Life & Health

LIBRARY GUIDE:
Pharmaceutical GMPs

Table of Contents

Courses Listed by Functional Area:

Core Knowledge

Production

Maintenance and Facilities

Warehousing & Distribution

QC Labs

IT Validation

Management/Supervision

R&D/Design Controls

QA – Manufacturing Process

QA – Validation

Inspections

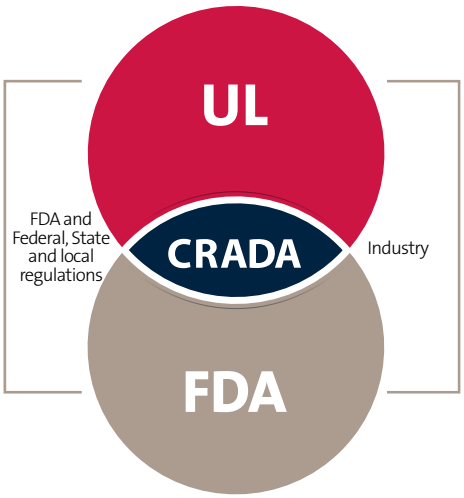
QA – Compliance

QA – Quality Systems

Overview:

UL EduNeering's Good Manufacturing Practices (GMP) Library is designed for professionals in the Biotechnology and Pharmaceutical industries, and is comprised of courses that cover underlying concepts and specific, advanced global information for professionals in regulatory affairs. The global curriculum includes courses describing Food and Drug Administration (FDA) regulations, European Union (EU) directives, and International Conference on Harmonisation (ICH) guidance; many feature course content provided by the FDA.

Content is continually updated to reflect changes in these regulations. Using innovative technology, all content is fully customizable to meet the specific needs of your employees and organization.



FDA Partnership

UL's 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 was recently renewed through 2014 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.

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.

Course Descriptions:

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.
- A basic understanding of the principles of process validation
- is recommended

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

References:
Two Applicable sections of 21 CFR Parts 211 and 820
FDA Guidelines on General Principles of Process Validation
FDA Guide to Inspection "Solid Oral Dosage Forms Pre-/Post-Approval Issues"
FDA Guide to Inspection "Validation of Cleaning Processes"
Process Validation Guidance for Medical Device Manufacturers, Global Harmonization Task Force, Document GHTF.SG3.N99-10, June 1999. SG3

A Tour of the FDA (PHDV60)

FDA CRADA

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 and learn about the function of each Center. 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

Application of GMPs to Analytical Laboratories (PHDV78)

A GMP has a significant effect on what we do in the lab. Even though GMP stands for Good Manufacturing Practice, these regulations also address how analytical labs should operate. A significant percentage of GMP regulations deal with laboratories, sample handling, materials testing, documentation and control of laboratory procedures. These requirements are intended to assure that manufactured products are safe, pure, effective and the correct strength or potency.

After completing this course, you will be able to describe GMP requirements as they apply to Analytical Laboratories, recognise key concepts related to laboratory documents, learn the requirements for laboratory training and gain a basic understanding of laboratory calibration requirements.

Topics include:

- Lab Documents and Lab Practices
- Raw Data
- Method Validation
- Calibration
- Training
- Out-of-Specification (OOS)
- Computer Systems

Application of GMPs to Microbiology Laboratories (PHDV72)

This program addresses the application of GMP principles to microbiology laboratories and discusses the general principles of GMPs and their importance in microbiology laboratories. Aspects of laboratory operations specifically required by GMPs and considered industry practice will be reviewed, including: general GMP requirements for microbiology laboratories, documents and document control, handling of raw data and laboratory control. Coverage of general laboratory control issues will be the focus of the program and cover GMP requirements for topics, such as: handling of chemicals, documentation practices, sample handling, prevention of cross-contamination, positive and negative controls, identification tests, sterility tests, handling of media, laboratory equipment, autoclaves and environmental monitoring. This is an excellent overview of specific laboratory requirements.

Topics include:

- GMP requirements for microbiology laboratories
- Laboratory documents and document control
- Handling and documentation of raw data
- Controlling growth media
- Aseptic techniques
- Monitoring
- Laboratory equipment
- Training practices
- Out-of-Specification results

Regulatory References:
21 CFR 211.160; 21 CFR 211.165; 21 CFR 211.194
FDA Guide to Inspections of Microbiological Pharmaceutical Quality Control Laboratories

Approach to Computerized Systems Validation and Compliance (ISPE02)

FDA CRADA

This course, the second in a three-part series, 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 and 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.

