



The AdvaMed and Kaplan EduNeering Alliance Course Guide



Bringing innovation to patient care worldwide



Courses in Alphabetical Order (By Title)

A Tour of FDA

Approach to Computerized Systems Validation and Compliance

Basics of AdvaMed Code

Basics of the Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct

Bioresearch Monitoring Program (BIMO): Introduction

Complaint Management for Medical Device Manufacturers

Computerized Systems Inspections in the Medical Device Industry

Courtroom Testimony

Destruction and Reconditioning

Essentials of an Effective Calibration Program

Evidence and Proof

Failure Investigations for Medical Device Manufacturers

FDA 483s: Inspectional Observations

FDA Establishment Inspection (EI)

FDA Establishment Inspection Report Writing

FDA Good Guidance Practices (GGPs)

Field Examinations

Gowning for Sterile Manufacturing

Handling a Product Recall

Handling an FDA Inspection

ICH Q7A: Introduction and Quality Management

ICH Q7A: Resources and Materials Management

Implementing an Equipment Qualification Program

Import Operations 1: Background

Import Operations 2: The Process

Import Operations 3: Other Activities

Interviewing Techniques

Introduction to GMPs

Introduction to Medical Device Compliance

Introduction to Quality System Regulations (QSR)

Part 11: Electronic Records and Signatures — Application

Part 11: Electronic Records; Electronic Signatures

Photography for FDA Enforcement

Principles of Aseptic Processing

Principles of Auditing

Principles of Cleaning Validation

Protection of Human Subjects in Clinical Trials

QS Regulation 1: Overview and General Provisions

QS Regulation 2: Quality System Requirements

QS Regulation 3: Design Controls

QS Regulation 4: Document and Purchasing Controls

QS Regulation 5: Identification and Traceability; Production and Process Controls

QS Regulation 6: Acceptance Activities; Nonconforming Product

QS Regulation 7: Corrective and Preventive Action

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

QS Regulation 9: Records

QS Regulation 10: Servicing; Statistical Techniques

QS Regulation 11: Application and Inspection of QS Regulation

QSIT 1 - Beginning the Inspection

QSIT 2 - The Management Controls Subsystem

QSIT 3 - Design Controls Subsystem

QSIT 4 — The Corrective and Preventive Actions Subsystem

QSIT 5 — The Production and Process Controls Subsystem

Quality System Inspection Technique (QSIT)

Recalls of FDA Regulated Products

Requirements for Computerized Systems Validation and Compliance

Risk Management 1: Key Concepts and Definitions

Risk Management 2: Pharmaceutical cGMPs for the 21st Century

Sample Collections

Special Investigations

Courses in Alphabetical Order (By Title)

A Tour of FDA

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

Take a virtual ‘tour’ of 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

Approach to Computerized Systems Validation and Compliance

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, biologics, and medical devices that are required to meet FDA's regulations. It outlines the kind of organization, policies and procedures, and plans 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. Before taking this course, you should have successfully completed Requirements for Computerized Systems Validation and Compliance.

Topics include:

- Description of a suitable framework for successful validation and compliance
- Planning and reporting requirement 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 & FDA Staff, FDA CDRH & CBER Jan. 2002
- Guidance for Industry — Part 11; Electronic Records; Electronic Signatures — Scope and Application (currently in draft), February 2003
- GAMP 4: GAMP Guide for Validation of Automated Systems, ISPE 2001
- Guideline on General Principles of Process Validation, FDA May 1987
- Guide to Inspection of Computerized Systems in Drug Processing, FDA ORA February 1983
- Software Development Activities, FDA ORA July 1987
- Glossary of Computerized System and Software Development Terminology, FDA ORA August 1995

Note: Content for this course is provided by the International Society of Pharmaceutical Engineers (ISPE) and reviewed by the US Food and Drug Administration as a result of a CRADA between EduNeering and FDA.

Basics of AdvaMed Code (MDSM01)

The Advanced Medical Technology Association (“AdvaMed”) represents companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities (“Medical Technologies”) in order to enable patients to live longer and healthier lives(collectively “Companies,” and individually “Company”).

On December 18, 2008 AdvaMed approved a major update of its Code of Ethics on Interactions with Health Care Professionals (the “Code”). It is crucial for all Medical Technology Companies to understand the guidelines and how they impact interactions with Health Care Professionals.

