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Overview:

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 Quality, Compliance and Learning’s systemic approach to employee learning has created the Active Pharmaceutical Ingredients (API) Curriculum that consists of more than 80 courses and focuses on the specialized knowledge needs of individual business functions in Pharmaceutical, Biotechnology and Biologic companies. 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 API 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)
- Management and Supervision

FDA Partnership

UL’s Cooperative Research and Development Agreement (CRADA) with the Food and Drug Administration (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 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 FDA 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, including the FDA’s new Pharmaceutical Good Manufacturing Practices (GMPs) for the 21st Century Initiative.
Driving Employee Comprehension

UL’s innovative technology-based solutions, deployed over the web, enable our clients 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.

Courses that Include the European Regulatory Perspective

In today’s business environment, Life Science organizations must consider their regulatory obligations on a global scale. UL has taken the necessary steps to ensure your key employees, subcontractors and vendors learn about these important regulations. When the “EU” image appears at the end of a course, that indicates that our European Union subject-matter expert has reviewed the course and added the EU guidelines.

UL’s Knowledge Platform for Pharmaceutical Manufacturing

UL’s Platform is a technology-based solution, deployed over the web that enables our customers to cost-effectively manage their expanding knowledge expectations of employees and designated individuals. The solution uses our validated and CFR 21 Part 11-compliant ComplianceWire® system to deliver, measure, document and track the online API Curriculum with content provided or reviewed by the FDA, as well as critical communications including Standard Operating Procedures (SOPs) that can be recorded and validated with e-signature procedures. Proprietary courses can also be developed that target specific customer process and/or operation needs. The solution also uses UL’s proprietary assessment tools to help assure supervisors that employees have the right knowledge to perform a job function efficiently and cost effectively.

Using our Competency Mapping process, UL works with clients to determine essential job competencies required for each position within their organization and to ‘map’ those competencies into a comprehensive plan.

All these components, working in concert, enable clients 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.
Sample Curriculums:

**Organized by functional areas and suggested learning sequence**

### Core Knowledge
- GxPs
- Orientation to GMP Compliance
- Biotechnology: An Overview of Compliance Considerations
- GMPs for API Bulk Manufacturers
- GMP Principles of SOPs
- Principles of Good Documentation
- Part 11 – Electronic Records; Electronic Signatures
- Key Concepts of Process Validation
- Change Control
- Awareness of FDA Inspections for Pharmaceutical Manufacturers
- Introduction to GMPs
- Understanding Post-Approval Changes

### Production
- Understanding the Principles and Practices of Process Controls
- Understanding GMPs for Facilities and Equipment
- Care and Handling of Drug Product Components, Labeling, Containers and Closures
- GMP Principles for Batch Records
- Maintenance and Cleaning of Drug Manufacturing Equipment
- Packaging and Labeling of Finished Pharmaceuticals
- Principles of Aseptic Processing
- Environmental Control and Monitoring
- Gowning for Sterile Manufacturers
- Vendor Certification for Pharmaceutical Manufacturers
- DEA Compliance

### Maintenance and Facilities
- Understanding GMPs for Facilities and Equipment
- Essentials of an Effective Calibration Program
- Implementing an Equipment Qualification Program
- Maintenance and Cleaning of Drug Manufacturing Equipment
- High Purity Water Systems
- Environmental Control and Monitoring
- Gowning for Sterile Manufacturers
- DEA Compliance

### Warehousing and Distribution
- Care and Handling of Drug Product Components, Labeling, Containers and Closures
- Meeting Process Requirements for Returned and Salvaged Drug Products

### Quality Control (QC) Labs
- Application of GMPs to Analytical Laboratories
- Application of GMPs to Microbiology Laboratories
- Writing Validation Protocols
- Collecting Samples and Establishing Limits for Cleaning Validation
- Documenting Validation Activities
- How to Meet Drug Retention and Stability Testing Requirements
- Principles of Aseptic Processing
- Environmental Control and Monitoring
- Gowning for Sterile Manufacturers
- Testing for Bacterial Endotoxins
- Resolving Out-of-Specification Test Results
- Failure Investigations for Pharmaceutical Manufacturers