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

This course addresses the following:
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff, FDA CDRH and CBER, January 2002
- Guidance for Industry – Part 11; Electronic Records; Electronic Signatures – Scope and Application, Final Rule, August 2003
- GAMP 5: GAMP Guide for Validation of Automated Systems (A Risk-Based Approach to Compliant GxP Computerized Systems), March 2008
- Guideline on General Principles of Process Validation, FDA, May 1987
- Guide to Inspection of Computerized Systems in Drug Processing, FDA ORA, February 1983
- Software Development Activities, FDA ORA, July 1987
- Glossary of Computerized System and Software Development Terminology, FDA ORA, August 1995

Awareness of FDA Inspections for Pharmaceutical Manufacturers (PHA65)

In this course, you will be provided with a general awareness of FDA inspections of pharmaceutical testing and manufacturing facilities, including purpose, types and areas/operations typically inspected. You will also explore how firms should handle FDA inspections and interact effectively with FDA investigators.

Topics include:

- Scope of FDA inspections
- Procedures for companies to be prepared
- Guidance on how to interact with the FDA
- What you can expect at the conclusion of an inspection

References:
Food, Drug and Cosmetic (FD&C) Act
Compliance Program Guidance Manual for FDA Staff: Drug Manufacturing Inspections Program 7356.002

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.

You will be able to explain the key elements and reasons for organized batch records and list many of the key components of batch records. You will 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

References:
21 CFR Part 211 Sections 188, 192 and 194

Biotechnology: An Overview of Compliance Considerations (PHDV68)

This course provides an overview of the fundamental compliance issues impacting the Biotechnology industry. It examines compliance requirements specific to the biotechnology processes such as: cell culture and fermentation; culture media and growth; antibody production; extraction, isolation and purification; cleaning procedures; and laboratory controls and testing.

Topics include:

- What are biotechnology-derived products?
- Why is the FDA concerned with cell culture and fermentation?
- Why is the FDA concerned with antibody production?
- What are the manufacturing controls for BDPs?
- What are the unique challenges of processing and filling BDP?
- What controls exist for BDPs?
- What are BDPs tested for?

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 medicinal products starting and packaging materials while meeting requirements set forth in the GMP regulations.

The learner is introduced to these key concepts by observing a tour of a modern medicinal product manufacturing facility. Proper procedures for the receipt, sampling, storage, testing and record-keeping of medicinal product starting and packaging materials 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

References:
21 CFR Parts 177, 210 and 211
FDA Guideline "Submitting Documentation for Container Closure Systems Used in the Packaging of Human and Veterinary Drugs"

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, learners 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

References:
CFR 21 Parts:
210, 211: How changes are handled by drug GMPs
314: Changes to drug applications
601: Changes to biologic licenses
606: How changes are handled by biologic GMPs
814: Changes to device applications
820: How changes are handled by medical device GMPs

Collecting Samples and Establishing Limits for Cleaning Validation (PHA54)

GMP regulations require that the 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. It is also important for manufacturers to set responsible limits for cleaning validation. 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.

Topics include:

- Sampling locations
- FDA-preferred sampling methods
- Advantages and disadvantages of sampling methods
- Approaches used to set cleanliness limits
- Factors that influence cleanliness limits
- Establishing cleanliness limits

References:
21 CFR Parts 211.67 and 211.110
FDA Guide to Inspection "Validation of Cleaning Processes" Complaint Management for Pharmaceutical Manufacturers

Complaint Management for Pharmaceutical Manufacturers (PHA71)

This course enables you to identify the primary elements in an effective pharmaceutical complaint handling system. You will recognize how to document complaint information as required by FDA regulations and understand the basic requirements for complaint evaluation and investigation. You will be able to recognize the types of complaints that must be reported to the FDA according to the Adverse Drug Experiences (ADE) regulations, and identify the importance of using statistical techniques to identify complaint trends that may indicate potential quality problems.

Topics include:

- System Elements
- ADE
- Complaint File
- Complaint Analysis
- Investigation

References:
21 CFR 211 Subpart J, 211.198, and 211.192
21 CFR 211 Part 310, Subpart D, Sec. 310.305

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 APRs can yield. After completing this course you will know the regulatory requirements and contents of an APR as well as the benefits of a good APR program.

