records ensure that they and any electronic signatures applied to them are trustworthy, reliable, and traceable to the person(s), events, and actions taken to generate the records.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- FDA Inspections and Enforcement
- Pharmaceutical GMPs

Functional Areas:

- 21 CFR Part 11

Languages Available:

- French (European) (FDA31)
- Chinese (Simplified) (FDA31)
- Japanese (FDA31)
- Korean (FDA31)

Personal Leadership Power

EHS66

This course presents information about the definition of leadership, how to increase your PLP, and how to apply PLP to increase the productivity of your company. Topics in this course include: Leaders, Key Traits, Barriers, Personal Leadership Power (PLP), Five Principles, Developing Your PLP, and Workplace PLP. After completing this course, learners should be able to identify and apply the five principles involved in increasing and effectively using PLP for themselves and for their organizations.

Format: eLearning - SCORM, eLearning - EduFlex

Libraries:

- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Functional Areas:

- Professional Development

Personal Protective Equipment (PPE) Overview

PS5-00286

Workplaces can be very dangerous and unpredictable places with loud noises, falling objects, flying sparks, toxic chemicals, whirling blades and belts, you name it. So what is one way to keep yourself safe? By wearing personal protective equipment, commonly known as PPE, you can protect yourself against hazards and reduce your chances of getting hurt or even killed.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Languages Available:

- French (Canadian)
- French (European)
- German
- Italian
- Japanese
- Korean
- Portuguese (Brazil)
- Russian
- Spanish (Latin America)

Pharmaceutical and Medical Device Supplier Quality Management

PHDV85

A growing list of unsafe, counterfeit, contaminated, and defective products has emphasized the need for increased supplier quality management. This course discusses the regulations and standards for supply chain integrity. Topics in this course include: Origin, New Regulations, ICH Q10, Supplier Quality Agreements, and FDA vs EMA. After completing this course, learners will be able to recognize regulations and guidances, identify critical supplier quality agreements and audits, and recognize the differences between U.S. FDA and EMA approaches to supplier quality.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- GMPs - Suppliers

Pharmaceutical Risk Management: Picking the Right CAPA Tools

PHA73

Any failure of a batch or its components to meet any of its specifications must be thoroughly investigated, whether or not the batch has already been distributed. This course describes the process of evaluating and using corrective and preventative actions (CAPA) systems and tools that align with an organization's methods and processes, so the Quality Assurance (QA) team can successfully determine which actions must be made to prevent future issues. Topics in this course include: CAPA Programs, Data Monitoring and Review, Analysis, and CAPA Software Tools. After completing this course, learners will be able to recognize the steps involved in the CAPA program. PHA40 Corrective and Preventive Actions is a prerequisite to this course and must be completed before taking this course.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Pharmaceutical GMPs

Functional Areas:

- Pharmaceutical GMPs - CAPA

Photography for FDA Enforcement

FDA47

This course covers the legal requirements of photographing evidence for FDA investigators who take photographs for law enforcement purposes. It addresses FDA's authority to take pictures, and covers handling film and digital images, investigative techniques, the use of close-up photography, and the differences between 35 mm cameras and digital cameras.

Format: eLearning - HIP2

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- FDA Inspection Readiness

Physical and Network Security

ETHICS21

Information security is critical for any business. This course identifies the types of assets that are at risk, outlines methods to protect them, and examines how every employee can develop a security mindset. Topics in this course include: The Security Mindset, Physical Security, Virtual Data Security, Use of the Internet, and Proprietary Information. After completing this course, learners will be able to recognize security risks to physical and virtual assets, identify their responsibilities for protecting all of these resources, and recognize requirements and guidelines for maintaining physical and network security.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Ethics & Corporate Responsibility

Functional Areas:

- EHS - Physical Security
- Corporate Ethics

Languages Available:

- Spanish (Latin America) (ETHICS21)
- Chinese (Simplified) (ETHICS21)
- Japanese (ETHICS21)

Physician Payment Sunshine Act

PHSM11

After completing this course, you will be able to recognize the meaning and purpose of the Physician Payment Sunshine Act. You will also be able to recognize key terms and phrases, such as, "applicable manufacturers," "covered drug, device, biological, or medical supply," "covered recipient," and "payments or other transfers of value." Lastly, you will be able to identify what needs to be reported, when it will be reported, how it will be reported, and the penalties for any failure to properly report.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Medical Device - Sales & Marketing
- Pharmaceutical - Sales & Marketing

Functional Areas:

- Corporate Ethics
- Sales Compliance

Content Bundles:

- Corporate Compliance - Pharmaceutical
- Corporate Compliance - Medical Device

Languages Available:

- French (European) (PHSM11)
- Spanish (Spain) (PHSM11)
- Chinese (Simplified) (PHSM11)
- German (PHSM11)

Postmarketing Reporting of Adverse Drug Experiences

PHSM08

This course explores the process for reporting postmarketing adverse drug experiences to FDA. Topics in this course include: Reports and Requirements. After completing this course, learners will be able to identify the process for reporting postmarketing adverse drug experiences to FDA.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Pharmaceutical - Sales & Marketing

Functional Areas:

- Pharmaceutical Sales Compliance

Powered Industrial Trucks Module 1 - Introduction to Powered Industrial Trucks

PS5-00607

Powered industrial trucks like forklifts, motorized pallet jacks, tuggers, tow motors and other powered equipment are used every day to lift and move equipment or materials. Every year, powered industrial trucks are involved in tens of thousands of accidents and injuries, some of which are fatal. If you are going to operate a powered industrial truck, you need to be trained and tested to make sure you know how to do it safely. Module 1 is an introduction to powered industrial trucks and their safe operation. Ideal learners are employees who operate powered industrial trucks.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Languages Available:

Czech
Dutch
German
Japanese
Polish
Portuguese (Brazil)
Spanish (Latin America)
Thai

Powered Industrial Trucks Module 2 - Pre-Operation Inspection and Maintenance

PS5-00771

Powered industrial trucks like forklifts, motorized pallet jacks, tuggers, tow motors and other powered equipment are used every day to lift and move equipment or materials. According to the U.S. Bureau of Labor Statistics, every year powered industrial trucks are involved in approximately 68,400 accidents, 34,000 injuries and 85 fatalities. Because of this high risk of injury and even death while operating a powered industrial truck, OSHA regulates their operation. This course covers OSHA-required information that needs to be communicated to operators during the classroom portion of their training. Module 2 covers pre-use inspections, maintenance and refueling/recharging.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Languages Available:

Czech
Dutch
German
Japanese
Polish
Portuguese (Brazil)
Spanish (Latin America)
Thai

Powered Industrial Trucks Module 3 - Stability and Handling Loads

PS5-00772

Powered industrial trucks like forklifts, motorized pallet jacks, tuggers, tow motors and other powered equipment are used every day to lift and move equipment or materials. Every year, powered industrial trucks are involved in tens of thousands of accidents and injuries, some of which are fatal. If you are going to operate a powered industrial truck, you need to be trained and tested to make sure you know how to do it safely. Module 3 covers stability and handling loads.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Languages Available:

Czech
Dutch
German
Japanese
Polish
Portuguese (Brazil)
Spanish (Latin America)
Thai

Pre- and Post-Approval FDA Drug Inspections

PHA75

This course will explore pre-approval and post-approval drug FDA inspections. Specifically, the purpose and focus of each type of inspection will be discussed, along with the key inspectional targets of each. For pre-approval inspections, the discussion will primarily focus on the process and documentation related to demonstrating equivalence of the bio-clinical batches to the proposed commercial product. Key discussion points will include: evaluation of bio-clinical batches, raw materials, manufacturing process, finished product, and general GMP compliance. For post-approval inspections, the discussion will primarily focus on general GMP compliance issues. The various inspection outcomes for each type of inspection will also be covered. Because all FDA-regulated facilities will undoubtedly be subject to FDA inspection, it is important that employees understand what to expect and what their role should be. When this lesson is completed, the learner will be able to discuss the differences between pre- and post-approval FDA inspections, why they occur, and possible outcomes of each.

