LIBRARY GUIDE:
Medical Device GMPs

Table of Contents

Course Descriptions:

LEGEND:

FDA CRADA symbol indicates that the content for this course was provided by the US FDA as a result of a CRADA between the FDA and UL.

Course is available in one or more foreign languages. Download Language Options for a Global Workforce for details.

Learners have the option to take this course via a mobile device, such as an iPad.

Overview:

GMPs: Medical Device

Profitability rests on product quality, operational efficiency and regulatory compliance. The common denominator of those objectives is the ability of employees – regardless of business function or physical location – to apply the right knowledge needed at the right time to fulfill their job responsibilities.

UL EduNeering's systemic approach to employee learning has created a Medical Device Good Manufacturing Practices (GMP) curriculum that focuses on the specialized knowledge needs of individual business functions within the Medical Device industry. Beginning with the core knowledge typically needed by new hires and reassigned workers, to the more advanced needs of managers and supervisors, UL's courses target the function-specific needs of the entire organization. UL's Medical Device GMP curriculum provides progressive training for such job functions as:

- Manufacturing and Packaging
- Production
- Maintenance and Facilities
- Warehousing and Distribution
- Quality Control Laboratories
- Quality Assurance (compliance, quality systems, validation)

FDA Partnership

ULs Cooperative Research and Development Agreement (CRADA) with the FDA has enabled the FDA to meet its significant training and documentation challenge – and also resulted in course content provided or reviewed and used by the FDA itself and available to FDA-regulated Life Science companies, all delivered in a valid and 21 CFR Part 11-compliant environment. The CRADA solution, which is available exclusively to UL's Life Science customers, provides the same level of preparedness and learning on which the FDA relies. The CRADA was recently extended through 2019 and expanded to include new technologies.

When the **FDA CRADA** symbol appears within the course description, it indicates that the content for the course was provided by the US Food and Drug Administration as a result of a CRADA between the FDA and UL.

Regular Content Updates

Regulatory agencies and related information sources are continually monitored, analyzed and incorporated into course updates or new courses. Most recently, UL released seven new courses and 31 updated courses to accommodate regulatory changes.

Driving Employee Comprehension

UL's innovative solution, deployed over the web, enables our customers to cost effectively drive employee comprehension through a combination of advanced learning methods, technology innovations and interactive techniques that engage the learner and promote learning that is integrated into new behaviors. Those new behaviors in turn lead to improved worker performance, greater efficiencies and regulatory compliance.

Compliance Learning for the Medical Device Enterprise

The UL Platform enables customers to cost-effectively manage their expanding knowledge expectations of employees and the supply chain (vendors, suppliers, contractors, etc). This web-based platform includes the CFR 21 Part 11-compliant ComplianceWire® Learning Management System (LMS) to deliver, measure, document and track our Medical Device GMP Library, which includes content provided or reviewed by the FDA, as well as other critical organization-created training items, such as Standard Operating Procedures (SOPs) and classroom events which can be recorded with validated e-signature procedures.

The Platform also leverages UL's proprietary assessment tools to help assure supervisors and compliance officers that learners have retained the right knowledge to perform a specific job function.

Optionally, UL works with customers to identify the essential job competencies required for each position within the organization and to 'map' those competencies to a comprehensive plan. All these components, working in concert, enable a customer to efficiently and effectively bridge the knowledge gap, thereby creating optimal performance and fewer compliance exposures.

The end result is a more knowledgeable, productive and effective organization, which delivers bottom-line improvements through improved manufacturing quality and compliance with regulatory requirements.

Courses Listed by Functional Area:

GMP Basics

R&D/Design Controls

Validation and Part 11 Compliance

Production and Process Controls

Maintenance and Facilities

Packaging, Warehousing and Distribution

QC Laboratories

QA Compliance

Inspections

Quality Systems

QSR Advanced Library

Computer Systems Validation Fundamentals

Corrective and Preventive Actions (CAPA)

Regulatory

QSR Basic Library:

Combination Products

Course Descriptions:

Listed Alphabetically

A Guide to ISO 13485 – The Quality Management System for Medical Devices (DEV50)

This course is designed to describe the basic requirements for ISO 13485 – the international quality management system 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 include:

- Process Approach
- Quality Management
- Management's Role
- Managing Resources
- Planning
- Design and Purchasing
- Production
- Monitoring and Analysis

A Step-by-Step Approach to Process Validation (PHDV79)

Using a sample product to demonstrate the "nuts and bolts" of process validation, this program outlines the important tasks performed during each phase of the validation lifecycle. You'll learn what type of information should (and should not) be included in validation documents and why processes must be monitored once they are validated.

Prerequisite:

- Key Concepts of Process Validation

Topics include:

- Tasks commonly executed during the Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ)
- Process monitoring
- Detection and response to variation in processes
- Revalidation
- Validation documentation

Note: A basic understanding of the principles of process validation is recommended.

A Tour of the FDA (PHDV60)

FDA-regulated industries must work closely with the FDA to comply with industry regulations and create safe and effective products. But how well do your employees know the FDA? "A Tour of the FDA" serves as an excellent introduction to its organizational structure and gives an overview of the different enforcement actions available to this critical Agency.

Take a virtual 'tour' of the FDA, learning about the function of each Center along the way. Afterwards, explore different actions the Agency may take in order to achieve compliance.

