LIBRARY GUIDE:
FDA Inspections and Enforcement
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Overview:

The US Food and Drug Administration (FDA) Office of Regulatory Affairs (ORA) has entered into a unique relationship with UL as the only company selected for a technology Cooperative Research and Development Agreement (CRADA). Under the CRADA, UL EduNeering provides the online training, documentation and technology-enabled management system for “ORA-U,” the FDA’s virtual university.

The FDA uses ORA-U to train and certify more than 30,000 federal, state and local inspectors and investigators. To date, more than 100,000 learning activities in areas such as Good Manufacturing Practices (GMP), Good Clinical Practices (GCP) and Good Laboratory Practices (GLP) have been created. 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.

FDA Partnership

UL’s Cooperative Research and Development Agreement (CRADA) with the FDA has enabled that agency 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 to 2019 and expanded to include new technologies.

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

LEGEND:

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

Course is available in one or more foreign languages. Download Language Options for a Global Workforce for details.
Course Descriptions by Functional Area:

Basics of Inspections:

Basics of Inspections: Beginning an Inspection (FDA38)
This is the first of two courses designed to inform the learner of the basic practices implemented during an inspection of a food establishment. This lesson explores the preparation needed before an inspection and identifies pre-inspection issues. This course also explores the many elements of a Hazard Analysis Critical Control Point (HACCP) plan that must be evaluated during pre-inspection.

Topics include:
- Preparing for an inspection
- Pre-Inspection issues
- HACCP
- Product protection — factors leading to hazardous food

Basics of Inspections: Issues and Observations (FDA39)
This is the second of two courses designed to inform the learner of the basic practices implemented during an inspection of a food establishment. This course explores the issues and observations that must be examined during an inspection, including: processing equipment, employee practices, food storage/display, water supply, plumbing and pest control.

Topics include:
- Employee practices
- Processing equipment
- Storing and displaying food
- Cross-contamination
- Chemical and physical hazards
- Final elements evaluated at the beginning of an inspection

Courtroom Testimony (FDA46)
This course will introduce you to your role if you are called as a FDA witness. The course will help you distinguish among grand jury, deposition, declaration and courtroom testimony. The lesson also discusses how to: prepare for testimony; identify the fundamental characteristics of appropriate courtroom conduct; and identify the components of effective testimony.

Topics include:
- Types of testimony
- Preparation
- Conduct
- Water supply
- Food sampling
- Inspection report
- Closing conference

Destruction and Reconditioning (FDA33)
It is imperative that violative articles be removed from the market place to protect consumers from harm and, in the case of some labeling violations, fraud or economic loss. FDA personnel are called upon to witness the destruction or reconditioning of violative products. The destruction and reconditioning of products are provided for in Sections 304 and 801(b) of the Food, Drug and Cosmetic (FD&C) Act.

After completing this course, you will be able to identify the circumstances and procedures under which articles may be destroyed or reconditioned.

Topics include:
- Destruction and reconditioning
- Claimant’s options for dealing with seized articles
- Imported products that are detained
- Voluntary correction
- Procedures for products damaged in a disaster
- Reconditioning procedures for specific products and types of damage
Basics of Inspections – continued:

**Enforcement of the Postmarketing Adverse Drug Experience Reporting Regulations (FDA64)**

The FDA’s Postmarketing Adverse Drug Experience Reporting Program (PADE) represents the Center for Drug Education Research’s (CDER) current thinking on how field postmarketing Acceptable Daily Exposure (ADE) reporting inspections support CDER’s drug-safety surveillance activities.

The course provides an overview of PADE regulations, guidance, inspectional candidate selection, inspectional techniques and regulatory actions to enhance the field investigator’s knowledge. It discusses how CDER’s medical reviewers and safety evaluators track drug products for potential safety signals and how field investigators determine if drug firms are providing the FDA with complete, accurate and timely safety data necessary for this evaluation.

**Evidence and Proof (FDA22)**

The FDA takes action based on information collected and developed by investigational and analytical personnel. The FDA’s ability to perform its function is based on the quality and care used in collecting and preserving information. Information is evidence; obtaining it properly is a vital portion of the FDA’s law enforcement work. This course explores the different types of evidence and how to collect and preserve this evidence. You will learn the importance of clearly documenting all processes involved in collecting and testing evidence. The learner will become familiar with the different types of proof required in FDA cases. After completing this course, you should be able to recognize the processes involved in gathering evidence and proof and the circumstances under which both can be used.