Languages Available:

Chinese (Simplified)
Japanese
Korean

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Pharmaceutical GMPs

Functional Areas:

- FDA Inspection Readiness

Content Bundles:

- GMP Inspection Readiness

Preventing Sexual Harassment

ETHICS18

You have a responsibility to yourself and your co-workers to take action when faced with sexual harassment in the workplace. This course describes workplace policies that ensure a harassment-free workplace. Topics in this course include: Definitions, Gray Areas, Taking Action, and Consequences. After completing this course, learners will be able to identify appropriate and inappropriate behavior as defined by the law and company policy.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Ethics & Corporate Responsibility

Functional Areas:

- Harassment Topics

Principles of Aseptic Processing

PHDV71

Because microbiological and particulate contamination can potentially cause serious health problems in animals and humans, it is vital that sterile products be manufactured, filled, and packaged in an aseptic environment. This course will address the general principles and practices necessary to assure product sterility and safety related to aseptic processing. Topics in this course include: Cleanroom Requirements, The Process, Employee Practices, Validation, and Monitoring. After completing this course, learners will be able to recognize the general principles and practices necessary to ensure product sterility and safety, as well as the Good Manufacturing Practices (GMP) requirements for areas where aseptically produced products are handled.

Languages Available:

French (European) (PHDV71)
German (PHDV71)
Spanish (Spain) (PHDV71)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- Pharmaceutical GMPs

Functional Areas:

- Aseptic Processing

Content Bundles:

- Basics of Aseptic Processing

Principles of Auditing

PHDV69

This course focuses on the purpose and conduct of internal and external quality audits. Topics in this course include: Scope, Types of Audits, Benefits, Preparation, Performing Audits, and Audit Closeout. After completing this course, learners will be able to recognize the importance of an effective audit program, the benefits that can result, actual conduct of an audit, and how proper corrective action and follow-up yield the ultimate benefits of the program.

Languages Available:

Chinese (Simplified) (PHDV69)
Japanese (PHDV69)
Korean (PHDV69)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- FDA Inspection Readiness

Content Bundles:

- GMP Inspection Readiness

Principles of Cleaning Validation

PHA37

The cleaning of equipment used in a pharmaceutical operation can be a complex process. Even the smallest amount of chemical residual material in equipment can be extremely dangerous. This course will identify the basics of cleaning validation in pharmaceutical manufacturing operations. Topics in this course include: Cleaning Validation, Proper Cleaning Procedures, Assessing Cleanliness, Proving the Method, Acceptance Limits, Test Procedure, and Control and Monitor. After completing this course, you will be able to recognize why a cleaning Standard Operating Procedure is necessary. You will also be able to identify EU and FDA requirements for cleaning validation.

Languages Available:

German
French (European)
Spanish (Spain)

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- Pharmaceutical GMPs

Functional Areas:

- Pharmaceutical GMPs
- Cleaning Validation

Content Bundles:

- Basics of Aseptic Processing

Principles of Good Documentation

PHA74

Documentation is an essential part of Good Manufacturing Practice (GMP). This course provides an overview for manufacturers of pharmaceutical and biological products of the documents required and the controls that should be in place. The regulatory requirements of FDA are addressed with reference also made to the requirements of the EU. The course provides an introduction to staff at all levels and highlights the personal responsibility they have for ensuring documentation is followed and documentation is correct.

Languages Available:

German (PHA74)
French (European) (PHA74)
Chinese (Simplified) (PHA74)
Japanese (PHA74)
Spanish (Spain) (PHA74)

Format: eLearning - EduFlex, eLearning - SCORM,
eLearning (Editable) - CREATE

Libraries:

- Pharmaceutical GMPs
- Global Regulatory

Functional Areas:

- GMP Basic Concepts

Content Bundles:

- Pharmaceutical - GMP

Principles of Sterilization

PHDV81

The success of sterilization can directly impact the quality and safety of products used by consumers. This course discusses the purpose of sterilization and basic principles of several commonly used sterilization techniques. Topics in this course include: Sterilization, Moist Heat, Dry Heat, Gas, Radiation, Chemical, Filtration, and Sterility Assurance. After completing this course the learner will be able to identify six types of sterilization, recognize methods for validating sterilization, and identify the key aspects of sterility assurance.

Languages Available:

German (PHDV81)
French (European) (PHDV81)
Spanish (Spain) (PHDV81)

Format: eLearning - EduFlex, eLearning - SCORM,
eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- Aseptic Processing

Content Bundles:

- Basics of Aseptic Processing

Privacy and Data Protection

ETHICS15

This course describes your responsibility for protecting any personal information that is under your control. Topics in this course include: Consequences, Personal Information, Laws, EU Regulations, and Reporting Problems. After completing this course, learners will be able to recognize what personal data must be protected according to the law and our company policies, as well as your personal responsibility in protecting this information. Learners will also be able to identify the risks involved in compromising personal data and know the basic guidelines for safeguarding it.

Languages Available:

German (ETHICS15)
Italian (ETHICS15)
French (European) (ETHICS15)
Chinese (Simplified) (ETHICS15)
Japanese (ETHICS15)
Portuguese (Brazil) (ETHICS15)
Spanish (Spain) (ETHICS15)
Turkish (ETHICS15)

Format: eLearning - EduFlex, eLearning - SCORM,
eLearning (Editable) - CREATE

Libraries:

- Ethics & Corporate Responsibility

Functional Areas:

- Data Privacy

Content Bundles:

- Corporate Compliance - Plan Sponsors
- Corporate Compliance - General Industry

Promotion of Pharmaceutical Products -- Field Facing

PHSM05

This course outlines the guidelines, rules, and regulations that pharmaceutical companies must follow when promoting their products to healthcare professionals and consumers. Topics in this course include: Foundation, Promotion, Sales Representatives, Promotional Programs, and Non-Promotional Activities. After completing this course, learners will be able to recognize the guidelines for promoting products to healthcare professionals and consumers.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:	Functional Areas:
<ul style="list-style-type: none"> • Pharmaceutical - Sales & Marketing 	<ul style="list-style-type: none"> • Pharmaceutical Sales Compliance

Promotion of Pharmaceutical Products -- In House

PHSM04

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Format: eLearning - EduFlex, eLearning - SCORM

Libraries:	Functional Areas:
<ul style="list-style-type: none"> • Pharmaceutical - Sales & Marketing 	<ul style="list-style-type: none"> • Pharmaceutical Sales Compliance

Protection of Human Subjects in Clinical Trials

PHA46

Protection of human subjects is the foremost and most important duty of investigators conducting clinical trials. This course will provide you with a working knowledge of informed consent regulations, Institutional Review Board/Independent Ethics Committee responsibilities, and the obligations of the individuals responsible for protecting patient rights and welfare. Topics in this course include: Consent Form, Consent Process, Consent Exceptions, IRB/IEC, and IRB/IEC Responsibilities. After completing this course, learners will be able to identify the measures that are in place to protect the rights and welfare of subjects in clinical studies. Learners will also be able to recognize informed consent requirements and regulations, the responsibilities of an IRB/IEC, and the obligations of individuals responsible for working according to GCP.