Topics include:

- FDA background
- The organizational structure of the FDA
- Office of the Commissioner
- Office of Regional Affairs
- The six main program Centers
- Enforcement actions:
  - Informal enforcement
  - Formal enforcement

An Introduction to ISO 13485 – The Quality Management System for Medical Devices (DEV48)

In this course, you will be able to identify why ISO 13485 is different from other quality system regulations and recognize management's role in its implementation. You will also be able to recognize the main clauses of ISO 13485:2003 and why they are critical in terms of an overall quality system. Lastly, you will be able to identify how to prepare to implement ISO 13485:2003.

Topics include:

- Process Approach
- Preparation
- Clauses in ISO 13485

Application of GMPs to Analytical Laboratories (PHDV78)

In this course, you will review the specific requirements of Good Manufacturing Practices, or GMPs, as they apply to Analytical Laboratories. It is crucial to understand the impact that GMPs have on everyday laboratory practices. Compliance with GMP requirements is essential in order to create products that are both safe and effective.

Topics include:

- Control of laboratory documents
- Specific aspects of day-to-day laboratory practices
- Requirements for collecting and maintaining raw data
- Method validation and method verification
- Calibration requirements for laboratory instruments
- Training practices required by GMPs
- Proper handling of Out-of-Specification (OOS) results
- GMP requirements for computer systems

Approach to Computerized Systems Validation and Compliance (ISPE02)

FDA CRADA

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 regulations. It outlines the kind of organization, policies, procedures and plans the 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.

Prerequisite:

- Requirements for Computerized Systems Validation and Compliance

Topics include:

- Description of a suitable framework for successful validation and compliance
- Planning and reporting requirements for computerized systems validation
- Selecting a validation strategy
- Ongoing activities that the user firm should perform to ensure continuing compliance

Batch Record Reviews (PHA53)

This course defines batch records and describes how to properly perform a batch record review. The course also covers the current Good Manufacturing Practices (cGMP) requirements for batch records and addresses how to maintain cGMP compliance throughout the review process.

After completing this course, you will be able to define batch records and understand the purpose of reviews. You will be able to explain the key elements and reasons for organized batch records and list many of the key components. You will also be able to identify the elements of compliance and completeness for batch records. Finally, you will understand the scientific and compliance reasoning behind product disposition decisions for many common product and process deviations and documentation of these decisions.

Topics include:

- Definition of a batch record review
- General documentation requirements for cGMP-compliant batch records
- Organizing a batch record review
- Key elements of reviewing manufacturing records
- Components of packaging record reviews
- Reviewing laboratory data
- Review issues
- Batch disposition

Care and Handling of Drug Product Components, Labeling, Containers and Closures (PHA41)

This lesson is designed to introduce the learner to those practices that control the handling and testing of drug product components, containers and closures while meeting requirements set forth in Good Manufacturing Practices (GMP) regulations. The learner is introduced to these key concepts by observing a tour of a modern drug manufacturing facility. Proper procedures for the receipt, sampling, storage, testing and recordkeeping of drug product components, containers and closures are covered in detail in this lesson.

Topics include:

- Definitions of components, containers and closures
- Impact of components, containers and closures on drug product safety, purity and effectiveness
- Receipt, storage, sampling and testing of components, containers and closures
- Documentation and records
- The relationship of components, containers and closures to stability and reserve sample programs

cGMP's for Combination Products (PHDV93)

After completing this course, you will be able to recognize the four different types of combination products. You will understand the scope of the new regulation in 21 CFR Part 4, and how to comply with each of the drug, device, and biological product provisions. You will understand the role of the Office of Combination Products (OCP), how post-marketing modifications are made, and how to report post-marketing adverse events.

Topics include:

- Background
- inal Rule
- Meeting compliance
- The Office of Combination Products
- Post-approval modifications

Change Control (PHA35)

In this program, the concept of change control is presented in a way that places the learner in the role of a change control manager. Throughout the program, participants will learn how to state the key elements of a change control program, identify key indicators of change and learn the regulatory requirements for change control. The program also defines how to identify the groups involved in change control and ways to describe the impact of change on product, process and people.

Topics include:

- The regulatory requirements for change control
- Steps in the basic model of change control
- Indicators of an improper change
- Elements of change control
- FDA notification

Complaint Management for Medical Device Manufacturers (DEV46)

This course will educate the learner about the importance of properly responding to reports of alleged medical device problems. The learner will be able to apply the knowledge acquired to handle complaint events in a manner that is compliant with FDA regulations.

Topics include:

- The FDA's definition of a complaint
- Effective complaint handling systems, including Corrective and Preventative Actions (CAPA)
- Complaint file maintenance
- Investigating a complaint
- Requirements of the Medical Device Reporting (MDR) regulation
- Analysis of complaint data

Computerized Systems Inspections in the Medical Device Industry (ISPE04)

This course, the third in a series, has been designed by ISPE and UL, Inc. in cooperation with the FDA/ORA, to assist FDA inspectors in recognizing the critical aspects of computerized systems in the Medical Device industry. The 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.

Prerequisite:

- Requirements for Computerized Systems Validation and Compliance
- Approach to Computerized Systems Validation and Compliance

Topics include:

- How computerized systems are used in the Medical Device industry
- How an investigator should approach computerized systems
- The focus of the investigator's review

Conducting Annual Product Reviews (PHA45)

This course identifies the regulatory requirements and contents of an Annual Product Review (APR) as well as the possible benefits that a good APR program can yield.