The term “Health Care Professional” (“HCP”) is defined broadly in the Code and includes persons and entities involved in the provision of patient care and involved in the decision to purchase, lease, or recommend a Medical Technology. These individuals may include purchasing agents, physician practice managers and management within group purchasing organizations.

It is also important to remember that some HCPs are also government employees. More restrictive legal restrictions may apply to such individuals.

After completing this course, you will understand how the AdvaMed Code guides your interactions with HCPs. This updated Code contains important revisions and new provisions including: Further clarifies and distinguishes between appropriate and inappropriate interactions between HCPs and represen-

tatives of Medical Technology Companies; A new Code compliance section that will list Companies that certify their adoption of the Code. This list will be available on the AdvaMed website; A prohibition on providing entertainment or recreation to HCPs, as well as a prohibition on gifts; Guidelines for entering into royalty arrangements with HCPs; Parameters for the provision of evaluation and demonstration products; An expanded section addressing the provision of objective reimbursement, coverage and health economics information to HCPs.

Topics include:

- AdvaMed Code
- Company Conducted Product Training and Education
- 3rd Party Educational Conferences and Business Meetings
- Consulting Arrangements
- Evaluation and Demonstration Products
- Modest Meals, Prohibition on Entertainment and Gifts
- Coverage and Reimbursement
- Grants and Donations

Basics of the Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct (MDSM03)

The Massachusetts Department of Public Health promulgated the Massachusetts Pharmaceutical and Medical Device Manufacturer Conduct Regulation 105 CMR 970.000 to implement the provisions of an Act enacted by the legislature to promote cost containment, transparency and efficiency in the delivery of quality health care. The regulation is intended to benefit patients, enhance the practice of medicine, and ensure that the relationship between manufacturers and health care practitioners does not interfere with the independent judgment of health care practitioners.

Although the 105 CMR 970.000 Regulation has similar provisions to the recently revised AdvaMed and PhRMA Codes of Ethics, it imposes a number of additional restrictions on pharmaceutical and medical device manufacturing companies' (including distributors') interactions with health care practitioners. The regulation also requires these companies to disclose annually certain payments to health care practitioners. These changes will directly affect how you and your company conduct business with Massachusetts-licensed health care practitioners.

The Massachusetts Regulation has the full force of law, including significant fines for non-compliance. You may be required to certify to the Massachusetts Department of Public Health that it

has a Code of Conduct in compliance with the regulation, has adopted training programs, and has procedures for conducting investigations of non-compliance. Your company must also provide the Department with the contact information of the Compliance Officer responsible for certifying compliance with the Regulation.

Topics include:

- Applicability
- Requirements
- Prescriber Data
- Contracts, Audits, and Meals
- CME
- Other Payments
- Disclosure of Payments

Bioresearch Monitoring Program (BIMO): Introduction

This is the first in a series of courses that provide an overview of FDA's Bioresearch Monitoring (BIMO) program and the methods and techniques used in conducting and reporting Nonclinical Laboratory, Clinical Investigator, Institutional Review Board (IRB), Sponsor/Monitor, and in vivo Bioequivalence inspections. This course provides an overview and historical perspective of FDA's BIMO program.

Topics include:

- Evolution of FDA's regulatory history
- BIMO terminology
- The purpose of FDA's BIMO program
- Regulations and expectations that are part of FDA's BIMO program
- How FDA implements the clinical BIMO program

References:

- FDA BIMO Compliance Program at <http://www.fda.gov/ora/cpgm/default.htm#bimo>

Complaint Management for Medical Device Manufacturers

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

Topics include:

- The FDA's definition of a complaint

- Effective complaint handling systems, including CAPA
- Complaint file maintenance
- Investigating a complaint
- Requirements of the MDR regulation
- Analysis of complaint data

Computerized Systems Inspections in the Medical Device Industry

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

Prerequisite:

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

Topics include:

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

References:

- 21CFR Part 820—Quality System Regulation, www.access.gpo.gov/nara/cfr/waisidx_00/21cfr820_00.html
- Compliance Program Guidance Manual: Inspection of Medical Device Manufacturers (CP7382.845), www.fda.gov/ora/cpgm/default.htm
- General Principles of Software Validation, www.fda.gov/cdrh/comp/guidance/938.html
- GAMP4 Guide for Validation of Automated Systems (ISPE, 2001)
- Guideline on General Principles of Process Validation, www.fda.gov/cdrh/ode/425.pdf
- Glossary of Computerized System and Software Development Terminology, www.fda.gov/ora/inspect_ref/jgs/gloss.html

Content for this course is provided by the International Society

of Pharmaceutical Engineers (ISPE) and reviewed by the US Food and Drug Administration as a result of a CRADA between EduNeering and FDA.