Languages Available:
 Chinese (Simplified)
 German
 Japanese

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE
Partners: FDA

Libraries:	Functional Areas:
<ul style="list-style-type: none"> • Clinical: Medical Device • Clinical: Pharmaceutical 	<ul style="list-style-type: none"> • GCP Basics

Q10 Pharmaceutical Quality System

ICHreg07

This course describes a model for an effective quality management system for the pharmaceutical industry. The course is based on guidance developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance is supported by the Food and Drug Administration (FDA) and is representative of their current thinking on this topic. Topics in this course include: Enablers, Management, Product Lifecycle, Process Performance, CAPA and Change, and Management Review and Improvement. After completing this course, learners will be able to recognize the approach to take in ensuring the pharmaceutical Quality System has the important principles needed to meet regulatory guidance. References: FDA Guidance for Industry "Q10 Pharmaceutical Quality System," ICH, April, 2009. 21 CFR Parts 210, 211, 600, and 606. Guidance for Industry, "Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations," FDA, September 2006. Compliance Program Guidance Manual for FDA Staff: Drug Manufacturing Inspections, Program 7356.002, FDA, September 11, 2015. "Quality Systems for Drugs and Biologics," Pharmaceutical Technology, February 2, 2008.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Global Regulatory

Functional Areas:

- ICH: Quality Management

Q9: Quality Risk Management

ICHreg05

This course introduces the definition and principles of quality risk management (QRM) and the basic steps of a typical QRM process. Topics in this course include: QRM Process, Tools, and Applying QRM. After completing this course, learners will be able to identify the methodology and tools used in a risk management process.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Global Regulatory

Functional Areas:

- ICH: Quality Management

Languages Available:

Japanese (ICHreg05)

QS Regulation 1: Overview and General Provisions

QSR01

This course introduces the Quality System (QS) Regulation (21 CFR Part 820) — a framework of basic requirements for manufacturers of finished medical devices. The course covers the history of the regulation, as well as its requirements, scope, and key terms. The course also discusses the manufacturer's responsibility for a quality system under this regulation. Topics in this course include: Origin, QS Regulation, Terms, Scope, and Responsibility. After completing this course, learners will be able to recognize the origin and scope of the QS Regulation. You will also be able to identify the purpose of the Preamble and general requirements of a quality system. Finally, you will be able to recognize key definitions.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- FDA Inspections and Enforcement
- Medical Device GMPs

Functional Areas:

- FDA QSR Basic Concepts

Content Bundles:

- QSR for Medical Device Companies - Basics

Languages Available:

Chinese (Simplified) (QSR01)
Japanese (QSR01)
Korean (QSR01)

QS Regulation 10: Servicing; Statistical Techniques

QSR10

The Quality System (QS) regulation sets forth certain responsibilities for manufacturers relative to the servicing and statistical techniques requirements of the QS Regulation. This course is the tenth in a series of Quality System (QS) Regulation courses and focuses on Servicing (21 CFR Part 820 Subpart N) and Statistical Techniques (21 CFR Part 820 Subpart O). Topics in this course include: Key Terms, Analysis, Statistical Techniques, Preamble, and FDA Resources. After completing this course, learners will be able to recognize requirements for identifying valid statistical techniques.

Languages Available:
 Chinese (Simplified) (QSR10)
 Japanese (QSR10)
 Korean (QSR10)

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- FDA Inspections and Enforcement
- Medical Device GMPs

Functional Areas:

- FDA QSR Advanced Concepts

Content Bundles:

- QSR for Medical Device Companies - Advanced

QS Regulation 11: Application and Inspection of QS Regulation Requirements

QSR11

The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. This course is the eleventh and final course in a series of Quality System (QS) Regulation courses. Topics in this course include: Key Terms, Seven Subsystems, Subsystems and QSIT, and Learn More. After completing this course, learners will be able to recognize the application and inspection of Quality System Regulation requirements within a medical device manufacturer's quality system.

Languages Available:
 Chinese (Simplified) (QSR11)
 Japanese (QSR11)
 Korean (QSR11)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- FDA Inspections and Enforcement
- Medical Device GMPs

Functional Areas:

- FDA QSR Advanced Concepts

Content Bundles:

- QSR for Medical Device Companies - Advanced

QS Regulation 2: Quality System Requirements

QSR02

The second in a series of Quality System (QS) Regulation courses, this course focuses on the management responsibility, quality auditing, and personnel requirements of 21 CFR Part 820, Subpart B. The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. Topics in this course include: Terms, Requirements, Structure, Management Representative, Management Reviews, Plan and Procedures, Audits, Personnel, and Preamble. After completing this course, learners will be able to recognize the QS Regulation requirements associated with a firm's management responsibility, quality auditing, and personnel.

Languages Available:
 Chinese (Simplified) (QSR02)
 Japanese (QSR02)
 Korean (QSR02)

Learners should complete QS Regulation 1: Overview and General Provisions before taking this course.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- FDA Inspections and Enforcement
- Medical Device GMPs

Functional Areas:

- FDA QSR Basic Concepts

Content Bundles:

- QSR for Medical Device Companies - Basics

QS Regulation 3: Design Controls

QSR03

Based on regulatory authority and findings that a significant portion of device recalls were attributed to faulty design, FDA included design control requirements in the Quality System (QS) Regulation. This course, the third in a series of Quality System Regulation courses, addresses design controls requirements of the Quality System Regulation. Topics include the design plan, the design review, verification, and validation. After completing this course, you will be able to recognize: the design control requirements of the QS Regulation; terms associated with design controls; and requirements for design control procedures. Learners should complete QS Regulation 1: Overview and General Provisions and QS Regulation 2: Quality System Requirements before taking this course.

Languages Available:
 Chinese (Simplified) (QSR03)
 Japanese (QSR03)
 Korean (QSR03)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- FDA Inspections and Enforcement
- Medical Device GMPs

Functional Areas:

- FDA QSR Basic Concepts
- Design Controls

Content Bundles:

- QSR for Medical Device Companies - Basics

QS Regulation 4: Document and Purchasing Controls

QSR04

The fourth in a series of Quality System Regulation (QS Regulation) courses, this course focuses on the document controls requirements of 21 CFR Part 820, Subpart D and the purchasing controls requirements of 21 CFR Part 820, Subpart E. The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. Topics in this course include: Key Terms, Document Control, Evaluation & Selection, Records & Data, and Preamble. After completing this course, learners will be able to recognize the document and purchasing controls requirements of the QS Regulation.

Languages Available:
 Chinese (Simplified) (QSR04)
 Japanese (QSR04)
 Korean (QSR04)

Learners should complete *QS Regulation 1: Overview and General Provisions*, *QS Regulation 2: Quality System Requirements*, and *QS Regulation 3: Design Controls* before taking this course.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- FDA Inspections and Enforcement
- Medical Device GMPs

Functional Areas:

- FDA QSR Basic Concepts

Content Bundles:

- QSR for Medical Device Companies - Basics

QS Regulation 5: Identification and Traceability; Production and Process Controls

QSR05

The fifth in a series of Quality System (QS) Regulation courses, this course focuses on Identification and Traceability (21 CFR Part 820, Subpart F) and Production and Process Controls (21 CFR Part 820 Subpart G). The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. Topics in this course include: Identify and Trace, Production Processes, Controlling Changes, Other Controls, Software Validation, Equipment Calibration, and Process Validation. After completing this course, learners will be able to recognize a manufacturer's responsibilities relative to the Identification and Traceability requirements and Production and Process Controls requirements of the QS Regulation.

Languages Available:
 Chinese (Simplified) (QSR05)
 Japanese (QSR05)
 Korean (QSR05)

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- FDA Inspections and Enforcement
- Medical Device GMPs

Functional Areas:

- FDA QSR Basic Concepts

Content Bundles:

- QSR for Medical Device Companies - Basics

QS Regulation 6: Acceptance Activities; Nonconforming Product

QSR06

The sixth in a series of Quality System (QS) Regulation courses, this course focuses on Acceptance Activities (21 CFR Part 820 Subpart H) and Nonconforming Product (21 CFR Part 820 Subpart I). The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices.