Topics include:

- Annual Product Review (APR)
- Benefits of APRs
- Key components of the APR Standard Operating Procedures (SOP)

Design Control Regulations for Medical Device Manufacturers (DEV40)

This course introduces the learner to FDA design control regulations by providing basic information about the key procedures followed during the design and development of a product. The design plan requires documentation of training, planning validation, design transfer and changes, formal review, a design history file and human factors.

Topics include:

- What are design control regulations?
- What is a design and development plan?
- What is design input?
- What is design output?
- What is design review?
- What is the purpose of design verification?
- What is the purpose of design validation?
- What is design transfer?
- How is design change control achieved?

Documenting Validation Activities (PHA55)

The process of validation in an FDA-regulated industry is important to gain FDA acceptance. Every step of a particular process must be documented with written procedures and validated with evidence. The key to successful validation is the understanding that it must be documented. The FDA issues Warning Letters to manufacturers that have inadequate validation activities. These observations are considered to be violations of Good Manufacturing Practices (GMP) regulations and not violations of validation. This course provides the learner with an overview of the types of documentation that are at the core of sound validation programs. The learner is introduced to the primary documents of validation, as well as the documentation requirements for equipment, materials, processes, products and personnel.

Topics include:

- Items that must be validated as specified by GMP requirements
- Validation documents requirements
- Equipment validation
- Proper documentation of materials
- Process documentation
- Documentation of procedures involving personnel

EU Medical Device Directive Part I: Introduction (MDD01)

The European Union (EU)'s Medical Device Directive (MDD) serves as the basis for the authorization to sell medical devices in the EU market. Every employee needs to become familiar with the rules developed by regulatory authorities to keep the market flowing while maintaining accountability for Medical Device manufacturers.

This training course provides basic components of the EU Medical Device Directive, as well as the definitions and classifications that describe the devices that fall under the Directive.

Topics include:

- History and Approaches
- Quality System: Learn the eight elements of the quality system, as defined in the Directive
- Classes of Medical Devices: Learn more about the 18 rules described in Directive 92/43/EEC Annex IX

EU Medical Device Directive Part II: Specific Procedures (MDD02)

The European Union (EU)'s Medical Device Directive serves as the basis for the authorization to sell medical devices in the EU market. This training course provides specific information regarding the EU Medical Device Directive and Council of Europe (CE) marking of medical devices, including how to assess conformity with the MDD, how to document conformity as well as incidents and events and how to conduct post-market research and follow-up.

Topics include:

- Conformity Assessment: How to determine in which class a device belongs
- Clinical Evaluation: Definition and clinical data requirements
- Technical File: What must be documented, including description, specifications, standards, etc.
- Risk Management: Based on EN ISO 14971, what the risk management process should include, including analysis, evaluation, control and post-production information
- Post-Market Surveillance (PMS): What manufacturers should consider before establishing and operating a PMS system
- Follow-Up: Criteria to consider before establishing Post-Market Clinical Follow-up (PMCF)

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. If an FDA inspection yields any Good Manufacturing Practices (GMP) compliance concerns or faults during the inspection, it is required to fill out a report immediately. It is important to understand the purpose and scope of both FDA 483s and Warning Letters so as to be able to respond to them quickly and effectively. After completing this course, you will understand the basic principles of FDA 483s and their use and the use of Warning Letters. In addition, you will recognize the significance of both these documents. You will also be able to describe the key aspects of written responses to both FDA 483s and Warning Letters.

Topics include:

- FDA 483s
- Responding to FDA 483s
- Purpose and scope of Warning Letters
- Responding to Warning Letters
- Avoiding mistakes when responding

Environmental Control and Monitoring (PHDV87)

Many important components and controls are necessary to assure high-quality pharmaceutical or medical device products — two of the most important are environmental control and environmental monitoring. Environmental control and monitoring go hand-in-hand. Together, they help to create and maintain a manufacturing environment that will prevent product contamination. This course examines the establishment of environmental control elements in the design of Good Manufacturing Practices (GMP) operations and the monitoring necessary to assure proper function. It will review the importance of maintaining an acceptable manufacturing environment, including control parameters and related regulatory requirements.

Topics include:

- An introduction to environmental control and monitoring
- Components of effective environmental control
- Facility and equipment design that assure environmental control
- Personnel practices that ensure effective environmental control
- Cleaning methods to ensure effective environmental control
- Necessary contents of the environmental monitoring Standard Operating Procedure (SOP)

Essentials of an Effective Calibration Program (PHDV75)

FDA CRADA

Injuries, fatalities, or major class action suits filed against a manufacturer can result when products are produced with out-of-calibration equipment. When lives are at stake and a company's reputation is in the balance, equipment must always be operating to its precise specifications. This course is designed to help the learner identify the key concepts of calibration and recognize the importance of calibration reference standards and Good Manufacturing Practices (GMP) calibration requirements in order to ensure an effective calibration program.

Topics include:

- Calibration
- Calibration standards
- GMP requirements for the calibration program
- Essential elements for a calibration program

Failure Investigations for Medical Device Manufacturers (DEV45)

This course will explore what a failure is, the regulatory and practical aspects of investigations and the elements that make these investigations effective. It will also provide guidance on conducting a comprehensive investigation and on developing corrective actions that prevent future recurrences. Product or process failures are often unavoidable events encountered in Medical Device manufacturing. How you handle these failures, however, can be significant in your ability to maintain a state of control in operations and prevent future failures. The success of a failure investigation can often be tied to whether the investigation was comprehensive enough to actually identify the root cause of the event.