Topics include:

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

References:
21 CFR Part 211 – cGMP Subpart J, Records and Reports
21 CFR 211.180(e) – General Requirements (for Annual Product Reviews)
21 CFR 211.192 Production Record Review

Corrective and Preventive Actions (PHA70)

The failure to take corrective and preventive actions can lead to continuing production problems, high scrap rates, product failures, customer dissatisfaction, and, most seriously, harm to a user or patient. When the FDA determines that a company's quality processes are not adequate or followed, they may take enforcement actions to prevent the distribution of the products produced by these processes.

After completing this course, you will be familiar with applicable regulatory requirements and other important aspects of implementing an effective Corrective and Preventive Actions (CAPA) procedure. This course was prepared in accordance with the FDA's Quality System guidance and experts from the Medical Device industry. Implementing a CAPA system is a requirement for both the Pharmaceutical and Medical Device industry.

Topics include:

- Quality System
- CAPA Program
- Nonconformities
- Root Cause Analysis
- Change Control

DEA Compliance (PHA40)

This course provides an overview of 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 include:

- The DEA's role and the laws under the CSA
- The DEA's classification of controlled substances
- DEA requirements for the manufacture and distribution of a controlled substance
- Production and distribution controls
- Controls for facilities that manufacture controlled substances
- Employee controls
- Recordkeeping requirements for manufacturers of controlled substances

References:
21 CFR Chapter 1 Parts 210 and 211
21 CFR Chapter 2 Parts 1300-1399
Food, Drug and Cosmetic Act (FD&C Act)
Controlled Substance Act (CSA)

Documenting Validation Activities (PHA55)

The process of validation in the 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 validation must be documented. The FDA issues Warning Letters to manufacturers that have inadequate validation activities. These observations are considered to be violations of 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 and 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

References:
21 CFR Parts 210 and 211 and 820 – Quality System Regulation
Guideline on General Principles of Process Validation, Sec VIIIA3
Guide to Inspections of Oral Solid Dosage Forms Pre-/Post-Approval Issues for Development and Validation
Guideline for Submitting Supporting Documentation on Drug Applications for the Manufacture of Drug Products

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, the FDA 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. 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 483s
- Purpose and scope of Warning Letters
- Responding to Warning Letters
- Avoiding mistakes when responding
- Scale-Up and Post Approval Changes (SUPAC) guidance

This course covers material referenced or implied from 21 CFR, Parts 210 and 211; 21 CFR, Part 820 (medical devices); and section 704 of the FD&C Act.

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 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 SOP

References:
FDA Guideline on Sterile Drug Products Produced by Aseptic Processing, June 1987
Fundamentals of a Microbiological Environmental Monitoring Program, FDA Environmental Task Force, Technical Report, Nov. 13, 1990
21 CFR Part 211.160

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. 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 key concepts of calibration and recognize the importance of calibration reference standards and 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

References:
21 CFR 211.67, 21 CFR 211.68 and 21 CFR 211.160(b)(4), 21 CFR 820.72
ANSI/NCSL Z540-I-1994 – Calibration Laboratories and Measuring and Test Equipment – General Requirements
ISO 10012-1:1992(E), Quality Assurance Requirements for Measuring Equipment – Part 1: Metrological Confirmation System for Measuring Equipment
ISO/IEC Guide 25, 1990, General Requirements for the Competence of Calibration and Testing Laboratories

Failure Investigations for Pharmaceutical Manufacturers (PHA59)

Conducting a failure investigation in a pharmaceutical environment is a complex process. If the root cause of a failure is not properly identified, there may be additional failures or missed opportunities for improvement of product quality. An effective system for conducting failure investigations can provide a means for preventing recurrences. It is for these reasons that it is important for those in a pharmaceutical manufacturing environment to know the characteristics and requirements of a good failure investigation. This course will familiarize the learner with GMP regulations regarding failure investigations and the key components of a good investigation. Additionally, the learner will 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.