Languages Available:
 Chinese (Simplified) (QSR06)
 Japanese (QSR06)
 Korean (QSR06)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- FDA Inspections and Enforcement
- Medical Device GMPs

Functional Areas:

- FDA QSR Basic Concepts

Content Bundles:

- QSR for Medical Device Companies - Advanced

QS Regulation 7: Corrective and Preventive Action

QSR07

The seventh in a series of Quality System (QS) Regulation courses, this course focuses on Corrective and Preventive Action (21 CFR Part 820 Subpart J). The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. Topics include: Key Terms, Investigate and Identify, Changes, Information, and Analyzing Data. After completing this course, you will be familiar with a manufacturer's responsibilities relative to the corrective and preventive action requirements of the QS Regulation. Learners should complete the previous courses in the series before taking this course.

Languages Available:
 Chinese (Simplified) (QSR07)
 Japanese (QSR07)
 Korean (QSR07)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- FDA Inspections and Enforcement
- Medical Device GMPs

Functional Areas:

- FDA QSR Advanced Concepts
- Corrective and Preventive Actions (CAPA)

Content Bundles:

- QSR for Medical Device Companies - Advanced

QS Regulation 8: Labeling and Package Control; Handling, Storage, Distribution, and Installation

QSR08

The eighth in a series of Quality System (QS) Regulation courses, this course focuses on Labeling and Package Control (21 CFR Part 820 Subpart K) and Handling, Storage, Distribution, and Installation (21 CFR Part 820 Subpart L). The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. Topics in this course include: Key Terms, Label Integrity, Labeling Operations, Handling/Storage Areas, Control & Distribution, and Device Installation. After completing this course, you will be able to recognize a manufacturer's responsibilities relative to the labeling, packaging control, handling, storage, distribution, and installation requirements of the QS Regulation.

Languages Available:
 Chinese (Simplified)
 Japanese
 Korean

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- FDA Inspections and Enforcement
- Medical Device GMPs

Functional Areas:

- FDA QSR Advanced Concepts

Content Bundles:

- QSR for Medical Device Companies - Advanced

QS Regulation 9: Records

QSR09

The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. This course, the ninth in a series of Quality System (QS) Regulation courses, focuses on Records (21 CFR Part 820 Subpart M). Topics include key terms, general requirements, Device Master Records, and investigations. After completing this course, you will be able to identify a manufacturer's responsibilities relative to the records requirements of the QS Regulation.

Languages Available:
 Chinese (Simplified) (QSR09)
 Japanese (QSR09)
 Korean (QSR09)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- FDA Inspections and Enforcement
- Medical Device GMPs

Functional Areas:

- FDA QSR Advanced Concepts

Content Bundles:

- QSR for Medical Device Companies - Advanced

QSIT 1 -- Beginning the Inspection

FDA50

This is the first in a series of courses designed to instruct on the Quality System Inspection Technique (QSIT). This course provides guidance for inspecting medical device manufacturers against the Quality System Regulation, 21 CFR Part 820. Topics in this course include: Scope, Other Considerations, Sampling, and Reporting. After completing this course, learners will be able to recognize the purpose of QSIT during investigations of medical device manufacturers

Languages Available:
 Japanese
 Chinese (Simplified)

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- FDA QSIT Inspection Readiness

Content Bundles:

- FDA QSIT Inspection Readiness

QSIT 2 -- The Management Controls Subsystem

FDA51

This is the second in a series of courses designed to instruct on the Quality System Inspection Technique (QSIT). This course will cover the Inspectional Objectives related to the Management Controls subsystem. Topics in this course include: Management Control Documents, Quality Policies and Objectives, Organizational Structure, Management Representative, Management Reviews, Quality Audits, and FDA 483. After completing this course, learners will be able to identify the seven Inspectional Objectives associated with the Management Controls subsystem.

Languages Available:
 Chinese (Simplified)
 Japanese

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- FDA QSIT Inspection Readiness

Content Bundles:

- FDA QSIT Inspection Readiness

QSIT 3 -- The Design Controls Subsystem

FDA52

This is the third in the a series of courses designed to instruct on the Quality System Inspection Technique (QSIT). This course will explain the Inspectional Objectives associated with the Design Control subsystem as part of QSIT. The topics in this course include: Getting Started, Design Plan, Inputs and Outputs, Criteria/Verification, Design Validation I, Design Validation II, and Completion. After completing this course, learners will be able to identify each objective in the Inspectional Objective and ways to accomplish each objective.

Languages Available:
 Chinese (Simplified)
 Japanese

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- FDA QSIT Inspection Readiness

Content Bundles:

- FDA QSIT Inspection Readiness

QSIT 4 -- The Corrective and Preventive Actions Subsystem

FDA53

This is the fourth in a series of courses designed to instruct on the Quality System Inspection Technique (QSIT). The series provides guidance for inspecting medical device manufacturers against the Quality System Regulation, 21 CFR Part 820. Topics in this course include: Procedures, Problems, Received Data, Failure Investigations, Actions, and Documentation and Communications. After completing this course, learners will be able to identify the ten inspectional objectives associated with the CAPA subsystem and recognize the ways to accomplish those inspectional objectives.

Languages Available:
Chinese (Simplified)
Japanese

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- FDA QSIT Inspection Readiness

Content Bundles:

- FDA QSIT Inspection Readiness

QSIT 5 -- The Production and Process Controls Subsystem

FDA54

This is the fifth in a series of courses designed to instruct on the Quality System Inspection Technique (QSIT). The series provides guidance for inspecting medical device manufacturers against the Quality System Regulation, 21 CFR Part 820. Topics in this course include: Selection, Control and Monitoring, Operating Limits, Validation, Software, and Personnel. After completing this course, learners will be able to recognize the inspectional objectives related to the Production and Process Controls subsystem.

Languages Available:
Chinese (Simplified)
Japanese

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- FDA QSIT Inspection Readiness

Content Bundles:

- FDA QSIT Inspection Readiness

Quality Management Refresher

EHS81

All firms must understand how to deliver products and services of high quality to remain competitive. In the end, quality management is not about buzzwords and labels; it is about performance, competitiveness, and customer satisfaction. This course presents refresher information about the fundamental ideas, principles, and tools of quality management. It assumes that basic quality practices are already in place, and is designed to help keep firms on track in their quality management practices.

Format: eLearning - HIP2

Libraries:

- HR Compliance & Risk Management

Functional Areas:

- Process Safety Management

Quality Systems Approach

ICHreg06

This course explains FDA's guidance on a modern quality systems approach to pharmaceutical manufacturing. Topics in this course include: FDA's Approach, Quality Concepts, FDA Compliance, Quality System Model, Management Responsibilities, Resources, Manufacturing Operations, and Evaluation Activities. After completing this course, learners will be able to identify the guidance that FDA has provided on quality systems, the ways in which this supports cGMP compliance, and the ways in which the application of a quality systems approach encourages the use of modern quality management principles and promotes innovation and continuous improvement.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Global Regulatory

Functional Areas:

- ICH: Quality Management

Quality Systems Inspection Technique (QSIT)

DEV42

Manufacturing companies within the biomedical industry are subject to routine inspections of their quality systems by FDA. This course describes an FDA Quality System inspection by explaining the key objectives that an investigator will address when reviewing each subsystem. Topics in this course include: Procedure, Management Controls, Design Controls, Corrective and Preventive Actions (CAPA), Production and Process Controls (P&PC), and Preparation. After completing this course, learners will be able to identify the key elements for meeting the Quality System Regulation requirements.