After completing this course, you will be able to recognize the basic definition of failures. You will be able to identify when a failure investigation should occur and the documentation required. You will also be able to describe the basic elements of a comprehensive failure investigation and the steps for management review and follow-up.

Topics include:

- Medical device product failure and GMP requirements
- Failure investigations
- Identifying the root cause of a failure
- Corrective and Preventive Actions (CAPA)
- Follow up on the CAPA
- Documenting and communicating failures, investigations and CAPA

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 will address the measures required to stay in compliance with FDA regulations and the requirements needed to implement an effective training and qualification program.

This course will identify FDA requirements concerning training and qualification, responsibilities of personnel, records that need to be maintained and how to measure training and qualification.

Topics include:

- Personnel training and qualification
- Who is responsible for personnel training and qualification
- Requirements for the training and qualification system
- Specific requirements for training
- Specific requirements for personnel qualification
- Metrics used to measure training and qualifications

Global Regulatory Strategy and Planning Process (DEV54)

This course is about 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.

GMP Principles for Batch Records (PHA60)

Pharmaceutical batch records are essential to ensuring that regulatory and product quality attributes are achieved. In this course you will explore the required components of batch records and the importance of carefully documenting the information generated during the manufacturing, packaging and in-process testing of pharmaceutical products. This course is intended for manufacturing and packaging operators who perform functions directly related to producing a batch of material or product and who record critical data on batch records.

Topics include:

- Batch records
- FDA requirements for current Good Manufacturing Practices (cGMP)-compliant batch records
- Manufacturing records
- Packaging batch records
- Deviations
- Batch record review

GMP Principles of SOPs (PHA64)

This course reviews the principles of Standard Operating Procedures (SOP) for an FDA-regulated environment and provides employees with a working knowledge of what SOPs are, their purpose, how they are structured, information provided, change control and how SOPs are used in the workplace. After completing this course, you will be able to recognize how to handle changes to SOPs, as well as how SOPs are used in the workplace.

Topics include:

- What are SOPs
- What information is contained in a SOP
- Change control
- Implementation of SOPs in the workplace

GMP Updates – Enforcement Changes at the New FDA (PHDV91)

FDA CRADA

After completing this course, you will be familiar with the significant changes coming to the FDA in its stepped up emphasis on inspections, warning letters, enforcement, and follow up. You will learn about the challenges facing FDA and the industry with outsourcing manufacturing, and you will also learn about what companies can do to prepare for the coming changes.

Topics include:

- Current Environment
- Enforcement Model
- Expectations
- Supply Chain
- Supplier Monitoring
- Prevention
- Future

GMPs for API Bulk Manufacturers (PHA52)

The Food, Drug and Cosmetic Act (FD&C) requires Active Pharmaceutical Ingredients (APIs) to be manufactured in accordance with current Good Manufacturing Practices (cGMPs) yet there are no specific regulations in 21 CFR for APIs like there are for drug products. The FDA is proposing regulations, however that are not yet final. This course is about the basic concepts of GMPs and how they can be applied to the manufacture of APIs.

Topics include:

- cGMP requirements for API manufacturing personnel
- GMP requirements for buildings and facilities
- cGMP requirements for manufacturing equipment
- Requirements for materials and packaging components
- Process controls for APIs
- Laboratory controls for APIs
- Recordkeeping requirements

Gowning for Sterile Manufacturing (PHA63)

FDA CRADA

In this course you will learn how to identify important sources and types of contamination in a manufacturing environment, recognize the importance of health issues and personal hygiene and describe the staged entry and use of cleanrooms. You will also be able to identify important practices and procedures for proper gowning.

Prerequisite:

- Principles of Aseptic Processing
- Principles of Sterilization.

Topics include:

- Why gowning is important
- Types of contamination
- Preparation in gowning rooms
- Gowning basics and procedures

Handling a Product Recall (PHDV64)

FDA CRADA

Companies undergo product recalls for various problems; it could happen to any company. A product recall is probably the most difficult and stressful situation that can be encountered in the Medical Device industry. Because a product recall can be critical, you need to understand what it is and how to handle it.

This lesson defines product recalls and explains their impact on the manufacturer, FDA requirements and enforcement when dealing with a product recall and the basic steps for handling a recall.

Topics include:

- Product recalls
- Steps in conducting a recall
- Roles and responsibilities during product recall
- Effect of a recall on a company
- Who a company must communicate with during a recall

Handling an FDA Inspection (PHDV74)

FDA CRADA

This course reviews the basics of handling an FDA inspection of a Pharmaceutical and Medical Device manufacturing facility. The course will clarify the roles and responsibilities of personnel during an inspection with an emphasis on being prepared and maintaining a positive, professional relationship with the FDA.

Topics include:

- Personnel Conduct
- Inspection Types
- The Process
- Records
- Samples and Photos
- Enforcement
- End of Inspection

High Purity Water Systems (PHDV82)

Water is one of the most important materials used in the manufacturing of pharmaceutical and medical device products. Because water quality can directly impact product quality, Good Manufacturing Practices (GMP) regulations require that water receive the same scrutiny, monitoring and control as any other critical raw material used in manufacturing processes. As a result, FDA investigators commonly cite manufacturing firms for their failure to assure the quality of the water in use.