Courtroom Testimony

This course will introduce you to your role if you are called as an FDA witness. The course will help you distinguish among grand jury, deposition, declaration, and courtroom testimony. The course 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
- On the stand
- After testifying

References:

- FDA Investigations Operations Manual, Chapter 7, Subchapter 700
- “How To Be A Good Witness” by Robert M. Spiller Jr., Office of Chief Counsel, FDA presented at FDA New Employee Course, May 3, 2001
- “Court Testimony” ST-1910 Federal Law Enforcement Training Center, Office of General Training, Legal Division 8-82
- FDA Regulatory Procedures Manual, Chapter 6, Injunctions
- FDA Regulatory Procedures Manual, Exhibit 6-18
- 28 United States Code 1746

Prerequisites:

- The pre-requisites for this course include:
- The Tour of FDA
- Orientation to FDA/ORA Fieldwork
- Expected Conduct of FDA Personnel
- Food and Drug Law: FDA Jurisdictions
- Food and Drug Law: Prohibited Actions
- Food and Drug Law: Criminal Acts Violations
- Food and Drug Law: Judicial Actions
- Food and Drug Law: Imports and Exports
- Evidence and Proof
- FDA Establishment Inspections
- FDA Establishment Inspection Reports
- Sample Collection
- Preparation of Analytical Worksheets (ORA U).

Destruction and Reconditioning

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, from 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 Act (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 specific types of damage

References:

- Food, Drug, and Cosmetic Act, Sections 304 and 801(b)
- Investigations Operations Manual (IOM), Chapters 7 and 9
- Regulatory Procedures Manual (RPM), Chapters 8 and 9
- Compliance Policy Guide (CPG) 7153.04 and 7153.14

Essentials of an Effective Calibration Program

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 the 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 included:

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

References:

- 21 CFR 211.67, 21 CFR 211.68, and 21 CFR

211.160(b)(4), 21 CFR 820.72

- ANSI/NCSL Z540-1-1994, Calibration Laboratories and Measuring and Test Equipment — General Requirements
- ISO 10012-1:1992(E), Quality Assurance Requirements for Measuring Equipment — Part 1: Metrological Confirmation System for Measuring Equipment
- ISO/IEC Guide 25 — 1990, General Requirements for the Competence of Calibration and Testing Laboratories

Evidence and Proof

FDA takes action based on information collected and developed by investigational and analytical personnel. 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 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.

Topics include:

- Evidence
- Physical evidence
- Photographic evidence
- Written or printed evidence
- Types of testimony
- Elements of proof
- Actions within FDA's jurisdiction

References:

- Federal Food, Drug, and Cosmetic Act (FD&C Act)
- Investigations Operations Manual (IOM) Subchapters 311, 410, 430, 450, and 520, Chapter 6 and Chapter 7
- Evidence and Proof (FDA/ORA publication)
- Federal Rules of Evidence
- Federal Rules of Criminal Procedure
- Federal Rules of Civil Procedure
- Regulatory Procedures Manual (RPM)
- Compliance Policy Guides (CPGs)
- Compliance Program Guidance Manual (CPGM)

Failure Investigations for Medical Device Manufacturers

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 included:

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

References:

- 21 CFR Part 820.100

FDA 483s: Inspectional Observations

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.

Topics include:

- Purpose of an FDA 483
- Objectionable condition
- Reportable Conditions
- Commandments

- Annotation

References:

- Federal Food, Drug, and Cosmetic Act (FD&C Act)
- Inspections Operations Manual (IOM)
- Compliance Program Guidance Manual (CPGM)
- 21 CFR (Code of Federal Regulations)

FDA Establishment Inspection (EI)

FDA's 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. This course identifies FDA's statutory authority in conducting establishment inspections. 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
- Observations during an inspection
- Procedures for gathering evidence
- Interviewing facility personnel
- Procedures for concluding the inspection

References:

- Food, Drug, and Cosmetic (FD&C) Act
- Investigations Operations Manual (IOM)
- Compliance Program Guidance Manual
- Regulatory Procedures Manual

FDA Establishment Inspection Report Writing

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 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

References:

- IOM 590–Reporting
- IOM 559–Device Inspection Reports
- IOM 549–Establishment Inspection Reporting (Drugs)
- IOM 539.2–Reporting (Foods)

FDA Good Guidance Practices (GGPs)

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 GGP implementation. This training fulfills a statutory requirement for the agency. After completing this course, you will be able to describe the history, development, issuance, and use of agency guidance, and you’ll learn how and why GGPs were established.

