Life & Health

LIBRARY GUIDE:
Global Regulatory

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Overview:

The Global Regulatory Library focuses on both the global submission process, as well as global harmonization standards that impact Pharmaceutical, Biotechnology and Medical Device companies. The library also consists of courses that contain both EU and US GMP regulations.

For submission courses, we focus on regulatory agencies, including the United States, China, Korea and others. Some of these courses are focused solely on the medical device industry.

For global harmonization standards, we focus on the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) brings together the regulatory and industry authorities of Europe, Japan and the United States. The purpose of ICH is to harmonize the interpretation and application of technical guidelines. Pharmaceutical companies that have adopted a business model based on global value chain are often advised to understand the principles and policies of ICH Q10. While ICH Q10 is not a replacement for regional GMP requirements, the US FDA has noted that implementing the Q10 model should help companies complement or enhance regional GMP requirements.

Regulatory agencies and related information sources are continually monitored, analyzed and incorporated into UL course updates or new courses.

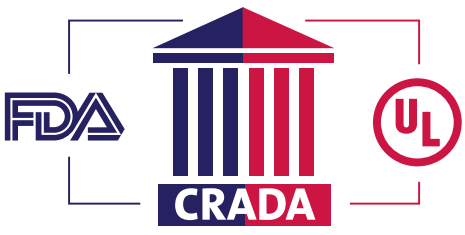
These courses target the function-specific needs of the entire organization. These GMP courses provide progressive training in areas that are of particular focus to today's European Union (EU) investigations:

- Manufacturing and Distribution
- Packaging and Documentation

FDA Partnership

These courses also provide the guidelines from the US Food and Drug Administration (FDA). 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 solution, which is available exclusively to UL's Life Science customers, provides the same level of preparedness and learning on which the FDA relies. The CRADA was recently extended through 2019 and expanded to include new technologies.

FDA CRADA



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.

This course contains European Union-specific content.

Courses Listed by Functional Area:

Global Regulatory Submissions

Manufacturing and Distribution (US and EU Regulations)

Packaging and Documentation (US and EU Regulations)

Global/ICH Regulations

Course Descriptions:

Listed Alphabetically

A Tour of Health Europe (PHDV90)

The system in Europe for ensuring safe, effective and high-quality health products is composed of national authorities in individual countries as well as bodies in the European Union and the Council of Europe.

After completing this course, participants will know the organisations that oversee the health industry in Europe and the bodies in those organisations that affected Pharmaceutical companies. In addition, participants will know the ways health products can be approved for sale to the public and the system for reporting and tracking defective products.

Topics include:

- Organisations overseeing the health industry in Europe
- How the EU works to ensure the health of Europeans
- The role of the Council of Europe
- Market authorization
- Pharmacovigilance

Application of GMPs to Analytical Laboratories (PHDV78-EU)

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-EU)

This program addresses the application of Good Manufacturing Practices (GMP) principles to Microbiology laboratories and discusses the general principles of GMPs and their importance. 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 (OOS) results

Batch Record Reviews (PHA53-EU)

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

After completing this course, you will be able to 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

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

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

Change Control (PHA35-EU)

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

Documenting the Drug Development Process (ICHQ8) (ISPE07)

In this course, the learner will be introduced to FDA guidance regarding the documentation of the Drug Development Process via the Common Technical Document. This guidance is part of the FDA's initiative to modernize the current Good Manufacturing Practices (cGMPs) and fits with other International Conference on Harmonisation (ICH) guidance on quality.

Topics include:

- CTD
- Pharmaceutical Development
- Drug Components
- Drug Product
- Manufacturing Process
- Container Closure System
- Microbial Attributes

Environmental Control and Monitoring (PHDV87-EU)

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. The European Union (EU) and FDA urge sterile product manufacturers to remain keenly aware of public health implications of distributing a nonsterile product.

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
- Personnel practices
- Cleaning methods
- Necessary contents of the environmental monitoring SOP

Failure Investigations for Pharmaceutical Manufacturers (PHA59-EU)

This course explains the GMP regulations related to failure investigations and the key components of a good investigation. After completing this course, 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:

- What events lead to a failure investigation?
- What is a root cause?
- What is a corrective action?
- Why is follow-up important in failure investigations?
- What is the purpose of an investigation report?

Global Regulatory Strategy and Planning Process (DEV54)

This course is about creating the strategy and planning documents that help companies align the development of new products with the regulatory submission process for those products. Along with the regulatory plan, a company's regulatory strategy describes the overall regulatory approach and the specific tactical steps required to meet regulatory objectives.

Gowning for Sterile Manufacturing (PHA63-EU)

In this course you will be able to identify important sources and types of contamination in a manufacturing environment, recognise the importance of health issues and personal hygiene and describe the staged entry and use of cleanrooms. You will also be able to identify important practices and procedures for proper gowning. The course covers requirements of the European Union (EU) and the FDA.