After completing this course, you will be able to identify the typical uses of water in pharmaceutical and medical device manufacturing. You will also be able to recognize the general process for producing high-quality water, various approaches for monitoring a water system and possible methods of solving water system problems.

Topics include:

- Defining high purity water
- Types or qualities of water
- Determining the quality of required water
- Steps for producing WFI water
- Monitoring high purity water systems
- Monitoring approaches
- Water system problems
- Correcting water system problems

Regulatory References:
FDA "Guide to Inspections of High Purity Water Systems," July 1993
21 CFR Parts 211 and 820

Implementing an Equipment Qualification Program (PHDV88)

Equipment qualification serves as the foundation for several currently recognized Health Care industry compliance requirements, such as analytical method, process, cleaning and automated systems validation. A well-developed and established equipment qualification program allows a company to meet current Good Manufacturing Practices (GMP) requirements and save operational costs at the same time. This course is designed to provide an introductory overview of the equipment qualification requirements that apply to the Pharmaceutical, Biotechnology and Medical Device industries.

After completing this course, you will be able to define equipment qualification, identify the importance of equipment qualification, recognize the GMP requirements in this area and identify the steps that must be followed in order to successfully implement equipment qualification.

Topics include:

- Importance of equipment qualification
- Equipment qualification protocol
- Design Qualification (DQ)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Legacy Equipment Qualification (LEQ)

Introduction to Good Manufacturing Practices (GMPs) (PHA38)

This interactive program introduces Good Manufacturing Practices (GMP) and the current regulations that pharmaceutical manufacturers must follow. It highlights employee responsibilities and the role of FDA and the Food, Drug & Cosmetic Act. Examples of GMPs are included.

Topics include:

- What are GMPs?
- What GMP requirements apply to basic procedures?
- What are the GMP requirements for documentation?
- What are your responsibilities?
- How can you control contamination?

Introduction to Quality System Regulations (QSRs) (DEV43)

Employees play an active part in ensuring the quality of the product. This interactive program provides employees with an overview of the FDA's current Quality Systems Regulation (QSR) for medical devices. Mastery of these concepts will provide employees with a good understanding of how the QSR affects operations in manufacturing facilities. This program emphasizes the elements of a Quality System that help to ensure products are safe and effective and that manufacturing operations are compliant with current medical device Good Manufacturing Practice (GMP).

Topics include:

- Management responsibilities
- Design controls
- Document controls
- Process controls
- Purchasing controls
- Corrective and preventive actions
- Device labeling and packaging procedures
- Training

Key Concepts of Process Validation (PHDV77)

Through the use of interactive examples focused on producing a fictitious product, this program will outline the actual activities that take place before, during and following the validation of a process. Throughout the program you will learn terminology and concepts related to the validation of manufacturing processes, the regulatory requirements for process validation and validation approaches. A validation lifecycle model is used to explain the major elements of validation and how they relate to one another. After completing this course, you will be familiar with applicable regulatory requirements and other important aspects of process validation. The validation lifecycle, which lays out the steps to effective process validation, will also be introduced.

Topics include:

- Why processes are validated
- Process validation vs. verification
- Types of processes that must be validated
- Common approaches to validation
- The validation lifecycle

Note: This program serves as a prerequisite for A Step-By-Step Approach to Process Validation.

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 (QSR).

Prerequisites:

A basic understanding of QSRs for Medical Device and Equipment manufacturers (21 CFR 820), quality control procedures and quality principles.

Topics include:

- What is medical device labeling?
- Safe and effective labeling and misbranding
- Label control
- Proper packaging procedures
- Distribution requirements for devices

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 Good Manufacturing Practice (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 lesson, 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.

Topics include:

- GMP training requirements
- Types of GMP training
- Approaches to GMP training
- Training verification

Orientation to GMP Compliance (PHDV73)

Many people, including those who work in the Pharmaceutical and Medical Device industries, find regulations confusing. Because FDA regulations have a direct impact on how you do your job, this interactive program is designed to take the mystery out of these regulations by giving you insight on how they are applied and interpreted. You will better understand how the FDA and your own company's compliance professionals interpret and apply these important regulations.

Upon completion of this lesson you will be able to explain how the Food, Drug and Cosmetic Act (FD&C) are tied to the Code of Federal Regulations Title 21 and how the GMPs are key elements in those regulations. In addition, you will understand how various FDA publications aid in interpreting and determining their expectations in regards to these regulations.

Topics Include:

- Definition
- Goal
- Interpretation
- Enforcement

Pre- and Post-Approval FDA Inspections (PHDV66)

This lesson explores pre- and post-approval FDA inspections. The purpose and focus of each type of inspection is discussed with the key inspectional targets. For Pre-Approval Inspections, the discussion focuses on the process and documentation related to demonstrating equivalence of the bio-clinical batches, raw materials, manufacturing process, finished product and general Good Manufacturing Practice (GMP) compliance. For post-approval inspection, the discussion focuses on general GMP compliance issues. The various inspection outcomes are also covered.

Because all FDA-regulated facilities will undoubtedly be subject to an 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 and reasons for between pre- and post-approval FDA inspections.