Topics include:

- Guidance documents
- GGPs origins
- Implementing GGPs
- Issuing guidance documents
- How guidance documents differ from regulations

References:

- Federal Food, Drug, & Cosmetic Act, Section 701 (h)
- 21 CFR Part 10.115
- FDA home page (www.fda.gov)

Field Examinations

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 course focuses on the purpose of field examinations and when they must be conducted. In addition, you will also learn about the types of field examinations, the equipment commonly used during field examinations, 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

References:

- The course will focus on Chapters 4, 5, and 6 of the Investigations Operations Manual (IOM) and applicable sections of the Federal Food, Drug, and Cosmetic (FD&C) Act.

Gowning for Sterile Manufacturing

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 be able to identify important practices and procedures for proper gowning. Before taking this course, make sure you have completed Principles of Aseptic Processing and Principles of Sterilization.

After completing this course, you’ll 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’ll also be able to identify practices and procedures for proper gowning.

Topics include:

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

References:

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

Handling a Product Recall

Companies undergo product recalls for various problems; it could even happen to your 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's 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 product recall
- Effect a recall on a company
- Who a company must communicate with during a recall

References:

- This course addresses key aspects of the following:
- 21 CFR, Part 7, Enforcement Policy, and SMDA of 1990

Handling an FDA Inspection

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 FDA.

Topics included:

- 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”

ICH Q7A: Introduction and Quality Management

This is the first in a series of courses designed to instruct on current good manufacturing practices (GMPs) 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. 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 Active Pharmaceutical Ingredients.

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.

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 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.
- <http://www.fda.gov/cber/gdlns/ichactive.pdf>

Note: Content for this course was provided by ISPE and reviewed by the US Food and Drug Administration as a result of the CRADA between EduNeering and FDA.

ICH Q7A: Resources and Materials Management

This is the second in a series of courses designed to instruct on Good Manufacturing Practices (GMPs) for Active Pharmaceutical Ingredients (APIs), as set out by the 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 Active Pharmaceutical Ingredients. Learners should have completed the course ICH Q7A: Introduction and Quality Management.

After completing this course, you will be able to identify the general requirements for qualification of API manufacturing personnel. You will be able to identify the requirements for build-

ings and facilities as well as API manufacturing equipment. You will also be able to recognize materials management and warehousing and distribution procedures.

Topics:

- 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 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients
- <http://www.fda.gov/cber/gdlns/ichactive.pdf>

Note: Course content was provided by ISPE and reviewed by the US Food and Drug Administration as a result of the CRADA between EduNeering and FDA.

Implementing an Equipment Qualification Program

Equipment qualification serves as the foundation for several currently recognized health care industry compliance requirements, such as analytical method, process, cleaning, and automated systems validation. A well-developed and established equipment qualification program allows a company to meet current GMP requirements and save operational costs at the same time. This course is designed to provide an introductory overview of the equipment qualification requirements that apply to the pharmaceutical, biotechnology, and medical device industries.

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

Topics include:

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

Import Operations 1: Background

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.

Topics include:

- 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

References:

- FD&C Act Chapter 3—Prohibited Acts and Penalties
- FD&C Act Chapter 8—Imports and Exports
- 21 CFR—Food and Drugs
- 19 CFR—Customs Duties
- 18 USC—Crimes and Criminal Procedure

Import Operations 2: The Process

The second in the series, this course addresses pre-entry activities, types of entries, admissibility decisions, and resources that help 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 FDA regulates imported products and decides which products to admit. You will also recognize the process of import operations and how FDA enforces regulations if problems arise.

Learners should complete Import Operations 1: Background, as well as five courses in the Food and Drug Law series (FDA Jurisdictions, Criminal Acts Violations, Imports and Exports,

Judicial Actions, and Prohibited Actions), Sample Collection, and Field Examinations, before taking this course.