**FDA 483s: Inspectional Observations (FDA30)**

This course is designed to familiarize FDA staff with the history of the FDA 483 (Inspectional Observations) form, when it is issued to the inspected firm’s management and how an FDA 483 can be annotated. After completing this course you will recognize the purpose of issuing an FDA 483. You will identify the kinds of inspectional observations that are included on an FDA 483 when it is issued to the inspected firm and how to annotate it during the discussion with management.
FDA Establishment Inspection (EI) (FDA32)

FDA findings during establishment inspections prevent violative and potentially dangerous products from reaching the consumer. It is for this reason that all FDA inspectors, investigators and analysts understand the fundamentals of performing an FDA establishment inspection and identifies the FDA’s statutory authority. After completing this course, you will recognize the basics of FDA establishment inspections including the procedures for preparing, initiating, conducting and concluding an inspection.

Topics include:
• FDA establishment inspections
• Conducting establishment inspections
• Preparing for an establishment inspection
• Procedures for initiating an inspection
• Handling inspection refusals

FDA Establishment Inspection Report Writing (FDA26)

This course will familiarize FDA staff members who will conduct establishment inspections with the purpose of the Establishment Inspection Report (EIR), what should be included in the report and how to make the report readable. The course will also provide an introduction into the new “Turbo EIR” concept as a work in progress. After completing this course you should understand why the FDA prepares reports using a standard format, what that format is and how to make your reports readable. You will also be able to identify additional formats and alterations for the EIR.

Topics include:
• Scope
• Preparation
• Readability
• Additional formats

FDA Good Guidance Practices (GGPs) (FDA21)

This course on FDA Good Guidance Practices (GGPs) explains which Agency documents are considered guidance documents. It also explains why we have GGPs, their legal effect, how they are developed and implementation. After completing this course, you will be able to describe the history, development, issuance and use of Agency guidance. You’ll also learn how and why GGPs were established.

This training fulfills a statutory requirement for the FDA.

Topics include:
• Guidance documents
• GGPs origins
• Implementing GGPs
• Issuing guidance documents
• How guidance documents differ from regulations
Basics of Inspections – continued:

Failures Investigations for Medical Device Manufacturers (DEV45)

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

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

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

Field Examinations (FDA28)

Field examinations help to ensure the safety, purity and effectiveness of products that are released for public use. Field exams cover the entire spectrum of FDA-regulated products, including foods, animal and human drugs and devices, biological products, electronic products for compliance with the Radiation Control Standards and cosmetics for label standards. This course is designed to familiarize individuals with the “what, why and when” of conducting examinations of products while performing inspections, sample collections or surveillance activities.

In this course you will learn the basics of field examinations, the purpose and when they must be conducted. In addition, you will also learn about the types of field examinations, the equipment commonly used and how these examinations are conducted.

Topics include:
• A field examination
• When to conduct a field examination
• Types of equipment used when conducting a field examination
• Conducting a field exam
The FDA acts as a public health protector by ensuring that all products within its jurisdiction are safe and effective. Authority to do this comes from the 1938 Federal Food, Drug and Cosmetic (FD&C) Act. Title 21 of the Code of Federal Regulations contains the regulations enforced by the FDA. Where felonies are associated with violations of the FD&C Act and its implementing regulations, the FDA has a number of statutes at its disposal. Title 18 (Crimes and Criminal Procedures) of the United States Code (USC) provides many of these statutes. This course will describe several felony criminal statutes available for use by the FDA that are not part of Title 21 of the USC. These are statutes that have been used in the past and are most likely to be used for felony violations associated with Title 21 criminal prosecutions. After completing this course, you should understand what constitutes criminal felony behavior, the means by which the FDA proves criminal intent and specific elements of proof for the statutes covered in this course.