Topics include

- Events leading to a failure investigation
- Root cause
- Corrective action
- Follow-up in failure investigations
- Purpose of an investigation report

References:
21 CFR Part 211.192
FDA correspondences, guidance and compliance actions
Guidance for Industry, "Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production," draft September 1998

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

References:
21 CFR 211.25(a) – cGMP for Finished Pharmaceuticals
21 CFR 58.29(a)(b) – Good Laboratory Practice for Nonclinical Laboratory Studies
21 CFR 820.25(a)(b) – Quality System Regulation

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 cGMPs. There are, however, no specific regulations in 21 CFR for APIs like there are for drug products. The FDA is proposing regulations, however, they 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 building and facilities
- cGMP requirements for manufacturing equipment
- Requirements for materials and packaging components
- Process controls for APIs
- Laboratory controls for APIs
- Recordkeeping requirements

References:
Food, Drug and Cosmetic Act (FD&C Act)
21 CFR Chapter 1 Parts 210, 211, 606 and 820

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 cGMP-compliant batch records
- Manufacturing records
- Packaging batch records
- Deviations
- Batch record review

References:
21 CFR 211.100, 211.101, 211.130, 211.180, 211.188, and 211.192

GMP Principles of SOPs (PHA64)

This course reviews the principles of SOPs for an FDA-regulated environment and provides employees with a working knowledge of what SOPs are, their purpose, how they are structured, information provided and change control. 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

References:
21 CFR Part 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals
21 CFR Part 820 – Quality System Regulation for Medical Devices
21 CFR Part 58 – Good Laboratory Practice for Nonclinical Laboratory Studies
Compliance Program Guidance Manual for FDA Staff: Drug Manufacturing Inspections program 7356.002

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

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

Gowning for Sterile Manufacturing (PHA63)

In this course you will be able 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 learn to identify important practices and procedures for proper gowning.

Prerequisites:

- Principles of Aseptic Processing
- Principles of Sterilization

Topics include:

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

References:
21 CFR 211.28 (a-d)
21 CFR 211.56
QSR 820.70

GxPs (PHDV61)

"GxP" is a collective term for the regulations known as Good Laboratory Practices (GLPs), Good Clinical Practices (GCPs) and Good Manufacturing Practices (GMPs). Without these combined regulations, the safety and efficacy of the pharmaceutical and medical device products would be in question. After completing this course, you will understand how these practices relate to each step in the development and manufacture of new drugs, biologics and medical devices..

Topics include:

- GxPs
- GLPs
- GCPs
- GMPs

References:
This course references regulations that are found in the Code of Federal Regulations Title 21

Handling a Product Recall (PHDV64)

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 this Life Science industry. Because 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

Note: This course addresses key aspects of 21 CFR, Part 7 – Enforcement Policy and SMDA of 1990.

Handling an FDA Inspection (PHDV74)

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

References:
Food, Drug, and Cosmetic (FD&C) Act
21 CFR Parts 10, 20, 207, 210, 211, 606, and 820
FDA Guide to Inspection "Dosage Form Drug Manufacturers – cGMPs"
FDA Guide to Inspection "Solid Oral Dosage Forms Pre/Post Approval Issues"

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, GMP regulations require that water receives 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 the 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

How to Meet Drug Retention and Stability Testing Requirements (PHA43)

This course is designed to provide the learner with an understanding of the principles and regulations of drug stability testing and requirements for maintaining reserve samples. After completing this course, you will recognize the importance of maintaining drug safety and effectiveness over a product's shelf life. You will be familiar with basic Principles of Stability and the relationship to product safety and effectiveness.

Topics include:

- Stability testing program
- Effects of environmental conditions on product stability
- Determining shelf life
- Requirements for stability testing protocols
- Purpose of retention testing

This course addresses the following:
- 21CFR Subpart I, Laboratory Controls Part 211.166 Stability Testing, and Part 211.170 Reserve Samples
- Guidance for Industry: ICH Q1A (R2) Stability Testing of New Drug Substances and Products, November, 2003

ICH Q7A: Introduction and Quality Management (ISPE05)

FDA CRADA

This is the first in a series of courses designed to instruct on cGMPs for active pharmaceutical ingredients (APIs), as set out by the ICH Q7A Guideline. This course covers the Introduction to ICH Q7A and Quality Management for API manufacture.

After completing this course, you will be able to describe the purpose of the Q7A Guideline and how it fits in with current regulatory expectations and practices in the United States – especially in the context of the FDA's systems-based inspections program, 7356.002F. You will also be able to recognize the basic terminology and applications of Q7A and the principles of an effective quality management system for API manufacture.

Prerequisites:

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 APIs.