Languages Available:

French (European)
Chinese (Simplified)
Japanese
Korean

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- Quality Assurance

Content Bundles:

- FDA QSIT Inspection Readiness

Recalls of FDA Regulated Products

FDA24

The monitoring of recalls of potentially hazardous consumer products is one of the most important activities performed by FDA personnel. This course explores the basics of product recalls and personnel responsibilities during recall situations. Topics in this course include: Purpose and Types, Causes, Classifying Recalls, Responsibilities, and Audit Check. After completing this course, learners will be able to recognize FDA's definition of a product recall; recognize the contents of a recall letter; identify the types, depth, and classification of a recall; and recognize the responsibilities of FDA personnel during a product recall.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- FDA Inspection Readiness

Recognizing and Avoiding Conflicts of Interest

ETHICS11

This course provides an overview of conflicts of interest, and also provides guidance and reporting mechanisms for conflicts of interest. Learners will be able to recognize the circumstances that can cause actual or potential conflicts of interest, and also recognize the steps to take to avoid these conflicts or to properly disclose them when they occur.

Languages Available:

Italian (ETHICS11)
French (European) (ETHICS11)
Chinese (Simplified) (ETHICS11)
Japanese (ETHICS11)
Spanish (Spain) (ETHICS11)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Ethics & Corporate Responsibility

Functional Areas:

- Corporate Ethics

Content Bundles:

- Corporate Compliance - Pharmaceutical
- Corporate Compliance - Medical Device
- Corporate Compliance - Plan Sponsors
- Corporate Compliance - General Industry

Recognizing and Avoiding Insider Trading

ETHICS23

This course will identify common situations that violate insider trading laws. Topics in this course include: Recognizing Inside Information and Insider Trading Situations. After completing this course, learners will be able to recognize what constitutes inside information, and how to recognize common insider trading violations.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Ethics & Corporate Responsibility

Functional Areas:

- Ethics Basics

Recognizing Electrical Hazards Awareness

PS5-00204

This course explains how and why electricity is dangerous so that employees may recognize when hazards are present. It is intended for workers in all industries.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Languages Available:

French (Canadian)
Czech
Dutch
French (European)
German
Italian
Japanese
Korean
Polish
Portuguese (Brazil)
Russian
Spanish (Latin America)
Thai
Chinese (Simplified)

Recruitment and Retention of Study Patients

GCP29

This course will discuss recruitment and retention of volunteers within a clinical trial. Topics in this course include: Pre-recruitment, Recruitment, Recruiting Methods, Special Populations, and Enrollment & Retention. After completing this course, learners will be able to identify acceptable ethical and regulatory recruitment and retention methods that can be used for clinical research trials and recognize key factors in recruiting and retaining subjects.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: Corexccl

Libraries:

- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:

- GCP Basics

Regulatory Requirements for Medical Devices in the Republic of Korea

DEV58

This course covers the regulatory framework for medical devices in the Republic of Korea, recent and upcoming regulatory changes, and the medical device market in the Republic of Korea.

Format: eLearning - EduFlex, eLearning - SCORM

Languages Available:

Korean

Libraries:

- Global Regulatory

Functional Areas:

- Medical Device Market Entry

Reporting Adverse Events for Medical Devices

MDSM02

This course introduces the process for filing medical device reports (MDRs) for adverse events and identifies the different types of reports used.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Medical Device - Sales & Marketing

Functional Areas:

- Vendor Credentialing

Content Bundles:

- Vendor Credentialing

Requirements for Computerized Systems Validation and Compliance

PHDV102

This course, the first in a four-part series, describes regulatory requirements and expectations regarding the validation and compliance of computerized systems used in the manufacture of pharmaceuticals, biologicals, and medical devices. It does not cover the detailed requirements of 21 CFR Part 11, except for the requirement that systems be validated. Even though it draws upon medical device guidance, it is not intended to cover all the requirements of producing software that subsequently becomes part of a medical device.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:	Functional Areas:	Content Bundles:
<ul style="list-style-type: none">• Medical Device GMPs• Pharmaceutical GMPs	<ul style="list-style-type: none">• Computer Systems Validation	<ul style="list-style-type: none">• Computer Systems Validation

Languages Available:
German (PHDV102)
French (European) (PHDV102)
Chinese (Simplified) (PHDV102)
Japanese (PHDV102)
Korean (PHDV102)
Spanish (Spain) (PHDV102)

Resolving Out Of Specification Test Results

PHA50

Obtaining an out of specification test result can be unsettling, and it is important that you know what to do with it. This course will provide you with the information to respond accordingly when an OOS result is encountered. Topics in this course include: Phase One, Phase Two, Averages, Outliers, and Failure Investigations. After completing this course, learners will be able to recognize what to look for and what to investigate when an OOS result occurs.

Format: eLearning - EduFlex, eLearning - SCORM **Partners:** FDA

Libraries:	Functional Areas:
<ul style="list-style-type: none">• Medical Device GMPs• Pharmaceutical GMPs	<ul style="list-style-type: none">• Pharmaceutical GMP Basics

Languages Available:
Chinese (Simplified)
Japanese

Resource Conservation and Recovery Act (RCRA) Part 1 (US)

PS5-00727

The Resource Conservation and Recovery Act (RCRA) places controls on the management of hazardous waste from its generation to its ultimate disposal. This course provides you with important information on RCRA, hazardous waste and your role in staying safe if your facility or organization produces, disposes of or accumulates hazardous waste.

Format: eLearning - PS5

Libraries:
<ul style="list-style-type: none">• EHS for Life Science - Basics

Resource Conservation and Recovery Act (RCRA) Part 2 (US)

PS5-00729

Whenever you generate hazardous waste and accumulate it on-site, you must take the necessary precautions and steps to prevent any sudden or accidental release into the environment. This course explores the actions you must take to carefully operate and maintain your facility and therefore reduce the possibility of fire, explosion and release of hazardous waste.

Format: eLearning - PS5

Libraries:
<ul style="list-style-type: none">• EHS for Life Science - Basics

Respiratory Protection

PS5-00276

A single exposure to an airborne chemical can cause health effects that may last for the rest of your life. If your workplace contains dangerous chemicals or hazardous atmospheres, you need to know when and how to wear a respirator. This training will present the basic requirements of respiratory protection and will focus on the types and limitations of respirators. Ideal learners include all employees.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Languages Available:

Czech
Dutch
French (European)
German
Italian
Japanese
Polish
Portuguese (Brazil)
Russian
Spanish (Latin America)
Thai

Review of Basic Statistical Techniques

DEV44

The use of statistics in medical device manufacturing is now expected and regulated by the Food and Drug Administration in the Quality System Regulation, Subpart O, "Statistical Techniques." This course describes the proper use of statistical techniques as they apply to medical device manufacturing. Topics in this course include: Data Analysis, Histograms, and Variability. After completing this course, learners will be able to recognize how to interpret data using basic statistical techniques.

Format: eLearning - EduFlex, eLearning - SCORM **Partners:** FDA

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- Statistics

Risk Management 1: Key Concepts and Definitions

FDA29

FDA manages risk in an attempt to prevent loss or injury by ensuring their medical devices, human and veterinary drugs, food additives, biologics, or other products are safe. This course focuses on Risk Management as it applies to FDA and its regulated industries. This course is also designed to provide an understanding of Risk Management as defined by the International Organization for Standardization (ISO). Topics in this course include: Risk, Calculating Risk, Safety, and Managing Risk. After completing this course, learners will be able to recognize the key concepts and definitions associated with risk management.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE **Partners:** FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- Risk Management

Languages Available:

Chinese (Simplified) (FDA29)
Japanese (FDA29)
Korean (FDA29)

Risk Management in Pharmaceutical Manufacturing

PHA72

This course covers the practical application of risk management principles, published in "Guidance for Industry: Q9 Quality Risk Management", through case studies applied to process design and manufacturing. Topics in this course include: Risk Assessment, Risk Control, Review and Communication, Validation Case Study, and Change Control Case Study. After completing this course, learners will be able to recognize risk management principles for the pharmaceutical industry and the tools that can be used to reduce patient risk and ensure quality throughout a product's lifecycle.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Pharmaceutical GMPs

Functional Areas:

- Pharmaceutical GMPs - Basics

Content Bundles:

- Pharmaceutical - Risk Management

Role of IEC 60601 Around the World

MDSafety_01

Gain a high-level understanding of how the IEC 60601 series and the IECEE CB Scheme are used to demonstrate compliance with regulatory requirements worldwide.