Topics include:
- Felony criminal behavior
- False statements
- Mail and wire fraud
- Obstruction of justice and witness tampering, conspiracy and aiding and abetting
- Proving intent

The FDA has undertaken the task of protecting, promoting and enhancing the health of the American public. The FDA started out with very little power; but over the years its authority has evolved and increased as a result of the establishment of various laws and regulations. These laws and regulations have increased FDA jurisdiction, empowering it to regulate foods, drugs, medical devices, biological products and cosmetics. This course is one in a series of five law courses. After completing this course, you should be able to recognize the scope and limits of FDA jurisdiction and how products are regulated within the different industries.

Topics include:
- The evolution of FDA jurisdiction over foods, drugs, devices and cosmetics
- The responsibilities of the FDA to ensure safe, pure and effective products
- How the FDA regulates foods
- How the FDA regulates drug products
- How the FDA regulates medical devices
- How FDA regulates cosmetics
- The limits of FDA jurisdiction
Basics of Inspections – continued:

Food and Drug Law: Imports and Exports (FDA05)

Did you know that 50 percent of the products you use every day are imported? It’s the FDA’s mission to enforce the Federal Food, Drug and Cosmetic (FD&C) Act, also called the “Act,” and other laws designed to protect the health, safety and wallet of our #1 customer, the consumer! The FD&C Act applies to imported as well as domestic products.

This course is designed to help you become familiar with the primary statutory requirements of the law along with the practical application of key provisions. This course also reviews additional agency rules and interpretations of the provisions of Chapter 8.

Prerequisite:
• FDA Jurisdictions and FDA Prohibited Actions

Topics include:
• Imports and exports
• Primary agencies that regulate imports and exports of FDA-regulated products
• Related agencies that monitor imports
• Nongovernment entities involved in import process
• Samples and violative sample
• Preventing violative products from entering the US
• Key regulatory and statutory provisions

Food and Drug Law: Judicial Actions (FDA03)

The FDA is responsible for the safety, effectiveness and proper manufacturing and labeling of a broad range of products, including items as diverse as artificial hearts, blood, lasers, microwave ovens and vaccines. This course will address the types of judicial actions, both criminal and civil, that are available to the FDA as part of its law enforcement armory in the event it encounters suspected violations of the Food, Drug and Cosmetic (FD&C) Act. You’ll learn how the FDA is empowered to take judicial action and what criminal and civil penalties may be imposed for violations of the FD&C Act and related laws.

Topics include:
• How the FDA is empowered to take judicial action
• Federal law enforcement procedures
• Laws enforced by the FDA
• Criminal penalties available to the FDA
• Civil penalties available to the FDA
The FD&C Act specifically describes what actions are violations and who will be held accountable for those actions. FDA investigators must have a thorough understanding of these sections of the law or they will not be able to determine, or adequately document, when a violation has occurred. All FDA enforcement actions are associated with specific prohibited acts and/or violations of the sections of the Act that define adulteration, misbranding or lack of required approval. After completing this course, you will recognize some of the specific acts that are prohibited under the Federal Food, Drug and Cosmetic (FD&C) Act. You will be able to identify the most commonly violated acts and recognize how the FDA determines who is responsible. Finally, you will be able to identify major cases that establish consequences for committing prohibited acts and recognize what these consequences may be.

**Topics include:**
- Common violations under the law
- Consequences of committing a prohibited act or marketing an adulterated, misbranded or unapproved product
- Who can be held responsible for violating a prohibited act
- Critical court cases that helped FDA define responsibility

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

**Topics included:**
- Personnel Conduct
- Inspection Types
- The Process
- Records
- Samples and Photos
- Enforcement
- End of Inspection

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

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

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

**References:**
Food, Drug and Cosmetic (FD&C) Act
Investigations Operations Manual (IOM)
DHRD Basic Investigative Interviewing Course
Basics of Inspections – continued:

MDR Regulation 1: Overview and General Provisions (FDA63)
This course discusses the origin and evolution of the Medical Device Reporting (MDR) regulation. It describes the key characteristics of the MDR and its preamble, as well as the key terms used in the MDR. It also explores to whom the MDR applies and who can be exempt. The MDR regulation provides one mechanism for the FDA and manufacturers to identify and monitor significant adverse events involving medical devices. The goal of the regulation is to detect and correct product problems in a timely manner.