Prerequisite:

- Principles of Aseptic Processing
- Principles of Sterilisation

Topics include:

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

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

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 completeing 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).

Introduction to CFDA and CFDA Registration (PHDV97)

This course introduces the basic structure of the China Food and Drug Administration (CFDA) and the process for approving medical devices in China. The course includes a chapter on the registration process and a chapter that focuses on CFDA changes in the application process, which took effect in October 2014.

Topics include:

- QRM Process
- Medical Device Regulation
- Registration Process
- Changes to Registration
- Hurdles
- Other Issues

Japanese Medical Device and Pharmaceutical Regulations (PHDV94)

This course introduces you to the Japanese medical device regulations. You will learn about the scope and applicability of Japan's Pharmaceutical Affairs Law (J-PAL) to business processes and internal audits. The course discusses the requirements of J-PAL and how the regulations differ from ISO 13485:2003 in certain areas.

Topics include:

- History
- Approval Process
- J-PAL vs ISO 13485
- Labeling/Audits

Medical Device Filings: 510(k) PMA, and IDE (DEV53)

This course covers the premarket approval and notification processes for medical devices in the U.S. As a result of the 1976 Act, FDA now requires specific device submissions and the appropriate agency review in order to market new or modified products in the U.S. This course will provide an overview of the different submission processes and give you information on how to successfully complete them for your products. After completing this course, you will have a good overview of the essential elements of the 510(k), PMA, and IDE filing processes for medical devices under FDA.

Packaging and Labeling of Finished Pharmaceuticals (PHA39-EU)

FDA CRADA

This course examines the packaging and labeling requirements 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 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

Principles of Aseptic Processing (PHDV71-EU)

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 Sterilisation (PHDV81-EU)

FDA CRADA

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

Topics include:

- Moist Heat
- Dry Heat
- Chemical Sterilisation
- Gas Sterilisation
- Filtration
- Sterility Assurance

Q9: Quality Risk Management (ISPE09)

This course introduces the principles of Quality Risk Management (QRM) developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This course explores the definition of QRM and the basic steps of a typical QRM process. Risk management tools will also be associated to the appropriate steps of the QRM process to further comprehend how to effectively handle QRM throughout the lifecycle of a product.

Topics include:

- QRM Process
- Tools
- Applying QRM

Q10: Pharmaceutical Quality System (ISPE11)

This course describes a model for an effective quality management system for the Pharmaceutical industry. The course is based on guidance developed by the ICH. The guidance is supported by the Food and Drug Administration (FDA) and is representative of their current thinking on this topic.

Topics include:

- Enablers
- Management
- Product Lifecycle
- Process Performance
- Corrcetive and Preventitive Action (CAPA) and Change
- Management Review
- Regulatory Improvement

Quality Systems Approach (ISPE10)

The FDA is continuing to modernize its approach to GMPs for Pharmaceutical and Biologic companies, as initially outlined under the “cGMPs for the 21st Century” initiative. This course explains the basis for this significant shift in FDA regulatory approach to manufacturing practices, outlines what it means for regulated industries and provides examples of actions that the FDA has already taken to implement its quality systems expectations.

Topics include:

- cGMP Overview
- Quality Concepts
- Quality Systems
- Quality Systems Model
- Resources
- Manufacturing
- Quality Evaluation

Regulatory Requirements for Medical Devices in the Republic of Korea (DEV58)

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

Course chapters focus on the registration process, testing Procedures, and the customs clearance schedule. This course also focuses on Class II devices and how to determine the device type before undertaking the correct registration process.

Topics include:

- Framework
- Definitions
- Registration
- Testing Procedures
- Post-Market Regulation
- KGMP
- Upcoming Changes

The Approval Process for New Medical Devices (DEV47)

FDA CRADA

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

Topics include:

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

Understanding the GMP Requirements for Facilities and Equipment (PHDV63-EU)

FDA CRADA

Facilities and equipment GMP requirements impact many aspects of plant operation – from setup to maintenance and cleaning. This interactive programme introduces the general layout and equipment used within a Pharmaceutical or Medical Device manufacturing plant. The course covers requirements of the European Union (EU) and the FDA.

Topics include:

- Facilities
- Cleanliness
- Process Flow
- Equipment
- Maintenance
- Calibration
- Cleaning

Validation of Analytical Laboratory Procedures (ISPE08)

This course introduces developers and those individuals involved in validation of analytical methods to the regulatory requirements for the validation of analytical laboratory procedures. After taking this course, you will be able to identify the purpose and benefits of validation, determine when validation is necessary and recognize common approaches to these activities.

Topics include:

- Validating Processes
- Specificity
- Linearity and Range
- Accuracy and Precision
- Detection/Quantitation
- Robustness
- Revalidation

About UL EduNeering

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a premier global independent safety science company that has championed progress for 120 years. Its more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

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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