Topics include:
- Pre-approval inspections
- Focus of Pre- and Post-Approval Inspections (PAIs)
- Post-approval inspections
- Reasons for post-approval inspections
- Possible FDA inspection outcomes

Principles of Auditing (PHDV69)

FDA CRADA

This program focuses on the purpose and conduct of internal and external quality audits. It discusses the purpose of conducting audits and focuses on the benefits to be derived if audits are conducted properly. It begins with a discussion on establishing an audit program to achieve internal Good Manufacturing Practice (GMP) compliance. The lesson is on the actual preparation, conduct and follow-up associated with an internal audit. The importance of establishing corrective action and follow-up and how these aspects of the audit program can yield opportunities and quality improvements will be illustrated.

At the conclusion of this program, you will be able to discuss 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.

Topics include:
- Audits
- Types of audits
- Benefits of performing an audit
- Preparing for an audit
- Performing an audit
- Audit closeout

Principles of Good Documentation (PHDV65)

Documentation is an important aspect of Good Manufacturing Practices (GMPS) . This course provides an overview of the importance of documentation,
batch records, procedures and testing throughout the manufacturing process.

Topics include:
- Good documentation practices
- Documenting weights
- Documents required by GMPs
- Proper documentation within a batch production record
- Documenting laboratory and inspection records

Principles of Sterilization (PHDV81)

This course discusses the basic principles of several commonly used sterilization techniques: moist-heat, dry-heat, gas, radiation, chemical, and filtration. It also provides an introduction to the microbiology involved in producing a sterile product. Finally, the key aspects of sterility assurance are discussed.

Topics include:

- Overview Principles of Sterilization
- Definition What is sterilization?
- What is moist-heat sterilization?
- What is dry-heat sterilization?
- How is gas used to sterilize materials?
- What is radiation sterilization?
- ChemiWhat is chemical sterilization?
- How is filtration used as a method of sterilization?
- How do you verify sterility?

QS Regulation 1: Overview and General Provisions (QSR01)

This course introduces the Quality System Regulation (QSR) (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.

QS Regulation 2: Quality System Requirements (QSR02)

The second in a series of Quality System Regulation (QSR) courses, it focuses on the management responsibility, quality auditing and personnel requirements of 21 CFR Part 820, Subpart B. The QSR provides a framework of basic requirements for manufacturers of finished medical devices.

Prerequisite:

- QS Regulation 1: Overview and General Provisions

QS Regulation 3: Design Controls (QSR03)

The third in a series of Quality System Regulation (QSR) courses, it addresses design control requirements of the QSR.

Prerequisite:

- QS Regulation 1: Overview and General Provisions
- QS Regulation 2: Quality System Requirements

QS Regulation 4: Document and Purchasing Controls (QSR04)

FDA CRADA

The fourth in a series of Quality System Regulation (QSR) courses, it 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 QSR provides a framework of basic requirements for manufacturers of finished medical devices.

Prerequisite:
- QS Regulation 1: Overview and General Provisions
- QS Regulation 2: Quality System Requirements
- QS Regulation 3: Design Controls

QS Regulation 5: Identification and Traceability; Production and Process Controls (QSR05)

FDA CRADA

The fifth in a series of Quality System Regulation (QSR) courses, it focuses on Identification and Traceability (21 CFR Part 820, Subpart F) and Production and Process Controls (21 CFR Part 820 Subpart G). The QSR provides a framework of basic requirements for manufacturers of finished medical devices.

The purpose of the Production and Process Controls requirements of the QSR (21 CFR 820.70, 21 CFR 820.72, 21 CFR 820.75) is to ensure that manufacturers produce devices that conform to their specifications. Where any deviations from specifications could occur during manufacturing, process control procedures must describe the controls necessary to ensure the devices will conform to their specifications. Process control procedures also help to ensure consistency in manufacturing.

After completing this course, you will be familiar with a manufacturer's responsibilities relative to the identification, traceability, production and process control requirements of the QSR.

Prerequisite:
- Learners should have completed QS Regulation courses 1-4.

QS Regulation 6: Acceptance Activities; Nonconforming Product (QSR06)

FDA CRADA

The sixth in a series of Quality System Regulation (QSR) courses, it 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.

Prerequisite:
- Learners should have completed QS Regulation courses 1-5.

QS Regulation 7: Corrective and Preventive Action (QSR07)

FDA CRADA

The seventh in a series of Quality System Regulation (QSR) courses, it focuses on Corrective and Preventive Action (21 CFR Part 820 Subpart J). The QSR provides a framework of basic requirements for manufacturers of finished medical devices. The intent of 21 CFR 820.100 is to correct or prevent poor practices, not simply to correct or prevent bad product. Correction and prevention of unacceptable quality system practices should result in fewer nonconformities related to product.

Compliance with the corrective and preventive action requirements of the QSR will allow a firm to monitor, identify and react to existing product and quality system problems, as well as indicators of potential problems. These activities will help manufacturers identify opportunities to improve their products and quality system, as well as protect consumers by initiating field actions where necessary. After completing this course, you'll be familiar with a manufacturer's responsibilities relative to the corrective and preventive action requirements of the QSR.

Prerequisite:

- Learners should have completed QS Regulation courses 1-6.