Topics include:
- Origin
- Characteristics
- Key Terms
- Compliance
- Foreign Manufacturers
- Exemptions

MDR Regulation 2: Device User Facility, Importer and Manufacturer Reporting Requirements (FDA65)
This course discusses important terms crucial to understanding the Medical Device Reporting (MDR) regulation. It also discusses the MDR requirements as they relate to user facilities, importers and manufacturers. It explores the requirements for MDR procedures and event files.

Topics Include:
- Definitions
- User Facility
- Importers

MDR Regulation 3: Requirements for Individual Adverse Event Reports (FDA66)
This course identifies how user facilities, importers and manufacturers report adverse events. It explores the proper forms to use to report adverse events, as well as the timeframes for reporting. It also discusses when it is not necessary to report an event.

Topics Include:
- Reporting
- MEDWATCH
- Deadlines

Photography for FDA Enforcement (FDA47)
This course covers the legal requirements of photographing evidence for FDA investigators who take photographs for law enforcement purposes. It addresses the FDA’s authority to take pictures and covers handling film and digital images, investigative techniques, the use of close-up photography and the differences between 35 mm and digital cameras.

Topics include:
- Authority
- Coverage
- Techniques
- Digital Cameras
- Evidence

References: This course incorporates information from the Investigations Operations Manual (IOM), 2003.
Recalls of FDA Regulated Products (FDA24)

Because recalls of FDA-regulated consumer products have continued to increase on an annual basis, the monitoring of recalls of potentially hazardous consumer products is one of the most important activities performed by FDA personnel. This course helps you recognize the FDA's definition of a product recall and the contents of a Recall Letter, as well as the types, depth and classification of a recall and the responsibilities of FDA personnel during a product recall.

Topics include:
- Product recalls
- Factors leading to product recalls
- Classifying product recalls
- Recall Letter
- Responsibilities of FDA personnel during a recall
- Recall audit check

Sample Collections (FDA23)

Samples are the starting point for nearly all actions taken by the FDA. Samples may prove a violation, interstate commerce, jurisdiction and responsibility, the four elements of proof required for most FDA actions. This course explores sample collection as a critical responsibility of field personnel. It explains the purpose of sampling and covers how to properly perform sampling. You’ll recognize the reasons for collecting and maintaining samples and identify the major samples types, as well as the differences between domestic and import samples. You will recognize how to prepare and conduct proper sampling. Finally, you will be able to identify the appropriate steps for submitting a sample.

Topics include:
- Reasons for collecting samples
- Sample types
- Preparing for sample collection
- Determining sample size
- Sampling techniques
- Conducting sampling
- Sample submission
- Maintaining sample validity

Special Investigations (FDA25)

This course provides an overview of the broad spectrum of investigations performed by the FDA. These investigations include consumer complaints, disaster investigations, surveillance, health fraud, tampering and criminal investigations.

After completing this course, you will be able to identify the purpose of special investigations. You will also learn the properties of special investigations as well as what to look for during each of these investigations.

Topics include:
- Investigations
- Complaint investigations
- Surveillance investigations
- Disaster investigations
- Health fraud investigations
- Product tampering investigations
- Criminal investigations

Systems-Based Drug Inspections (FDA55)

This course is intended to introduce the FDA Drug Manufacturing Inspections program. The course covers systems inspections, including the specifics that an inspection should cover for each system. It also covers the importance of a firm operating in a state of control and discusses what can happen if a firm is found to be out of control.

Topics:
- Quality
- Facilities and Equipment
- Materials
- Production
- Packaging and Labeling
- Laboratory Control
Import Operations:

Import Operations 1: Background (FDA37)

This is the first in a series of three courses that addresses FDA import and export programs, procedures and policies. Its purpose is to introduce the FDA import program and to familiarize the learner with the application of the law to products that are offered for entry into the US and intended for export from the US. This course includes information on key references, laws and regulations related to imports. Learners should complete five courses in the Food and Drug Law series (FDA Jurisdictions, Criminal Acts Violations, Imports and Exports, Judicial Actions and Prohibited Actions), as well as the courses Sample Collection and Field Examinations, before taking this course.

Import Operations 2: The Process (FDA42)

The second in the series, this course addresses pre-entry activities, types of entries, admissibility decisions and resources that help the FDA make sound admissibility decisions. The course also addresses the evaluation of entries, laboratory analysis and what happens to products after examination. After completing this course, you will recognize how the FDA regulates imported products and decides which products to admit. You will also recognize the process of import operations and how the FDA enforces regulations if problems arise.