Topics include:

- How FDA regulates imported products before entry into the US
- Types of entries for imported products
- How 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 FDA

References:

- FD&C Act Chapter 3—Prohibited Acts and Penalties
- FD&C Act Chapter 8—Imports and Exports
- 21 CFR—Food and Drugs
- 19 CFR—Customs Duties
- 18 USC—Crimes and Criminal Procedure

Import Operations 3: Other Activities

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 FDA's electronic review system, how FDA identifies and removes violative imports, and how domestic and import operations can help FDA identify potential problems. The course also addresses the responsibilities FDA shares with other government agencies, and the provisions that allow the export of products that do not comply with the FD&C Act.

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), Sample Collection, Field Examinations, and the first two Import Operations courses before taking this course.

Topics include:

- How import filers participate in OASIS
- Who FDA shares information with to identify violative imported products in the US market
- How FDA regulates exports
- Export certificates
- Who FDA shares responsibility with

References:

- Federal Food, Drug, and Cosmetic (FD&C) Act
- Guidance for Industry FDA Export Certificates

Interviewing Techniques

Interviews are an important part of virtually every operation performed by FDA inspectors, investigators, and analysts. Interviews are conducted during inspections, sample collections, recalls, and special investigations; therefore, it is important that FDA field personnel possess good interviewing skills and develop them as they move forward in their careers. After completing this course you will be able to recognize the fundamentals of conducting an effective interview. You will be able to identify the traits of a successful interviewer and the importance of appropriate interpersonal skills. You will also be able to identify appropriate questioning techniques to use in an interview.

Topics include:

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

References:

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

Introduction to GMPs

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

Introduction to Medical Device Compliance (MDSM05)

This course provides high level introduction and background regarding the compliance environment affecting the medical device industry. These topics are especially important in our

industry, as the development of medical device products involves a close collaboration between the industry and health-care professionals, and their use may require the interaction and skill of medically trained personnel.

This course is designed to make employees aware of pertinent laws, regulations and industry guidance that regulate the medical device industry.

Topics include:

- Food and Drug Administration (FDA) regulations
- The Federal Anti-Kickback Statute
- The Office of the Inspector General (OIG) Compliance Program Guidance
- AdvaMed Code of Ethics
- Foreign Corrupt Practices Act (FCPA)
- False Claims Act
- State Ethics and Compliance Legislation

Introduction to Quality System Regulations (QSR)

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

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

References:

- 21 CFR Parts 808, 812, 820, 820.20, 820.25, 820.30, 820.40, 820.70, 820.100, 820.120, 820.130

Note: This course is available in multiple languages.

Part 11: Electronic Records and Signatures – Application

This course will provide the learner with an understanding of how to implement Part 11 and what it means in terms of 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, August 2003.

Topics include:

- Identify Steps to prepare for an inspection
- Security
- Electronic Signatures
- System Documentation
- Audit Trails

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 Kaplan EduNeering in collaboration with EduQuest, Inc.

Part 11: Electronic Records; Electronic Signatures

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 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

Regulatory Reference:

- 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 EduNeering in collaboration with EduQuest, Inc.

Photography for FDA Enforcement

This course covers the legal requirements of photographing evidence for FDA investigators who take photographs for law enforcement purposes. It addresses 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 cameras and digital cameras.

Topics include:

- Authority
- Coverage
- Techniques
- Digital Cameras
- Evidence

References:

- This course incorporates information from the Investigations Operations Manual (IOM), 2003.

Principles of Aseptic Processing

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 a 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 Good Manufacturing Practice Regulations (GMPs) as they apply to aseptic processing.

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 7356.002A Guide to Evaluation of Sterile Process Inspections
- Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice, August 2003

- current USP

PHDV71-EU contains the same content as noted above, and also includes these references:

- E. C. Guide to Good Manufacturing Practice Revision to Annex 1, Manufacture of Sterile Medicinal Products, September 2003
- EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use

Principles of Auditing

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 program of 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.

At the conclusion of this program, you will be able to discuss the importance of an effective audit program, the benefits that can result, actual conduct of an audit, and how proper corrective action and follow-up yield the ultimate benefits of the program.