### Information Technology (IT) Validation
- Understanding the Principles and Practices of Process Controls
- A Step-by-Step Approach to Process Validation
- Approach to Computerized Systems Validation and Compliance
- Requirements for Computerized Systems Validation and Compliance
- Part 11: Electronic Records and Signatures – Changes in Enforcement Policy
- The Design and Development of Software Used in Automated Process Controls
- Writing Validation Protocols
- Documenting Validation Activities
- Implementing an Equipment Qualification Program
- Principles of Cleaning Validation

### Management/Supervision
- A Tour of the FDA
- Principles of FDA Inspections for Pharmaceutical Manufacturers
- Part 11: Electronic Records and Signatures – Changes in Enforcement Policy
- Meeting GMP Training Requirements
- Writing and Reviewing SOPs
- Batch Record Reviews
- Principles of Auditing
- Pre- and Post-Approval FDA Inspections
- Managing FDA Inspections for Pharmaceutical Manufacturers

### Research and Development (R&D)/Design Controls
- Review of Basic Statistical Techniques
Quality Assurance (QA)

**QA – Manufacturing Process**
ICH Q7A: Introduction and Quality Management
ICH Q7A: Resources and Materials Management
Understanding the Principles and Practices of Process Controls
Understanding GMPs for Facilities and Equipment
Care and Handling of Drug Product Components, Labeling, Containers and Closures
Essentials of an Effective Calibration Program
Implementing an Equipment Qualification Program
Maintenance and Cleaning of Drug Manufacturing Equipment
Packaging and Labeling of Finished Pharmaceuticals
High Purity Water Systems
Principles of Aseptic Processing
Environmental Control and Monitoring
Gowning for Sterile Manufacturers
Batch Record Reviews
Principles of Auditing
Failure Investigations for Pharmaceutical Manufacturers
Vendor Certification for Pharmaceutical Manufacturers

**QA – Validation**
Understanding the Principles and Practices of Process Controls
A Step-by-Step Approach to Process Validation
Approach to Computerized Systems Validation and Compliance
Requirements for Computerized Systems Validation and Compliance
Part 11: Electronic Records and Signatures – Changes in Enforcement Policy
The Design and Development of Software Used in Automated Process Controls
Writing Validation Protocols
Documenting Validation Activities
Implementing an Equipment Qualification Program
Principles of Cleaning Validation

**Inspections**
Handling an FDA Inspection

**QA – Compliance**
A Tour of the FDA
Principles of FDA Inspections for Pharmaceutical Manufacturers
Part 11: Electronic Records and Signatures – Changes in Enforcement Policy
Meeting GMP Training Requirements
Writing and Reviewing SOPs
Batch Record Reviews
Vendor Certification for Pharmaceutical Manufacturers
Principles of Auditing
Pre- and Post-Approval FDA Inspections
Managing FDA Inspections for Pharmaceutical Manufacturers
Effectively Responding to FDA 483s and Warning Letters
Meeting Process Requirements for Returned and Salvaged Drug Products
Handling a Product Recall
DEA Compliance

**QA – Quality Systems**
How to Meet Drug Retention and Stability Testing Requirements
Meeting GMP Training Requirements
Writing and Reviewing SOPs
Conducting Annual Product Reviews
FDA Training and Qualification Requirements

**Courses that Include European Union (EU) Guidelines**
Application of GMP to Microbiology Labs
Batch Record Reviews
Care and Handling of Medicinal Product Starting Materials
Environmental Control and Monitoring
Failure Investigations for Pharmaceutical Manufacturers
Gowning for Sterile Manufacturing
Packaging and Labeling of Finished Pharmaceuticals
Principles of Aseptic Processing
Principles of Good Documentation
Principles of Sterilisation
Understanding GMPs for Facilities and Equipment
Course Descriptions:

Listed Alphabetically

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”

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
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 OOS (Out-of-Specification) results
- GMP requirements for computer systems

References:
Guidance for Industry: Analytical Procedures and Methods Validation, August 2000
Note: PHDV78-EU contains the same content as noted above and also includes EU guidelines.

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
PHDV72-EU contains the same content as noted above and also includes these references.
Note: EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use, Chapters 4 and 6
**Approach to Computerized Systems Validation and Compliance (ISPE02)**

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.