Topics include:

- The FDA approach to ensuring imported products meet US public health standards
- The FD&C Act and the treatment of foreign and domestic products
- Sections of the FD&C Act on imports and exports
- Sections of 21 CFR that address imports and exports of FDA-regulated products
- Sections of 19 CFR that address customs enforcement of imports and exports
- Sections of 18 USC that address criminal activity associated with imports and exports
- Guidance and policy documents that provide more information about import and export operations

Prerequisites:

- Import Operations 1: Background
- Food and Drug Law courses: (FDA Jurisdictions, Criminal Acts Violations, Imports and Exports, Judicial Actions and Prohibited Actions)
- Sample Collection
- Field Examinations

Topics include:

- How the FDA regulates imported products before entry into the US
- Types of entries for imported products
- How the FDA makes entry decisions
- What resources are available to assist in determining admissibility
- Entries requiring further evaluation
- Entries requiring sample analysis
- Entries that have undergone further evaluation
- Enforcement tools available to the FDA
Import Operations 3: Other Activities (FDA43)

This is the last in a three-course series that addresses FDA import and export programs, procedures and policies. This course addresses how import filers participate in the FDA’s electronic review system, how the FDA identifies and removes violative imports and how domestic and import operations can help the FDA identify potential problems. The course also addresses the responsibilities the FDA shares with other government agencies and the provisions that allow the export of products that do not comply with the FD&C Act.

Prerequisites:
- Import Operations 1, Background and 2, The Process
- Food and Drug Law courses: (FDA Jurisdictions, Criminal Acts Violations, Imports and Exports, Judicial Actions and Prohibited Actions)
- Sample Collection
- Field Examinations

Topics include:
- How import filers participate in Operational and Administrative System for Import Support (OASIS)
- Who the FDA shares information with to identify violative imported products in the US market
- How the FDA regulates exports
- Export certificates
- Who the FDA shares responsibility with
Quality System Regulations and Inspections:

**Introduction to Quality System Regulations (QSR) (DEV43)**

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

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

**QS Regulation 1: Overview and General Provisions (QSR01)**

This course introduces the Quality System Regulation (QSR) (21 CFR Part 820) – a framework of basic requirements for manufacturers of finished medical devices. The course covers the history of the regulation, as well as its requirements, scope and key terms. The course also discusses the manufacturer’s responsibility for a quality system under this regulation.

**Prerequisite:**
- QS Regulation 1: Overview and General Provisions (QSR01)

**QS Regulation 2: Quality System Requirements (QSR02)**

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

**Prerequisite:**
- QS Regulation 1: Overview and General Provisions (QSR01)

**QS Regulation 3: Design Controls (QSR03)**

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

**Prerequisite:**
- QS Regulation 1: Overview and General Provisions (QSR01)
- QS Regulation 2: Quality System Requirements (QSR02)
QS Regulation 4: Document and Purchasing Controls (QSR04)

The fourth in a series of Quality System Regulation (QSR) courses, this course focuses on the Document Controls requirements of 21 CFR Part 820, Subpart D and the Purchasing Controls requirements of 21 CFR Part 820, Subpart E. The QSR provides a framework of basic requirements for manufacturers of finished medical devices.

Prerequisite:
• Learners should have completed QS Regulation courses 1-3.

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

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

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

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

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

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

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

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

QS Regulation 7: Corrective and Preventive Action (QSR07)

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

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

Prerequisite:
• Learners should have completed QS Regulation courses 1-6.
Quality System Regulations and Inspections – continued:

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

This course is the eighth in a series of Quality System Regulation (QSR) courses. This course focuses on Labeling and Package Control (21 CFR Part 820 Subpart K) and Handling, Storage, Distribution and Installation (21 CFR Part 820 Subpart L). The QSR provides a framework of basic requirements for manufacturers of finished medical devices. The requirements of the QSR relative to the handling, storage, distribution and installation of medical devices are intended to help ensure that medical device mix-ups, damage, deterioration, contamination or other adverse effects do not occur.