Topics include:

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

References:

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

Principles of Cleaning Validation

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 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 Standard Operating Procedure is necessary
- Assessing “clean”
- Testing for chemical residues
- Proving methods
- Acceptance limits
- Testing and monitoring the cleaning procedures
- Control and monitoring procedures

Reference:

- 21 CFR Part 211
- FDA Guide to Inspections of Validation of Cleaning Processes
- Amendments to the current Good Manufacturing Practices Regulations for Finished Pharmaceuticals: Final Rules effective December 8th, 2008
- Guidance for Industry: CGMP for Phase 1 Investigational Drugs—July, 2008

Protection of Human Subjects in Clinical Trials

This course provides the learner with a working knowledge of informed consent regulations, Institutional Review Board / Independent Ethics Committee responsibilities, and the obligations of the individuals responsible for protecting patient rights and welfare.

Topics include:

- Protecting subjects
- Consent forms
- Consent process
- Consent exceptions
- IRB/IEC
- Responsibilities
- Procedures and records

References:

- International Conference on Harmonization (ICH) Harmonised Tripartite Guideline for Good Clinical Practice

- Declaration of Helsinki "World Medical Association, Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects, 5th revision. 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996 and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000.
- Directive 2001/20/EC of the European Parliament and the Council of 4 April 2001 OJ, 2001, L121, 34-44.
- 21 Code of Federal Regulations (CFR) Parts 50, 56, and 312
- ABPI Clinical Trial Compensation Guidelines (1991). <http://www.abpi.org.uk/>

QS Regulation 1: Overview and General Provisions

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

References Include:

- The Preamble to the QS Regulation, 61 Fed. Reg. 52601 (October 7, 1996) <http://www.fda.gov/cdrh/humfac/frqsr.html>
- Federal Food, Drug, and Cosmetic Act (Act) <http://www.access.gpo.gov/uscode/title21/chapter9.html>
- 21 CFR Part 820, The Quality System Regulation http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr820_02.html

QS Regulation 2: Quality System Requirements

The second in a series of Quality System Regulation courses, this course focuses on the management responsibility, quality auditing, and personnel requirements of 21 CFR Part 820, Subpart B. The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. Learners should complete QS Regulation 1: Overview and General Provisions before taking this course.

References Include:

- The Preamble to the QS Regulation, 61 Fed. Reg. 52601 (October 7, 1996) <http://www.fda.gov/cdrh/humfac/frqsr.html>
- Federal Food, Drug, and Cosmetic Act (FD&C Act)

http://www.access.gpo.gov/uscode/title21/chapter9_02.html

- 21 CFR Part 820, The Quality System Regulation
http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr820_02.html

QS Regulation 3: Design Controls

The third in a series of Quality System Regulation courses, this course addresses design controls requirements of the Quality System Regulation. Learners should complete QS Regulation 1: Overview and General Provisions and QS Regulation 2: Quality System Requirements before taking this course.

References Include:

- The Preamble to the Quality System Regulation, 61 Fed. Reg. 52601 (October 7, 1996)
<http://www.fda.gov/cdrh/humfac/frqsr.html>
- 21 CFR Part 820, The Quality System Regulation
http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr820_02.html

Content for this course was provided by ISPE and reviewed by the US Food and Drug Administration as a result of a CRADA between EduNeering, Inc. and FDA

QS Regulation 4: Document and Purchasing Controls

The fourth in a series of Quality System Regulation (QS Regulation) 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 QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. Learners should complete QS Regulation 1: Overview and General Provisions, QS Regulation 2: Quality System Requirements, and QS Regulation 3: Design Controls before taking this course.

References Include:

- The Preamble to the QS Regulation, 61 Federal Register 52601 (October 7, 1996)
<http://www.fda.gov/cdrh/humfac/frqsr.html>
- 21 CFR Part 820, The Quality System Regulation
http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr820_02.html

QS Regulation 5: Identification and Traceability; Production and Process Controls

The fifth in a series of Quality System (QS) Regulation 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 QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices.

The purpose of the Production and Process Controls requirements of the QS Regulation (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 Controls requirements of the QS Regulation.

Learners should complete the previous courses in the series before taking this course.