Topics:

- What is Q7A
- How APIs differ from drug products
- When Q7A guidelines apply to the API manufacturing process
- The purpose of quality management
- Key production activity that ensures API quality
- Why a formal change control system is needed
- What complaints and recalls share in common

Regulatory References:
This course incorporates information from Guidance for Industry: Q7A GMP Guidance for APIs.
http://www.fda.gov/cber/gdlns/ichactive.pdf

Note: Content for this course is provided by the International Society of Pharmaceutical Engineers (ISPE).

ICH Q7A: Resources and Materials Management (ISPE06)

FDA CRADA

This is the second in a series of courses designed to instruct on GMPs for Active Pharmaceutical Ingredients (APIs), as set out by the International Conference on Harmonisation (ICH) Q7A 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 APIs. After completing this course, you will be able to recognize materials management and warehousing and distribution procedures.

Prerequisite:

- ICH Q7A: Introduction and Quality Management

Topics include:

- Personnel qualifications
- Buildings and facilities requirements used for
- API manufacturing
- Process equipment requirements used for
- API manufacturing
- Purpose of materials management
- Storage/Distribution

Regulatory References:
Guidance for Industry: Q7A GMP Guidance for API
www.fda.gov/cber/gdlns/ichactive.pdf

Note: Content for this course is provided by the International Society of Pharmaceutical Engineers (ISPE).

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 cGMP requirements and save on 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)

Interviewing Techniques (FDA27)

Interviews are an important part of virtually every operation performed by FDA inspectors, investigators and analysts. Interviews are conducted during inspections, sample collections, recalls and special investigations; therefore, it is important that FDA field personnel possess good interviewing skills and develop them as they move forward in their careers.

After completing this course you will be able to recognize the fundamentals of conducting an effective interview. You will be able to identify the traits of a successful interviewer and the importance of appropriate interpersonal skills. You will also be able to identify appropriate questioning techniques to use in an interview.

Topics include:

- Purpose of an interview
- Preparing for an interview
- Specific considerations for the persons being interviewed
- Traits of a successful interviewer
- Keys to asking effective questions
- Nonverbal behaviors you should observe

References:
Food, Drug and Cosmetic (FD&C) Act
Investigations Operations Manual (IOM)
DHRD Basic Investigative Interviewing Course

Introduction to GMPs (PHA38)

In this course, you'll examine the history of Good Manufacturing Practices (GMPs) and explore the importance of training, as well as quality control and personal responsibilities. In addition, you'll discover the importance of documentation and tracking practices.

Topics include:

- Procedures
- Documentation
- Responsibilities
- Contamination control
- Inspections

References:
21 CFR Parts 210, 211, 606 and 820

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.

Topics include:

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

References:
This course is based upon applicable sections of 21 CFR Parts 211 and 820, as well as:
FDA Guidelines on General Principles of Process Validation.
FDA Guide to Inspection "Solid Oral Dosage Forms Pre-/Post-Approval Issues."
FDA Guide to Inspection "Validation of Cleaning Processes."
Process Validation Guidance for Medical Device Manufacturers, Global Harmonization Task Force, SG3. Document GHTF.SG3.N99-10, June 1999.

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

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 interactive program you'll assume the role of the new manager of the engineering department. You will be involved in equipment selection, installation, qualification and maintenance.

Upon completing this lesson, learners will be able to describe cleaning and maintenance practices for equipment used in manufacturing, as well as how a Pharmaceutical company incorporates this equipment in their work. Additionally, learners will be able to identify the necessary documentation and records for equipment used in the manufacture of prescription and over-the-counter drugs.

Topics include:

- GMPS for equipment design and construction
- Objectives for equipment maintenance and cleaning
- Equipment validation
- GMP requirements for identifying equipment
- GMP requirements for equipment records

References:
This course addresses the following regulations:
21 CFR Parts 211.46, 211.63, 211.65, 211.67, 211.68, 211.105, 211.182, 211.180 and 211.188

Managing FDA Inspections for Pharmaceutical Manufacturers (PHA66)

This course reviews effective measures for managing FDA inspections of Pharmaceutical drug manufacturing facilities. The measures reviewed include preparation, interaction, handling and follow-up.

Topics include:

- How should companies prepare for FDA inspections?
- How does an Inspection Guide help firms manage FDA inspections?
- What systems are covered under the FDA's "Systems-Based Approach for Inspections"?
- How can you ensure the best interaction with the FDA?
- How should FDA inspections be managed?
- Why is managing the inspection closeout meeting important?
- How should companies follow up to FDA inspections?