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

**Prerequisite:**
- Learners should have completed QS Regulation courses 1-7.

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

**QS Regulation 9: Records (QSR09)**

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

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

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

**Topics include:**
- General Requirements
- Device Master Records
- Device History Records
- Quality System Records
- Complaint Records
- Investigations
- Complaint Unit
QS Regulation 10: Servicing; Statistical Techniques (QSR10)

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

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

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

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

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

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

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

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

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

Prerequisite:
• Learners should have completed QSR Regulation courses 1-10.

Topics include:
• Key Terms
• Seven Subsystems
• Subsystems and QSIT
Quality System Regulations and Inspections — continued:

Quality System Inspection Technique (QSIT) (DEV42)
Manufacturing companies within the Biomedical industry are subject to routine inspections of their quality systems by the FDA. The FDA investigator(s) audits four major quality subsystems, which include: Management Controls, Design Controls, Corrective and Preventive Actions and Production and Process Controls. Quality System Inspection Technique (QSIT) is a “top-down” approach to evaluating a quality system. You will become familiar with the key objectives that an investigator will address when reviewing each subsystem. The subsystem approach focuses on the elements that are key to meeting the requirements of the Quality System Regulation (QSR).

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

QSIT 1: Beginning the Inspection (FDA50)
This is the first in a series of courses designed to instruct on the Quality System Inspection Technique (QSIT). This course provides guidance for inspecting medical device manufacturers against the Quality System Regulation, 21 CFR Part 820. After completing this course, you will be able to recognize the origin and scope of QSIT. You will also recognize the basic concepts associated with how to sample records for review during a QSIT inspection and report your findings (if necessary) in an Establishment Inspection Report (EIR).

Topics include:
- Scope
- Other considerations
- Sampling
- Reporting

QSIT 2: The Management Controls Subsystem (FDA51)
This is the second in a series of courses designed to instruct on the Quality System Inspection Technique (QSIT). The series provides guidance for inspecting medical device manufacturers against the Quality System Regulation (QSR), 21 CFR Part 820. This course will cover the inspectional objectives related to the management controls subsystem.

Prerequisites:
- QSIT 1: Beginning the Inspection
- Level I New Hire Investigator Certification
- Employees should also review The IOM (as it pertains to the inspection of Medical Device manufacturers), CP 7382.845 “Inspection of Medical Device Manufacturers,” 21 CFR Part 820 – Quality System Regulation and The Guide to Inspection of Quality Systems

Topics include:
- Discussion of each of the seven Management Controls Inspectional Objectives
**QSIT 3: Design Controls Subsystem (FDA52)**

This is the third in a series of courses designed to instruct on the Quality System Inspection Technique (QSIT). The series provides guidance for inspecting Medical Device manufacturers against the Quality System Regulation (QSR), 21 CFR Part 820. This course will cover the inspectional objectives related to the design controls subsystem.

**Prerequisites:**

- QSIT 1: Beginning the Inspection, and QSIT 2: The Management Controls Subsystem
- Level I New Hire Investigator Certification
- Employees should also review The IOM (as it pertains to the inspection of Medical Device manufacturers), CP 7382.845 “Inspection of Medical Device Manufacturers,” 21 CFR Part 820 – Quality System Regulation and The Guide to Inspection of Quality Systems

**Topics include:**

- Beginning to inspect the Design Controls subsystem
- The design plan review
- The inputs and outputs of the design process
- Assessing acceptance criteria and design verification
- Design validation
- Completing the Design Controls subsystem inspection

**QSIT 4: The Corrective and Preventive Actions Subsystem (FDA53)**

This is the fourth in a series of courses designed to instruct on the Quality System Inspection Technique (QSIT). The series provides guidance for inspecting Medical Device manufacturers against the QSR, 21 CFR Part 820. This course will cover the inspectional objectives related to the Corrective and Preventive Actions subsystem.

**Prerequisites:**

- QSIT 1: Beginning the Inspection, QSIT 2: The Management Controls Subsystem and QSIT 3: The Design Controls Subsystem
- Level I New Hire Investigator Certification
- Employees should also review The IOM (as it pertains to the inspection of Medical Device manufacturers), CP 7382.845 “Inspection of Medical Device Manufacturers,” 21 CFR Part 820 – Quality System Regulation and The Guide to Inspection of Quality Systems

**Topics include:**

- Procedures
- Problems
- Received data
- Failure investigations
- Actions
- After actions
This is the fifth in a series of courses designed to instruct on the Quality System Inspection Technique (QSIT). The series provides guidance for inspecting medical device manufacturers against the Quality System Regulation (QSR), 21 CFR Part 820. This course covers the inspectional objectives related to the Production and Process Controls subsystem.