References Include:

- 21 CFR Part 820, The Quality System Regulation -
http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr820_02.html
- 21 CFR Part 820, The Quality System Regulation and Preamble- <http://www.fda.gov/cdrh/humfac/frqsr.html>

QS Regulation 6: Acceptance Activities; Nonconforming Product

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

References Include:

- 21 CFR Part 820, The Quality System Regulation
http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr820_02.html
- 21 CFR Part 820, The Quality System Regulation and Preamble
<http://www.fda.gov/cdrh/humfac/frqsr.html>

QS Regulation 7: Corrective and Preventive Action

The seventh in a series of Quality System (QS) Regulation courses, this course focuses on Corrective and Preventive Action (21

CFR Part 820 Subpart J). The QS Regulation 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 Quality System (QS) Regulation 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 QS Regulation. Learners should complete the previous courses in the series before taking this course.

References Include:

- 21 CFR Part 820, The Quality System Regulation
http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr820_02.html
- 21 CFR Part 820, The Quality System Regulation and Preamble
<http://www.fda.gov/cdrh/humfac/frqsr.html>

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

This course is the eighth in a series of Quality System (QS) Regulation 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 QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. The requirements of the QS Regulation 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 QS Regulation.

Learners should complete the previous courses in the series before taking this course.

Topics include:

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

References Include:

- 21 CFR Part 820, The Quality System Regulation - http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr820_02.html
- 21 CFR Part 820, The Quality System Regulation and Preamble- <http://www.fda.gov/cdrh/humfac/frqsr.html>

QS Regulation 9: Records

The ninth in a series of Quality System (QS) Regulation courses, this course focuses on Records (21 CFR Part 820 Subpart M). The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices.

One of the basic themes of the Quality System Inspection Technique (used during inspections of medical device manufacturers) is the "Establish Test." The QS Regulation requires many procedures to be "established" and defines "establish" as "define, document (in writing or electronically), and implement." Records play a vital role in 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 QS Regulation.

Learners should complete the previous courses in the series before taking this course.

Topics include:

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

References Include:

- 21 CFR Part 820, The Quality System Regulation
http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr820

_02.html

- 21 CFR Part 820, The Quality System Regulation and Preamble

<http://www.fda.gov/cdrh/humfac/frqsr.html>

QS Regulation 10: Servicing; Statistical Techniques

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

Statistical techniques may be employed to fulfill a number of QS Regulation requirements. Where statistical techniques are used, manufacturers must establish procedures for identifying valid statistical techniques.

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

Learners should complete the previous courses in the series before taking this course.

Topics include:

- Key Terms
- Servicing Requirements
- Analysis
- Statistical Techniques

References Include:

- 21 CFR Part 820, The Quality System Regulation
http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr820_02.html
- 21 CFR Part 820, The Quality System Regulation and Preamble
<http://www.fda.gov/cdrh/humfac/frqsr.html>

QS Regulation 11: Application and Inspection of QS Regulation

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

During inspections, FDA will assess whether a manufacturer has

established procedures and followed requirements that are appropriate to a given device under the current state-of-the-art manufacturing for the specific device.

After completing this course, you will be familiar with the application and interrelationship of QS Regulation 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

Learners should complete the previous courses in the series before taking this course.

Topics include:

- Key Terms
- Seven Subsystems
- Subsystems and QSIT

References Include:

- 21 CFR Part 820, The Quality System Regulation
http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr820_02.html
- 21 CFR Part 820, The Quality System Regulation and Preamble
<http://www.fda.gov/cdrh/humfac/frqsr.html>

QSIT 1 - Beginning the Inspection

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

References:

- 21 CFR Part 820, The Quality System Regulation
(http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr)

820_02.html)

- Guide to Inspections of Quality Systems (http://www.fda.gov/ora/inspect_ref/igs/qsit/qsitguide.htm)

QSIT 2 - The Management Controls Subsystem

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, 21 CFR Part 820. This course will cover the Inspectional Objectives related to the Management Controls subsystem. Employees should complete QSIT 1: Beginning the Inspection prior to taking this course. They must also complete the Level I New Hire Investigator Certification. Employees should 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 a discussion of each of the seven Management Controls Inspectional Objectives.

References:

- 21 CFR Part 820, The Quality System Regulation http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr820_02.html
- Guide to Inspections of Quality Systems http://www.fda.gov/ora/inspect_ref/igs/qsit/qsitguide.htm
- CP 7382.845, "Inspection of Medical Device Manufacturers" http://www.fda.gov/ora/cpgm/7382_845/html/7382_845_cover_page.html

QSIT 3 - Design Controls Subsystem

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, 21 CFR Part 820. This course will cover the inspectional objectives related to the Design Controls subsystem. Before taking this course, you must complete Level I New Hire Investigator Certification and 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. You must have completed QSIT 1 - Beginning the Inspection and QSIT 2 - The Management Controls Subsystem.