Format:

Libraries:

- Engineering Safety

Functional Areas:

- IEC 60601

Role of the Qualified Person

PHA76

The role of the Qualified Person (QP) is defined in European Union legislation. This course explains the release of medicinal products to the market, the release of clinical trial materials, and pharmacovigilance. Topics in this course include: Regulation, Qualifications/Codes of Practice, Batch Certification, Different Supply Situations, Clinical Trials, and Pharmacovigilance. After completing this course, learners will be able to identify the role and responsibilities of both types of QP defined in EU legislation.

Languages Available:

- German (PHA76)
- French (European) (PHA76)
- Spanish (Spain) (PHA76)

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- GMP Pharmaceuticals
- EU Regulations

Safeguarding Intellectual Property

ETHICS12

This course discusses how to identify and protect the Intellectual Property (IP) assets of a company. It also covers the four primary types of intellectual property with which a company deals. This course explores the business, ethical, and legal consequences of violating IP laws and protections, and an individual's responsibility for safeguarding the IP of a company and that of others.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Ethics & Corporate Responsibility

Functional Areas:

- Intellectual Property

Safety Orientation

PS5-01352

This employee safety program is much more than an examination of set rules. It is a common sense approach to training employees in order to prevent injuries and illness. Ideal learners are new employees.

Languages Available:

- Chinese (Simplified)
- Czech
- Dutch
- French (European)
- German
- Polish
- Portuguese (Brazil)
- Spanish (Latin America)
- Thai

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Safety Signs (US)

PS5-100757

You can tell a great deal about the hazardous conditions in a work area by looking at the safety signs that are posted there. Take this course to find out why we have safety signs, what they mean and what you need to know about them. This course is ideal for all workers who visit or perform work at factories, construction jobsites or healthcare facilities.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Sample Collection

FDA23

This course explores sample collection as a critical responsibility of field personnel. It explains the purpose of sampling and covers how to properly perform sampling. Topics in this course include: Purpose, Types, Preparation, Size, Techniques, Conduct, Submission, and Sample Validity. After completing this course, learners will be able to recognize the reasons for collecting and maintaining samples, identify the major samples types, and identify the differences between domestic and import samples. Learners will also be able to recognize how to prepare and conduct proper sampling and identify the appropriate steps for submitting a sample.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- FDA Inspection Readiness

Sarbanes-Oxley Act: An Overview

ETHICS07

The Sarbanes-Oxley Act of 2002 initiated the biggest change in corporate governance since the Great Depression. This course describes each section of the Sarbanes-Oxley Act along with insights about how it impacts companies and their employees. Topics in this course include: Purpose, Effects, Audit Committees, Executives, Government Agencies, and Crimes and Penalties. After completing this course, learners will be able to identify the purpose and main provisions of the Sarbanes-Oxley Act.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Ethics & Corporate Responsibility

Functional Areas:

- Corporate Ethics

Scope of Standard and Equipment Classification

MDSafety_04

Learn how to easily identify the equipment covered under the IEC 60601-1 standard and how to evaluate equipment based on the classifications found in Clause 6.

Format:

Libraries:

- Engineering Safety

Functional Areas:

- IEC 60601

Section 1557 of the Affordable Care Act

PPACA04

This course discusses the requirements of Section 1557 of the Affordable Care Act. After completing this course, learners will be able to identify the Section 1557 requirements, who they apply to, and consequences for not meeting the requirements.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- PPACA

Security Measures for Employees

Secure06

This course offers all employees ways to ensure they are helping to protect against theft, sabotage, or harm to themselves, their fellow employees, and their company.

Format: eLearning - HIP2

Libraries:

- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Selecting and Managing Clinical Contract Research Organizations (CROs)

GCP12

This course provides information on the processes commonly used to select and manage a clinical contract research organization (CRO) and other supportive contract service providers for the clinical stages of the investigation product development process. Topics in this course include: Outsourcing, Pre-Selection Criteria, Selection Techniques, Managing CROs, and Communications. After completing this course, learners will be able to identify the requirements for selecting and effectively managing CROs and other service providers.

Languages Available:

French (European)
German
Spanish (Spain)

Format: eLearning - EduFlex, eLearning - SCORM,
eLearning (Editable) - CREATE

Libraries:

- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:

- GCP - Clinical Management

Self-Motivation

EHS94

This course covers the five characteristics of self-motivated people and the five skills that are necessary to develop these characteristics. Topics in this course include: Self-Motivation, Skills, Mission Statement, Goals, Creative Thinking, Self-Discipline, and Self-Talk. After completing this course, learners will be able to recognize how to apply the skills and characteristics of self-motivation at work, at home, and in the community.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Functional Areas:

- Professional Development

Sexual Harassment Awareness for California Employees

LAV24

Sexual harassment is a serious issue facing employers. This course is designed to educate you about the State of California's and the Equal Employment Opportunity Commission's (EEOC) definition of sexual harassment as well as to present information on identifying harassing behavior, avoiding harassment, and what steps to take should harassment issues arise involving the workplace. Topics in this course include: Definition, Guidelines, Confrontation, and Reporting Incidents. After completing this course, learners will be able to recognize that harassment is a personal issue and that your definition of offensive behavior may differ from that of your coworkers. Learners will also be able to identify behaviors that are considered inappropriate and know how to avoid engaging in inappropriate behaviors.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- HR Compliance & Risk Management
- Ethics & Corporate Responsibility

Functional Areas:

- Harassment Topics

Sexual Harassment Awareness for Employees

LAV08

Sexual harassment is a serious issue facing employers. This course is designed to educate you about the definition of sexual harassment as well as to present information on identifying harassing behavior, avoiding harassment, and what steps to take should harassment issues arise involving the workplace. Topics in this course include: Definition, Guidelines, Confrontation, and Reporting Incidents. After completing this course, learners will be able to recognize that harassment is a personal issue and that your definition of offensive behavior may differ from that of your coworkers. Learners will also be able to identify behaviors that are considered inappropriate and know how to avoid engaging in inappropriate behaviors.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Functional Areas:

- Harassment Topics

Content Bundles:

- HR Compliance

Sexual Harassment Awareness for Managers

LAV09

This course presents an overview of sexual harassment and emphasizes the specific responsibilities of managers and supervisors in preventing and responding to sexual harassment. Responding appropriately to sexual harassment may reduce the potential liability of employers in this area. It is highly recommended that individuals take Investigating Employee Claims in conjunction with this course. Reviewing Sexual Harassment Awareness for Employees will also be helpful. Topics in this course include: Definitions, Employer Liabilities, Prevention and Response, and Legal Issues. After completing this course, learners will be able to recognize, prevent, and respond to sexual harassment in a responsible manner.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Functional Areas:

- Harassment Topics

Sexual Harassment Awareness for New York Employees and Supervisors

LAV23

Sexual harassment is a serious issue facing employers. This course is designed to educate you about New York and federal laws regarding sexual harassment as well as to present information on identifying harassing behavior, avoiding harassment, and what steps to take should harassment issues arise involving the workplace. Topics in this course include: Guidelines, Confrontation, Reporting Incidents, Supervisor Responsibilities, and Rights and Remedies. After completing this course, learners will be able to recognize that harassment is a personal issue and that definitions of offensive behavior may differ amongst coworkers. Learners also will be able to identify behaviors that are considered inappropriate and recognize how to avoid engaging in inappropriate behaviors.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- HR Compliance & Risk Management
- Ethics & Corporate Responsibility

Functional Areas:

- HR Compliance

Sexual Harassment Policy

LAVP01

The Sexual Harassment Policy states that this Company is committed to a work environment free from any form of sexual harassment. It defines harassment and outlines employee responsibility as it relates to both the harasser and the harassed.