QS Regulation 8: Labeling and Package Control; Handling, Storage, Distribution and Installation (QSR08)

FDA CRADA

This course is the eighth in a series of Quality System Regulation (QSR) courses. It 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 QSR provides a framework of basic requirements for manufacturers of finished medical devices. The requirements of the QSR relative to the handling,storage, distribution and installation of medical devices are intended to help ensure that medical device mixups, damage, deterioration, contamination or other adverse effects do not occur.

After completing this course, you will be familiar with a manufacturer's responsibilities relative to the labeling, packaging control, handling, storage, distribution and installation requirements of the QSR.

Prerequisite:

- Learners should have completed QS Regulation courses 1-7.

Topics include:

- Key Terms
- Label Integrity
- Labeling Operations
- Handling/Storage Areas
- Control and Distribution
- Device Installation

QS Regulation 9: Records (QSR09)

The ninth in a series of Quality System Regulation (QSR) courses, it focuses on Records (21 CFR Part 820 Subpart M). The QSR provides a framework of basic requirements for manufacturers of finished medical devices. One of the basic themes of the Quality System Inspection Technique (QSIT) (used during inspections of Medical Device manufacturers) is the "Establish Test." The QSR requires many procedures to be "established" and defines "establish" as "define, document (in writing or electronically) and implement." Records play a vital role in the FDA's ability to confirm that procedures have been appropriately implemented and, on a broader scope, that an adequate and effective quality system has been established and maintained by the firm being inspected.

After completing this course, you will be familiar with a manufacturer's responsibilities relative to the records requirements of the QSR.

Prerequisite:
- Learners should have completed QS Regulation courses 1-8.

Topics include:
- General Requirements
- Device Master Records
- Device History Records
- Quality System Records
- Complaint Records
- Investigations
- Complaint Unit

QS Regulation 10: Servicing; Statistical Techniques (QSR10)

The 10th in a series of Quality System Regulation (QSR) courses, it focuses on Servicing (21 CFR Part 820 Subpart N) and Statistical Techniques (21 CFR Part 820 Subpart O). The QSR provides a framework of basic requirements for manufacturers of finished medical devices.

Statistical techniques may be employed to fulfill a number of QSR requirements. Where statistical techniques are used, manufacturers must establish procedures for identifying their validity.

After completing this course, you will be familiar with a manufacturer's responsibilities relative to the servicing and statistical techniques requirements of the QSR.

Prerequisite:
- Learners should have completed QS Regulation courses 1-9.

Topics include:
- Key Terms
- Servicing Requirements
- Analysis
- Statistical Techniques

QS Regulation 11: Application and Inspection of QS Regulation (QSR11)

This is the 11th and final course in the series of Quality System Regulation (QSR) courses. The QSR provides a framework of basic requirements for manufacturers of finished medical devices. This course focuses on the application and inspection of QSR requirements within a Medical Device manufacturer's quality system.

During inspections, the FDA will assess whether a manufacturer has established procedures and followed requirements that are appropriate under the current state-of-the-art manufacturing of the specific device.

After completing this course, you will be familiar with the application and interrelationship of QSR requirements within a Medical Device manufacturer's quality system. You will also be familiar with the basic concepts of the Quality System Inspection Technique (QSIT), which is the inspection process currently used by the FDA to conduct Level 2 Baseline (Comprehensive) quality system inspections.

Prerequisite:

• Learners should have completed QS Regulation courses 1-10.

Topics include:

• Key Terms
• Seven Subsystems
• Subsystems and QSIT

Quality System Inspection Technique (QSIT) (DEV42)

Manufacturing companies within the Biomedical industry are subject to routine inspections of their quality systems by the FDA. The FDA investigator(s) audits four major quality subsystems, which include: Management Controls, Design Controls, Corrective and Preventive Actions and Production and Process Controls. Quality System Inspection Technique (QSIT) is a "top-down" approach to evaluating a quality system. You will become familiar with the key objectives that an investigator will address when reviewing each subsystem. The subsystem approach focuses on the elements that are key to meeting the requirements of the Quality System Regulation (QSR).

Topics include:

• Assuring documents are in a state of compliance
• Inspectional Objectives for each subsystem:
  • Management Controls
  • Design Controls
  • Corrective and Preventative Actions (CAPA)
  • Production and Process Controls (P&PC)

Requirements for Computerized Systems Validation and Compliance (ISPE01)

This course 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 the requirement for systems to 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.

Topics include:

• Computerized or automated systems
• Regulations addressing the requirements for validating computerized systems
• Three types of validation
• How software differs from hardware
• Guiding principles for computerized systems validation and compliance
• Installation Qualifications (IQ), Operational Qualifications (OQ) and Performance Qualifications (PQ) as related to computerized systems validation
• FDA expectations for validation activities and documentation

Resolving Out-of-Specification Test Results (PHA50)

Obtaining an Out-of-Specification (OOS) test result can be unsettling and it is important that you know what to do with it. You will learn what the FDA says about handling batch or product samples that indicate OOS results. You will also learn how to evaluate suspect results as well as how to conduct preliminary investigations in response to OOS results.

This lesson will provide you with the information to respond accordingly when an OOS result is encountered. Mastering this content will enable you to know what to look for and what to investigate when an OOS result occurs. It will also explain the cautions involved in handling data that may be related to OOS results, such as re-testing, averaging and outliers.