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

Regulatory Reference:

- 21 CFR Part 820, The Quality System Regulation http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr820_02.html
- Guide to Inspections of Quality Systems http://www.fda.gov/ora/inspect_ref/igs/qsit/qsitguide.htm

QSIT 4 – The Corrective and Preventive Actions Subsystem

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 Quality System Regulation, 21 CFR Part 820. This course will cover the inspectional objectives related to the Corrective & Preventive Actions subsystem. Before taking this course, you must complete Level I New Hire Investigator Certification and 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. You must also have completed QSIT 1 – Beginning the Inspection, QSIT 2 – The Management Controls Subsystem, and QSIT 3 – The Design Controls Subsystem.

Topics include:

- Procedures
- Problems
- Received data
- Failure investigations
- Actions
- After actions

Regulatory Reference:

- 21 CFR Part 820, The Quality System Regulation (http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr820_02.html)
- Guide to Inspections of Quality Systems (http://www.fda.gov/ora/inspect_ref/igs/qsit/qsitguide.htm)

QSIT 5 – The Production and Process Controls Subsystem

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, 21 CFR Part 820. This course covers the inspectional objectives related to the Production and Process Controls subsystem. Before taking this course, you must complete Level I New Hire Investigator Certification and 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. You must also have completed 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.

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

Regulatory Reference:

- 21 CFR Part 820, The Quality System Regulation (http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr820_02.html)
- Guide to Inspections of Quality Systems (http://www.fda.gov/ora/inspect_ref/igs/qsit/qsitguide.htm)

Quality System Inspection Technique (QSIT)

Manufacturing companies within the biomedical industry are subject to routine inspections of their quality systems by 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. 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.

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 Subsystem (P & PC)

References:

- 21 CFR Part 7
- 21 CFR Parts 803, 806, 820, 821

Recalls of FDA Regulated Products

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 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

Regulatory Reference:

- Chapter 8 of FDA’s “Investigations Operations Manual”
- Chapter 8 insert of the Investigator Training Manual: Recalls

References:

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

Requirements for Computerized Systems Validation and Compliance

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
- IQ, OQ, and PQ as related to computerized systems validation
- FDA's expectations for validation activities and documentation

References:

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

Note: Content for this course is provided by the International Society of Pharmaceutical Engineers (ISPE) and reviewed by the US Food and Drug Administration as a result of a CRADA between EduNeering and FDA.

Risk Management 1: Key Concepts and Definitions

This course provides key concepts and definitions necessary to understand Risk Management. The course focuses on Risk

Management as it applies to 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 FDA uses to judge safety for different types of products. And you'll learn the risk management process steps.

Topics include:

- Defining risk
- Calculating and expressing risk
- How FDA relates risk to safety
- Risk management

Regulatory Reference:

- 21 CFR Parts 56, 312, 314, 812, 814, and 821
- ISO 14971

Risk Management 2: Pharmaceutical cGMPs for the 21st Century

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 is a follow up to Risk Management 1 and focuses on the importance of the FDA initiative Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach. 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 FDA has planned
- Milestones that have already been achieved
- Additional accomplishments
- Risk-based quality systems
- Future of the initiative

Sample Collections

Samples are the starting point for nearly all actions taken by 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 differ-

ences 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

References:

- IOM chapters 4, 7, and 9
- FD&C Act sections 702 and 704

Special Investigations

This course provides an overview of the broad spectrum of investigations performed by 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

References:

- FD&C Act
- Investigations Operations Manual (IOM) Ch. 7 & 9
- Compliance Program Guidance Manual
- Regulatory Procedures Manual
- Compliance Policy Guide Manual
- Federal Anti-Tampering Act
- Field Management Directive (FMD) 130 Official Establishment Inventory (OEI)



About Kaplan EduNeering

Kaplan EduNeering (www.kaplaneduneering.com) is part of Kaplan, Inc., a worldwide education services leader and a subsidiary of The Washington Post Company (NYSE: WPO). Kaplan EduNeering develops technology-enabled knowledge solutions for improving business performance and assuring regulatory compliance.

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