Format: Policy

Libraries:

- HR Compliance & Risk Management

Functional Areas:

- Harassment Topics

SMART Goal Setting

EHS99

Goals that adhere to Specific, Measurable, Attainable, Results-Oriented, and Time-Bounded (SMART) criteria are more likely to lead to completion of tasks and higher satisfaction. This course will help participants understand the impact of goal setting on their lives, and give them a road map they can use to achieve higher personal and professional productivity. Topics in this course include: Goals, Specific, Measurable, Attainable, Results-Oriented, Time-Bound, and Putting It Together. After completing this course, learners will be able to recognize the essential elements of effective goal setting. Learners will also be able to differentiate between well-written and poorly written goals.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- HR Compliance & Risk Management

Functional Areas:

- Professional Development

Special Investigations

FDA25

This course will provide an overview of the broad spectrum of investigations performed by the Food and Drug Administration (FDA). Topics in this course include: Complaint Investigation, Surveillance Investigation, Disaster Investigation, Health Fraud Investigation, Product Tampering Investigation, and Criminal Investigation. After completing this course, learners will be able to identify the purpose of special investigations. Learners will also be able to recognize the properties of special investigations, as well as things to look for during each of these investigations.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- FDA Inspections and Enforcement

Functional Areas:

- FDA Inspection Readiness

Special Needs Plans: Model of Care

MAPD05

The Model of Care (MOC) is considered a vital quality improvement tool and integral component for ensuring that the unique needs of each beneficiary enrolled in a Special Needs Plan (SNP) are identified and addressed. Topics in this course include: Background, MOC 1: SNP Population, MOC 2: Care Coordination, MOC 3: SNP Provider Network, and MOC 4: Quality Measurement and Performance Improvement. After completing this course, learners will be able to identify the required elements of a Special Needs Plan's Model of Care as well as the scoring criteria that are used as part of the review and approval process.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Medicare Advantage
- Medicare Part D

Functional Areas:

- Medicare Advantage

Spill Prevention, Control and Countermeasure (SPCC) (US)

PS5-00191

You have seen media reports about the catastrophic effects an oil spill has on wildlife, the environment, and the livelihood of affected communities. The SPCC regulation was developed to prevent oil releases at facilities from polluting navigable waters of the United States. This course gives employees a general overview of SPCC requirements. Ideal learners include any employee involved in oil handling, transfer, storage, spill response or maintenance of oil equipment.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Stormwater Pollution Prevention (US)

PS5-00256

Laws require us to regulate stormwater in order to reduce the pollution of rivers and lakes. Identifying sources of storm water pollution and keeping them from coming in contact with runoff is one of the best and most economical ways of protecting the quality of our waters. This course presents best management practices to prevent stormwater pollution.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Languages Available:

Chinese (Simplified)
Czech
Dutch
French (European)
German
Japanese
Polish
Portuguese (Brazil)
Spanish (Latin America)
Thai

Structure of IEC 60601

MDSafety_02

Gain an understanding of the nomenclature and structure around the 60601 series and explore the relationships of the general standard to collateral standards, particular standards, amendments and national deviations.

Format:**Libraries:**

- Engineering Safety

Functional Areas:

- IEC 60601

Substance Abuse

LAV10

Employee substance abuse is one of the most troubling issues facing modern businesses. This course discusses substance abuse as it affects both the workplace and the home. Topics in this course include: Substance Abuse, Alcohol Abuse, Alcoholism and Self-Evaluation, Drug Abuse and Addiction, and Response. After completing this course, learners will be able to recognize psychological and physical effects of substance abuse and the common behavior characteristics of co-workers and family members with abuse problems.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Functional Areas:

- HR Compliance

Content Bundles:

- HR Compliance

Systems Based Drug Inspections

FDA55

FDA has a series of compliance programs that provide guidance and instructions to help meet FDA regulations for pharmaceutical manufacturers. This course describes FDA's Drug Manufacturing Inspections program. Topics in this course include: Guidance, Systems, Inspections, Quality, Facilities and Equipment, Materials, Production, and Laboratory Control. After completing this course, learners will be able to recognize what can happen if a firm is not following FDA regulations.

Languages Available:
Chinese (Simplified)
Japanese

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
• FDA Inspections and Enforcement

Functional Areas:
• FDA Inspection Readiness

Testing for Bacterial Endotoxins

PHDV86

This course will provide a general overview of bacterial endotoxins and the methods used to test for their presence in products. Topics in this course include: Endotoxin Reduction, Gel-Clot LAL Testing, Chromogenic LAL Testing, and Choosing a Test. After completing this course, learners will be able to recognize the principles of bacterial endotoxins and ways they are detected in products.

Format: eLearning - EduFlex, eLearning - SCORM **Partners:** FDA

Libraries:
• Medical Device GMPs
• Pharmaceutical GMPs

Functional Areas:
• GxP Basics

The Approval Process for New Medical Devices

DEV47

This course provides an overall view of the development regulatory process for legally marketing a new medical device in the US. Topics in this course include: Classification, Approval Process, IDE, Clinical Studies, and PMA. After completing this course, learners will be able to identify the major steps in new device development and the required regulatory process for the US market. Learners will also recognize the purpose and requirements of clinical studies. Learners will be able to identify the elements of a 510(k), an IDE, and a PMA. Finally, learners will recognize key information about the classification of medical devices and the role of FDA in the approval of medical devices for the US marketplace.

Languages Available:
Chinese (Simplified) (DEV47_SCH)
Japanese (DEV47_JP)
Korean (DEV47_KOR)

Format: eLearning - EduFlex, eLearning - SCORM **Partners:** FDA

Libraries:
• Global Regulatory

Functional Areas:
• Medical Device Market Entry

The Clinical Development Process: Investigational Product, Plan, and Data Management

GCP28

This course will discuss the clinical development process, including the regulatory obligations of the sponsor of a new drug or product. Topics in this course include: Clinical Research Plan, Protocol Plan, Subject Selection Process, Data Collection, and NDA Submission. After completing this course, learners will be able to identify the steps leading to the final FDA review and approval for marketing of a new product.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:
• Clinical: Medical Device
• Clinical: Pharmaceutical

Functional Areas:
• GCP - Clinical Management

The Design and Development of Software Used in Automated Process Controls

PHDV80

Regulators require that manufacturers apply the principles and practices of software quality assurance to automated systems that may ultimately affect product safety and effectiveness. This course examines the process of developing software for automated process control. Topics in this course include: Automated Process Controls, Specifications and Design, Verification and Validation, and Maintenance and Retirement. After completing this course you will be able to identify the Software Development Life Cycle (SDLC) and recognize several aspects of software quality assurance and documentation.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: FDA

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- GMPs - Process Validation

The Role of the Clinical Research Associate

GCP17

This course explores the role of the clinical research associate (CRA) in monitoring a clinical trial and acting as a liaison between the investigative site and the sponsor company. The course will introduce key CRA responsibilities widely recognized throughout the industry and globally applicable. Topics in this course include: Definition, Visits, Recruitment and Retention, Informed Consent, Source Documentation, and Essential Documents. After completing this course, learners will be able to recognize the current role of the CRA during each stage of a clinical trial and identify specific responsibilities for documents and processes in those stages.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:

- GCP Basics

The Role of the Clinical Research Coordinator

GCP18

The clinical research coordinator (CRC) has a key role in executing a clinical trial and acting as a liaison to the investigator, sponsor, and monitor. This course will introduce key CRC responsibilities at the site, including subject recruitment, informed consent, source document and case report form (CRF) completion, and test article accountability. Topics in this course include: CRC, Visits Before Study, Visits During & After Study, Recruitment & Retention, Informed Consent, Source Documentation, Case Report Forms, and Essential Documents. After completing this course, learners will be able to identify the CRC's key roles in research and patient protection from pre-study visits through study completion.