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 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

References:
21 CFR Parts 211, 820 and 600

Meeting Process Requirements for Returned and Salvaged Drug Products (PHA42)

Learn the specific requirements set forth in the GMP Regulations to assure the purity, safety and effectiveness of returned and salvaged drugs when they are deemed suitable for distribution. This program examines the relationship of product complaints and investigations to drug products that have been returned or salvaged and how these may impact what can be done with such drug products.

This program addresses the unique principles and practices involved in the proper handling and processing of returned and salvaged products, GMP requirements, acceptable practices and procedures, and documentation.

Topics include:

- Returned and salvaged drug products
- Procedures for processing returned and salvaged products
- Evaluating returns for resale
- Products that can be salvaged
- Documentation requirements for returned and salvaged products

References:
21 CFR Part 211.204 – Returned Drug Products
21 CFR Part 211.208 – Drug Product Salvaging

Orientation to GMP Compliance (PHDV73)

Many people, including those who work in the Drug 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 (FD&C) Act 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 its expectations.

Topics include:

- What regulations are
- The goal of GMP regulations
- Interpreting the regulations
- Enforcing regulations

References:
Food, Drug and Cosmetic Act
CFR 21 Chapter 1
CFR 21 Parts 210 and 211
CFR 21 Part 11
FDA "Good Guidance Practices"
FDA Guide to Inspection "Dosage Form Drug Manufacturers – cGMPs"

Packaging and Labeling of Finished Pharmaceuticals (PHA39)

This course examines the packaging and labeling of pharmaceutical products. Included is a discussion on the importance of these activities, possible impact of mix-ups that can occur with packaging or labeling and the controls for these activities required by the cGMP regulations. In addition, typical approaches taken with packaging to protect consumers are reviewed.

Topics include:

- GMP principles for packaging and labeling
- Primary and secondary packaging
- Consumer protection
- Preventing packaging mix-ups
- Proper product labeling
- Label control prior to production
- Online controls used during production

Reference:
The content of this course is based on 21 CFR Parts 211.122 to 211.137 and 211.188; the FDA Guide to Inspection of Dosage Form Drug Manufacturers – cGMPs; and 21 CFR Parts 201, 606 and 610

Part 11: Electronic Records; Electronic Signatures (FDA31)

The principle purpose of 21 CFR Part 11 is to ensure that when electronic records and signatures are used, they meet the minimum requirements of trustworthiness, reliability and compatibility with the FDA's mission of public health and safety. This interactive lesson is designed to introduce you to the regulatory requirements for electronic records and electronic signatures, as well as FDA expectations for compliance. You will learn specific Part 11 requirements that govern the use of electronic records and signatures as well as FDA enforcement of Part 11.

Topics include:

- Part 11
- Basic requirements for electronic records
- Security requirements for electronic records
- Basic requirements for electronic signatures
- Controls for electronic signatures
- FDA enforcement of Part 11

References:
21 CFR Part 11 – Electronic Records; Electronic Signatures
FDA Guidance for Industry – Computerized Systems Used in Clinical Trials, April 1999
FDA Guidance for Industry; Part 11, Electronic Records; Electronic Signatures – Scope and Application, August 2003

Note: This course was created by UL in collaboration with EduQuest, Inc.

Part 11: Electronic Records and Signatures – Changes in Enforcement Policy (FDA57)

This course will provide the learner with an understanding of the change in enforcement policy of the FDA for 21 CFR Part 11, Electronic Records; Electronic Signatures. The course discusses the Guidance for Industry; Part 11, Electronic Records; Electronic Signatures – Scope and Application, August 2003.

Topics include:

- Part 11
- Basic requirements for electronic records
- Security requirements for electronic records
- Basic requirements for electronic signatures
- Controls for electronic signatures
- FDA enforcement of Part 11

References:
21 CFR Part 11 – Electronic Records; Electronic Signatures
FDA Guidance for Industry; Part 11, Electronic Records; Electronic Signatures – Scope and Application, August 2003

Note: This course was created by UL in collaboration with EduQuest, Inc.

Pharmaceutical Risk Management: Picking the Right CAPA Tools (PHA73)

One of the elements in FDA's Q10 Pharmaceutical Quality System document is corrective and preventive action (CAPA). This course focuses on the CAPA process, including the investigation process, root cause determination, data collection, and preventive actions that come from that analysis, based on industry best practices. Learners will also become familiar with software tools available that can help achieve an effective CAPA process.