**Prerequisite:**
- 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

**References:**
- General Principles of Software Validation, Final Guidance for Industry and FDA Staff, FDA CDRH and CBER Jan 2002
- Guideline on General Principles of Process Validation, FDA, May 1987
- Software Development Activities, FDA ORA, July 1987
- Glossary of Computerized System and Software Development Terminology, FDA ORA, August 1995

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

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**Awareness of FDA Inspections for Pharmaceutical Manufacturers (PHA65s)**

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

Note: PHDV53-EU contains the same content as noted above and also includes these references: EU Guidelines to GMP Medicinal Products for Human and Veterinary Use, Part 1, Chapter 1 Quality Management, Chapter 2 Personnel, Chapter 4 Documentation, Chapter 6 Quality Control EU Guide to GMP Annex 16, Certification by a Qualified Person and Batch Release, January 2002.

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**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. After completing this course, you will recognize what a biotechnology-derived product is. You will also be able to identify why and how the FDA regulates them. You will also be able to identify the key manufacturing process for these products, as well as recognize the challenges involved with working with these products. Finally, you will be able to identify various controls for biotechnology-derived products.

**Topics include:**
- Biotechnology-Derived Pharmaceuticals (BDPs)
- Cell culture
- Antibody production
- European Innovation Partnership (EIP)
- Processing and packaging
- Controls
- Testing

**References:**
21 CFR Parts 210, 211, 806 and 820
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 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 and containers and closures are covered in detail.

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"

Note: PHDV41-EU contains the same content as noted above and also includes these references:
EU Guidelines to GMP Medicinal Products for Human and Veterinary Use, Chapters 4, 5 and 6
EU Guidelines to GMP Medicinal Products for Human and Veterinary Use, Annex 8, Sampling of Starting and Packaging Materials.

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 and 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

Note: This course is also available in French.
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”

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

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 inspection, but it does happen. If an FDA inspection yields any 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 and use of both and be able to describe the key aspects of written responses.

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

References:
- 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
- 21 CFR Part 211.160

Note: PHDV87-EU contains the same content as noted above and also includes these references:
- EU Guide to GMP Revision to Annex 3, Manufacture of Sterile Medicinal Products, September 2003
- EU Guidelines to GMP Medicinal Products for Human and Veterinary Use.

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
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 — even a risk to patient safety. An effective system for conducting failure investigations can provide a means of 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 familiarise the learner with GMP regulations regarding failure investigations and the key components of a good investigation. Additionally, the learner will also be able to identify how to determine the “root cause” of a failure and recognise 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

Note: PHDV59-EU contains the same content as noted above and also includes these references:
EU Guidelines to GMP Medicinal Products for Human and Veterinary Use, Part 1, Chapters 1 – Quality Management, 5 – Production, 8 – Complaints and Product Recall

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

Note: PHDV59-EU contains the same content as noted above and also includes these references: EU Guidelines to GMP Medicinal Products for Human and Veterinary Use, Part 1, Chapters 1 – Quality Management, 5 – Production, 8 – Complaints and Product Recall.
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.

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 Standard Operating Procedures (SOPs) for a 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.

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 – cGMP for Finished Pharmaceuticals
21 CFR Part 820 – Quality System Regulations for Medical Devices
21 CFR Part 58 – Good Laboratory Practices for Nonclinical Laboratory Studies
Compliance Program Guidance Manual for FDA Staff: Drug Manufacturing Inspections
Program 7356.002

GMPs for API Bulk Manufacturers (PHA52)

The Food, Drug and Cosmetic (FD&C) Act 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 buildings 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
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 gowns.

Prerequisites:
- Principles of Aseptic Processing
- Principles of Sterilization

Topics include:
- Why gowns are important
- Types of contamination
- Preparation in gowns
- Gowns basics and procedures

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

Note: PHDV63-EU contains the same content as noted above and also includes these references:
EU Guide to GMP Revision to Annex 1, Manufacture of Sterile Medicinal Products, September 2003

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
Note: This course is also available in French.

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 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 included:
- Product recalls
- Steps in conducting a recall
- Roles and responsibilities during a 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.

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 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 they 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 Water for Injection (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 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 become familiar with basic Principles of Stability and the relationship to product safety and effectiveness as well as reserve sample regulations and retention testing programs.