Format: eLearning - EduFlex, eLearning - SCORM

Partners: Corexcel

Libraries:

- Clinical: Medical Device
- Clinical: Pharmaceutical

Functional Areas:

- GCP Basics

Trade Secrets

ETHICS28

This course discusses trade secrets and keeping a competitive edge in the marketplace. Topics in this course include: Definition, Risks, and Protecting Trade Secrets. After completing this course, learners will be able to identify trade secrets, and recognize the necessary steps to safeguard trade secrets in the workplace.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Ethics & Corporate Responsibility

Understanding GMPs for Facilities and Equipment

PHDV63

Facilities and equipment GMP requirements impact many aspects of plant operation — from setup to maintenance and cleaning. This course introduces the general layout and equipment used within a pharmaceutical or medical device manufacturing plant. Topics in this course include: Facilities, Cleanliness, Process Flow, Equipment, Maintenance, Calibration, and Cleaning. After completing this course, you will recognize the importance of Good Manufacturing Practices and you will be able to identify the requirements that specifically apply to facilities and equipment.

Languages Available:

German (PHDV63)
 French (European) (PHDV63)
 Japanese (PHDV63)
 Spanish (Spain) (PHDV63)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- Maintenance and Facilities

Content Bundles:

- Medical Device - GMP
- Maintenance and Facilities - Basics

Understanding Post-Approval Changes

PHA49

FDA has made a number of recent changes to its regulations concerning post-approval manufacturing changes for drug products. This course covers categories of post-approval changes (PAC), the requirements for each, and PAC guidance. Topics in this course include: SUPAC, Components and Composition, Site of Manufacture, Scale of Manufacture, and Manufacturing. After completing this course, learners will be able to recognize the requirements related to PAC and FDA guidance for those requirements.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- Pharmaceutical GMP Basics

Understanding the Principles and Practices of Process Controls

PHA47

Recently FDA has become increasingly concerned with the number of Warning Letters being issued due to problems with the control of manufacturing processes. Items listed in these various Warning Letters include lack of validation of manufacturing processes, lack of written procedures, improper sampling and testing of materials, and failure to follow written procedures. This course provides an understanding of what process control is. You will also learn about the written procedures involved in validation, how equipment affects process controls, batch production records, correct sampling and testing methods, proper reprocessing techniques, contamination control, change control, and process analytical technology.

Languages Available:

Japanese (PHA47)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- Production and Process Controls
- Computer Systems Validation

Content Bundles:

- Pharmaceutical - GMP

US Trade Controls

ETHICS27

US trade control regulations are designed to control access to US products and information that could be misused in ways that are contrary to US interests. This course covers the scope and contents of those regulations. Topics in this course include: Trade Control, Regulatory Environment, Item and Classification, Destination, Receiving Party, High-Risk Factors, Boycotts, End Use, Export License, and Documentation and Disclosure. After completing this course, learners will be able to recognize potential US trade control violations and identify ways to find help.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Ethics & Corporate Responsibility

Using Electrical Safety Programs (US)

PS5-00207

Electricity can kill. That is why NFPA 70E® was created. It requires employers to develop and implement an electrical safety program. This course explains basic electrical safety practices that apply to electrical work. These practices include wearing personal protective equipment and completing arc-flash hazard analyses. Ideal learners include people in all industries, particularly supervisors, electrical maintenance and installation workers, and safety managers.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Languages Available:

French (Canadian)
Portuguese (Brazil)
Spanish (Latin America)
English
Chinese (Simplified)
Czech
Dutch
French (European)
German
Japanese
Polish
Thai

Validation of Analytical Laboratory Procedures

ICHreg04

This course introduces developers and those individuals involved in validation of analytical methods to the regulatory requirements for the validation of analytical laboratory procedures. Topics in this course include: Validation Characteristics, Specificity, Linearity and Range, Accuracy and Precision, Detection/Quantitation, Robustness, and Revalidation. After completing this course, learners will be able to identify applicable regulatory requirements and recognize the important aspects of analytical methods validation, including the data that must be generated.

Format: eLearning - EduFlex, eLearning - SCORM

Libraries:

- Global Regulatory

Functional Areas:

- ICH: Quality Management

Violence in the Workplace

LAV11

Disputes between employees, or between employees and their supervisors, are not unusual in a stressful workplace environment. Occasionally, conflicts may escalate into heated exchanges or even a physical confrontation. Every year, a handful of cases involve extreme violence, including the use of firearms, and result in severe injuries or the tragic loss of life. After completing this course, participants will know how to identify individuals prone to violent behavior and apply proven techniques to diffuse dangerous situations.

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Libraries:

- Ethics & Corporate Responsibility
- HR Compliance & Risk Management

Functional Areas:

- HR Compliance

Walking/Working Surfaces

PS5-01378

Slips, trips and falls remain one of the most common causes of employee injury in the workplace. Understanding the actions you can take to prevent these incidents will pay off in the long run by keeping you safe and cutting down on expenses. This course provides a clear understanding of the general requirements for the OSHA standard on walking and working surfaces. Ideal learners are all employees.

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Languages Available:

Czech
Dutch
German
Japanese
Polish
Portuguese (Brazil)
Spanish (Latin America)
Thai

Welding, Cutting and Brazing

PS5-01400

Welding, cutting, brazing and other hot work are common, and inherently dangerous, activities on many jobsites. Care must be taken to ensure that work is performed safely. This course introduces common hazards associated with welding, cutting and brazing and ways to prevent injury and damage. Ideal learners are workers who perform welding, cutting and brazing.

Languages Available:
Portuguese (Brazil)
Spanish (Latin America)

Format: eLearning - PS5

Libraries:

- EHS for Life Science - Basics

Writing and Reviewing SOPs

PHA48

Manufacturing facilities rely on Standard Operating Procedures (SOPs) to establish controlled manufacturing processes for quality products. This course identifies the principles and practices applicable to written SOPs. Topics in this course include GMP Requirements, Elements of SOPs, Review & Approval, and Document Control. After completing this course, learners will be able to recognize the different types of SOPs and methods for developing them. Learners will also be able to identify the appropriate measures for document control.

Languages Available:
Spanish (Latin America) (PHA48)
German (PHA48)
French (European) (PHA48)
Chinese (Simplified) (PHA48)
Japanese (PHA48)

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- Pharmaceutical GMP Basics

Writing Validation Protocols

PHA51

This course is an introduction to the importance and content of the documentation that comprises validation. Topics in this course include: Validation, Documentation, and Elements. After completing this course, you will be able to identify validation protocols and the three types of qualifications. You will also be able to recognize the key elements involved in writing a validation protocol.

Languages Available:
Chinese (Simplified)
Japanese

Format: eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

Partners: FDA

Libraries:

- Medical Device GMPs
- Pharmaceutical GMPs

Functional Areas:

- Computer Systems Validation

Content Bundles:

- Computer Systems Validation



About UL PURE™ Learning

Since 1980, UL PURE™ Learning has been providing computer-based instruction, compliance management solutions, and advisory services to corporate and government customers with a strong focus on the needs of Life Sciences, Health Care, Energy, and Industrial sectors.

Our unique partnership with the FDA provides online training tools to train and certify more than 36,000 federal, state, local and global investigators in the areas of quality and compliance. UL and the FDA jointly develop content and deliver it via ComplianceWire®, our award-winning learning and performance platform.

UL is a premier global independent safety science company that has championed progress for 120 years. More than 12,000 professionals are guided by the UL mission to promote safe working and living environments for all people.