Topics include:

- CAPA Programs
- Data Monitoring and Review
- Analysis
- CAPA Software Tools

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 are 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 GMP compliance. For post-approval inspection, discussion focuses on general GMP compliance issues. For each type of inspection, 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.

Topics include:

- Pre-approval inspections
- Focus of Pre- and Post-Approval Inspections (PAI)
- Post-approval inspections
- Reasons for post-approval inspections
- Possible FDA inspection outcomes

Note: The content in this course addresses key aspects of 21 CFR Parts 210, 211 and 314 – Applications for FDA Approval to Market a New Drug, FDA Guide to Inspections of Quality Systems and Part 820: Medical Device Quality System Regulation.

Principles of Aseptic Processing (PHDV71)

FDA CRADA

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. It will also address the GMP principles for aseptic processing as required by both the European Union (EU) and the FDA.

Topics include:

- Aseptic processing
- Controlling the aseptic processing environment
- Employee requirements for aseptic processing
- Preparing components for sterile products
- Media fill
- Environmental monitoring programs

Principles of Auditing (PHDV69)

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 GMP compliance. The lesson is on the actual preparation, conduct and follow-up associated with an internal audit. Finally, 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.

Topics include:

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

References:
21 CFR Parts 211.84 and 820.22
FDA Compliance Program 7346.832 – Pre-Approval Inspections
QSIT Guidance

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 – even deadly. It is for these reasons that the FDA enhanced cleaning requirements for Pharmaceutical manufacturers.

In this course you will learn the basics of cleaning validation in pharmaceutical manufacturing operations. The lesson will focus on cleaning procedures and the development of methods and approaches to validating your processes. In addition, assessing "clean" and developing methodologies for sampling and analyzing chemical residuals are discussed.

Topics include:

- Cleaning validation
- Choosing the proper cleaning method
- Why a cleaning SOP is necessary
- Assessing "clean"
- Testing for chemical residues
- Proving methods
- Acceptance limits
- Testing and monitoring the cleaning procedures
- Control and monitoring procedures

References:
21 CFR Part 211
FDA Guide to Inspections of Validation of Cleaning Processes
Amendments to the current GMPs Regulations for Finished Pharmaceuticals: Final Rules effective December 8, 2008
Guidance for Industry: cGMP for Phase 1 Investigational Drugs, July 2008

Principles of FDA Inspections for Pharmaceutical Manufacturers (PHA61)

This course reviews the basics of FDA inspections of drug manufacturing facilities, including authority, purpose, types and areas/operations typically inspected. The course also reviews how companies and their personnel should generally handle FDA inspections and interact effectively with investigators.

Topics include:

- Scope of FDA inspections
- Types of inspections
- How inspections are initiated
- Guidance for handling inspections
- Areas the FDA will likely inspect
- Interacting with the FDA
- What happens at the end of an inspection

References:
FD&C Act, Chapter VII – General Authority, Section 704 – Factory Inspection
Compliance Program Guidance Manual for FDA Staff: Drug Manufacturing Inspections Program 7356.002

Principles of Good Documentation (PHDV65)

Documentation is an important aspect of 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

References:
21 CFR Parts 210, 211, 606 and 820

Requirements for Computerized Systems Validation and Compliance (ISPE01)

FDA CRADA

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 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 Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) as related to computerized systems validation
- FDA expectations for validation activities and documentation

References:
21 CFR Part 11 – Electronic Records; Electronic Signatures
21 CFR Part 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals
21 CFR Part 820 – Quality System Regulation
GAMP 4: GAMP Guide for Validation of Automated Systems, ISPE, 2001
General Principles of Software Validation; Final Guidance for Industry and FDA Staff, FDA CDRH, January 2002
Glossary of Computerized System and Software Development Terminology, FDA ORA, August 1995
Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures Validation, FDA, August 2001 (Draft Guidance)
Guide to Inspection of Computerized Systems in Drug Processing, FDA ORA, February 1983
Guideline on General Principles of Process Validation, FDA, May 1987
Software Development Activities, FDA ORA, July 1987

Note: Content for this course is provided by the International Society of Pharmaceutical Engineers (ISPE).