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

Regulatory References:
- 21CFR Subpart I – Laboratory Controls Part 211.166 – Stability Testing and Part 211.170 – Reserve Samples
- ICH Q1A, Guideline for Industry, Stability Testing of New Drug Substances and Products, August 2001 (Revision 1)

ICH Q7A: Introduction and Quality Management (ISPE05)

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...
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.

Prerequisite:
- ICH Q7A: Introduction and Quality Management

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)

ICH Q7A: Resources and Materials Management (ISPE06)

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 define 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).
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)
- DHQD Basic Investigative Interviewing Course

Introduction to GMPs (PHA38)

In this course, you’ll examine the history of 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 “Validation of Cleaning Processes.”
  - Process Validation Guidance for Medical Device Manufacturers, Global Harmonization Task Force,
- 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

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**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. After completing this course, you will be able to identify various industry practices that are essential for managing FDA inspections effectively.

**Topics include:**
- How to prepare for an FDA inspection
- Key areas of the Inspection Guide
- Systems covered in the System-based Approach
- FDA Interaction
- Inspection Conduct
- How to close-out an FDA inspection
- Follow-up

**References:**
21 CFR Part 211 – Good Manufacturing Practice for Finished Pharmaceuticals
Draft Guidance for "Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP"
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
- 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

Note: PHDV39-EU contains the same content as noted above and also includes these references: EU Guidelines on the Packaging Information of Medicinal Products for Human Use Authorised by EURy
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.
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)

Because microbiological (bacteria, molds and fungi) 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 lesson will address the general principles and practices necessary to assure product sterility and safety related to aseptic processing. It will also address the principles of GMP regulations as applicable.

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

References:
21 CFR 211.63, 21 CFR 211.65, 21 CFR 211.67, 21 CFR 211.113
FDA Compliance Program 7356.002 A Guide to Evaluation of Sterile Process Inspections
Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice, August 2003
Current USP

Note: PHDV71-EU contains the same content as noted above, and also includes these references:
EC Guide to Good Manufacturing Practice Revision to Annex 3, Manufacture of Sterile Medicinal Products, September 2003, EU Guidelines to GMP Medicinal Products for Human and Veterinary Use.
**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
- QUT Guidance

Note: PHDV69-EU contains the same content as noted above and also includes EU guidelines.

**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 the FDA’s 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
Note: PHDV65-EU contains the same content as noted above and also includes these references:
EU Guidelines to GMP Medicinal Products for Human and Veterinary Use, Part 1, Chapter 4, Documentation.
Note: This course is also available in Spanish and French.

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.

After completing you will be able to define sterilization and list the most common sterilization methods. You will also be able to recognize the general approaches for validating and monitoring sterilization processes and identify the key aspects of sterility assurance.

Topics include:
- Sterilization
- Moist heat (or steam) sterilization
- Dry heat sterilization
- Gas sterilization (Ethylene oxide)
- Radiation sterilization
- Chemical sterilization
- Filtration sterilization
- Sterility assurance
Requirements for Computerized Systems Validation and Compliance (ISPE01)

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 620 – Quality System Regulation
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

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

References:
21 CFR Subpart J Laboratory Controls
Subpart J Records and Reports, Parts 211.192 and 211.194
FDA Guide to Inspections of Pharmaceutical Quality Control Laboratories

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

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**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

**References:**
FDA “Guideline on Sterile Drug Products Produced by Aseptic Processing,” June, 1987
Current USP
A draft revision to this guideline is available: FDA “Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing, cGMP.” September 3, 2003 (draft contains nonbinding recommendations)

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**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 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. 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:**
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 Guidance for Industry: General Principles of Software Validation, June 1997
Understanding Post-Approval Changes (PHA49)

This course covers the definition and purpose of post-approval changes. 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.

In this course, you will learn about Post-Approval Changes (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. 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

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, FDA Center for Drug Evaluation and Research (CDER), November 1999
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

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 and change control.

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
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.

**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

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 9 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.

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.

**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, by studying a basic model, you’ll 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
- Components of an SOP
- Review and approval process
- Document control

Note: This course addresses requirements set forth in 21 CFR Parts 210, 211, 606 and 820
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. The learner will also be able to identify the three types of qualifications, as well as the properties of each.

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 Quality, Compliance and Learning

UL Quality, Compliance and Learning 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 Quality, Compliance and Learning 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 Quality, Compliance and Learning 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.