**QSIT 5: The Production and Process Controls Subsystem (FDA54)**

**Prerequisites:**
- QSIT 1: Beginning the Inspection, QSIT 2: The Management Controls Subsystem, QSIT 3: The Design Controls Subsystem and QSIT 4: The Corrective and Preventive Actions Subsystem
- Level I New Hire Investigator Certification
- Employees should also review The IOM (as it pertains to the inspection of Medical Device manufacturers), CP 7382.845 “Inspection of Medical Device Manufacturers,” 21 CFR Part 820 – Quality System Regulation and The Guide to Inspection of Quality Systems

**Topics include:**
- Selecting a process for review
- How selected process is controlled and monitored
- How to proceed if the process is/was not operating within specified limits
- How to confirm the validation of a process when the results cannot be fully verified
- Software and personnel
Risk Management:

Risk Management 1: Key Concepts and Definitions (FDA29)

This course provides key concepts and definitions necessary to understanding Risk Management. The course focuses on Risk Management as it applies to the FDA and its regulated industries. This course is also designed to provide an understanding of Risk Management as defined by the International Organization for Standardization (ISO). You’ll be able to define risk and related terms. You will be able to identify the ways risk can be expressed, differentiate between safety and risk and describe the criteria the FDA uses to judge safety for different types of products. You will also learn the risk management process steps.

Topics include:
- Defining risk
- Calculating and expressing risk
- How the FDA relates risk to safety
- Risk management

Risk Management 2: Pharmaceutical cGMPs for the 21st Century (FDA62)

The FDA launched “Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach” in order to stay current with advances in pharmaceutical manufacturing and to effectively allocate its limited regulatory resources. This course will familiarize learners with the purpose and provisions of the initiative, why it was undertaken, its scope and goals and the progress that has been achieved.

Topics include:
- Purpose of the initiative
- Principles that guide the initiative
- Action steps the FDA has planned
- Milestones that have already been achieved
- Additional accomplishments
- Risk-based quality systems
- Future of the initiative
Validation and Part 11 Compliance:

**Computerized Systems Inspections in the Pharmaceutical Industry (ISPE03)**

This course, the third in a three-part series, has been designed by International Society of Pharmaceutical Engineers (ISPE) and UL in cooperation with the FDA/Office of Regulatory Affairs (ORA) to assist FDA personnel in recognizing the critical aspects of computerized systems in the pharmaceutical industry during Pre-Approval and routine GMP inspections. The course explains how computerized systems are used in the Pharmaceutical manufacturing process and provides an approach to inspecting these computerized systems. After completing this course, you should be able to recognize the FDA's approach to inspecting computerized systems and identify the levels of review that may be used and what comprises each level.

**Topics include:**
- How computerized systems are used in the Pharmaceutical industry
- How an investigator should approach computerized systems
- The focus of the investigator's review

**Computerized Systems Inspections in the Medical Device Industry (ISPE04)**

This course has been designed by International Society of Pharmaceutical Engineers (ISPE) and UL in cooperation with the FDA/Office of Regulatory Affairs (ORA) to assist FDA inspectors in recognizing the critical aspects of computerized systems in the Medical Device industry. The course explains how computerized systems are used in the medical device manufacturing process and provides an approach to inspecting these systems. This course does not cover the detailed review of software that forms part of a medical device; it covers only inspection of systems that automate part of the device production process or part of the quality system.

**Prerequisites:**
- Requirements for Computerized Systems Validation and Compliance
- Approach to Computerized Systems Validation and Compliance

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

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

Part 11: Electronic Records and Signatures – Application (FDA61)

This course will provide the learner with an understanding of how to implement Part 11 and what it means in terms of the FDA’s enforcement policy 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.

Topics include:
- Meeting expectations
- Records
- Security
- Electronic Signatures
- System Documentation
- Audit Trails

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

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

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

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

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