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 and 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:

- Out-of-Specification (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

References:
21 CFR Subpart I, Laboratory Controls;
Subpart J Records and Reports, Parts 211.192, and 211.194.
FDA Guidance Document (draft): Investigating Out-of-Specification Test Results for Pharmaceutical Production
FDA Guide to Inspections of Pharmaceutical Quality Control Laboratories

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, Subpart O, Statistical Techniques.

Topics include:

- Definition
- Data Analysis
- Histograms
- Variability

References:
21 CFR 820.250 – "Statistical Techniques"

Risk Management in Pharmaceutical Manufacturing (PHA72)

This course will cover the practical application of Risk Management principles, published in "Guidance for Industry: Q9", through case studies applied to process design and manufacturing.

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 Limulus Amebocyte Lysate (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

References:
The content in this course addresses key aspects of 21 CFR Parts 210, 211, and 314 - Applications for FDA Approval to Market a New Drug, FDA Guide to Inspections of Quality Systems, and Part 820: Medical Device Quality System Regulation.

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, more accurate and more consistent. As a result, the use of computerized systems 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. At the conclusion of this module you will be able to explain the software development lifecycle, including basic verification and validation activities, and describe several 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 software validation
- Final two phases of the software development lifecycle

References:
Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systems in Pharmaceutical Manufacture, Volume 1, Parts 1 and 2, Volume 2, GAMP Forum, Version 3, March 1998
1983 Guide to Inspection of Computerized Systems in Drug Processing (FDA)
1987 Guide to General Principles of Process Validation (FDA)
21 CFR Part 211.68
21 CFR Part 11
FDA Technical Report: Software Development Activities, July 1987
FDA Guidance for Industry: General Principles of Software Validation, June 1997

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 interactive program introduces the general layout and equipment used within a Pharmaceutical or Medical Device manufacturing plant.

References:
21 CFR Parts 210, 211 and 820
PHDV63-EU contains the same content as noted above and also includes these references:
EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use, Part 1, Chapter 3 Premises and Equipment and Chapter 5 Production
EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use, Annex, 15 Qualification and Validation

Note: This course is also available in French.

Topics include:

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

References:
21 CFR Part 314.70
Federal Register Volume 64, No. 123, June 28, 1999, Supplements and Other Changes to an Approved Application
Guidance to Industry: Changes to an Approved NDA or ANDA, Food and Drug Administration Center for Drug Evaluation and Research (CDER), November 1999
FDA CDER, SUPAC-IR: Immediate-Release Solid Oral Dosage Forms: Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls; In Vitro Dissolution Testing and In Vivo Bio-equivalence
FDA CDER, SUPAC-MR: Modified Release Solid Oral Dosage Forms Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls; In Vitro Dissolution Testing and In Vivo Bio-equivalence Documentation
FDA CDER, SUPAC-SS: Nonsterile Semisolid Dosage Forms: Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation
FDA CDER, BACPAC I: Intermediates in Drug Substance Synthesis: Bulk Actives Post-Approval Changes – Chemistry, Manufacturing and Controls Documentation
FDA CBER, Guidance for Industry: Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products, US Department of Public Health, FDA
FDA CBER, Guidance for Industry: Changes to an Approved Application, Biological Products, US Department of Public Health, FDA
Changes to an Approved NDA or ANDA

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.

Topics include:

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

References:
21 CFR Parts 211.100-211.115 and 211.188

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
- Testing

References:
For Drug Products: 21 CFR Part 211 Section 211.22 Responsibilities of the Quality Control Unit
21 CFR Part 211 Subpart E, Control of Components and Drug Product Containers and Closures
For Medical Devices: 21 CFR 211, Part 820 Quality System Regulation 21 CFR Subpart E, Section 820.50 Purchasing Controls

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. This lesson is designed to help you understand and recognize the principles and practices applicable to written procedures. You'll learn the rationale and GMP requirements for written procedures as well as the different types of procedures and how they are developed. Additionally, you'll become familiar with the format and content of a procedure.

Topics include:

- Standard Operating Procedures (SOPs)
- GMP requirements for SOPs
- Elements of an effective SOP
- SOP design
- Components of a SOP
- Review and approval process
- Document control

This course addresses requirements set forth in 21 CFR Parts 210, 211, 606, and 820

Note: This course is also available in French.

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:

- Validation
- Basic protocol format
- Elements of a validation protocol

References:
21 CFR Parts 210, 211, and 820
FDA Guideline for General Principles of Process Validation
Guide to Inspections of Solid Oral Dosage Forms, Pre/Post Approval Issues for Development and Validation.

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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