Topics include:

- OOS test results
- Purpose of a laboratory investigation
- Performing a formal investigation
- Use of averaging
- Outliers
- What is required when an OOS result is determined to be valid

Review of Basic Statistical Techniques (DEV44)

This course will explore the proper use of statistical techniques as they apply to Medical Device manufacturing. More than just a set of mathematical tools, the use of statistics in Medical Device manufacturing is now expected and regulated by the FDA in the Quality System Regulation (QSR), Subpart O, Statistical Techniques.

Topics include:

- Definition
- Data Analysis
- Histograms
- Variability

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. The specific techniques for conducting the gel-clot Lymulus Amebocyte Lusate (LAL) test will be presented, including extensive discussion on standards and controls used. In addition, variations to the gel-clot test will be presented, including the chromogenic and kinetic alternatives along with the advantages and disadvantages of each method.

Topics include:

- Bacterial endotoxins
- Performing the gel-clot LAL test
- Chromogenic LAL assay
- Determining appropriate testing methods

The Approval Process for New Medical Devices (DEV47)

FDA CRADA

This course gives an overall view of the development process for admitting a new medical device into the marketplace. After completing this course, you will be able to list the major steps in new device development. You will also be able to define an IDE and PMA. You will be able to identify the purpose and requirements of clinical studies. In addition you will also be able to recognize key information about the classification of medical devices and the role of the FDA in the approval of medical devices for the marketplace.

Topics include:

- How medical devices are classified
- Approval process
- Investigational Device Exemption (IDE)
- Clinical studies
- Pre-market approval application (PMA)

The Design and Development of Software Used in Automated Process Controls (PHDV80)

Both the Pharmaceutical and Medical Device industries automate their manufacturing processes in order to make them more efficient, accurate and consistent. As a result, the use of computerized systems in the Pharmaceutical and Medical Device industry has become common. This lesson serves as an introduction to the design and development of process-control software.

Compliance requires that manufacturers apply the principles and practices of software quality assurance to automated systems that may ultimately affect product safety and effectiveness. The software development lifecycle is reviewed, including basic verification and validation activities and aspects of software quality assurance, including training and qualification of vendors.

Topics include:

- Automated process controls
- Types of software used to automate processes
- Software requirements
- Design implementation and development
- Software verification and validation
- Final two phases of the software development lifecycle

Understanding GMPs for Facilities and Equipment (PHDV63)

Facilities and equipment Good Manufacturing Practice (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 manufacturing plant.

Topics include:

- GMP regulations
- General GMP requirements for facilities
- Requirements for the cleanliness of facilities
- Design of facilities to promote proper flow
- Equipment requirements and maintenance
- Equipment calibration

Understanding Post-Approval Changes (PHA49)

This course covers the definition and purpose of Post-Approval Changes (PAC). In addition, it explores the four categories of change: Components and Composition, Scale of Manufacture, Site of Manufacture and Manufacturing and the requirements for each level of change.

You will learn about PAC guidance and how these documents are used to provide notification to the FDA for PAC to an approved drug application. You will examine the levels of PAC and the recommended Chemistry, Manufacturing and Control (CMC) requirements for each level. You will also explore the categories of change. Finally, you will be able to identify the tests and documents needed for each level and category of change.

Topics include:

- Defining post-approval changes
- PAC guidance documents
- Scale-Up and Post-Approval Changes (SUPAC) guidance
- Components and composition category
- Site of manufacture category
- Scale of manufacture category
- Manufacturing category

Understanding the Principles and Practices of Process Controls (PHA47)

Recently the 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 and change control.

Topics include:

- Validation
- Equipment's affects on process controls
- Batch production record
- Sampling and testing
- Reprocessing
- Contamination control
- Change control

Vendor Certification for Pharmaceutical Manufacturers (PHDV85)

This course discusses the process of vendor certification — a means of ensuring that a company is receiving the best possible materials, products and services from its vendors or suppliers. This course covers the common practices and concepts associated with vendor certification. After completing this course, you will have a basic understanding of the value and process of vendor certification.

Topics include:

- Vendor certification process
- Criteria for selecting vendors for certification
- Vendor audits and testing

Writing and Reviewing SOPs (PHA48)

If you are directly involved in the manufacture and/or testing of a regulated product, chances are you are familiar with the role Standard Operating Procedures (SOPs) play in helping to establish a controlled manufacturing process. Understanding how SOPs are written and reviewed is an important insight into how quality products are manufactured.

The course outlines the principles and practices applicable to written procedures. You will learn the rationale and GMP requirements for written procedures as well as the different types of procedures and how they are developed. Additionally, by studying a basic model, you will become familiar with the format and content of a procedure.

Topics include:

- Standard Operating Procedure (SOP)
- GMP requirements for SOPs
- Elements of an effective SOP
- SOP design and components
- Review and approval process

Writing Validation Protocols (PHA51)

This course provides the learner with the information that should be included in a validation protocol. The learner is introduced to the key components of the protocol, such as information related to materials, equipment, and acceptance criteria. This course is an introduction to the importance and content of the documentation that comprises validation.

After completing this course, the learner will understand what validation protocols are. The learner will also be able to identify the three types of qualifications, as well as the properties of each qualification. The learner will also be able to describe the key elements involved in a validation protocol.

Topics include:

- What processes or systems require validation?
- What is the basic format of a protocol?
- What should be included in a validation protocol?

About UL EduNeering

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a global independent safety science company offering expertise across five key strategic businesses: Life & Health, Product Safety, Environment, Verification Services and Enterprise Services.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council and the Duke Clinical Research Institute.

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