

# On-Site GMP Training

GMP ◊ COMPLIANCE ◊ TECHNICAL

523 N Bay Avenue  
North Massapequa, NY  
11758



**Phone:** 516-752-2558  
**Fax:** 516-752-8931  
[www.gmpseminars.com](http://www.gmpseminars.com)

## Key to Level of Program

- Level A: Program includes advanced or technical information, and is suitable for all levels of plant personnel.
- Level B: Program prepared specifically for line employees. Some of the information may be too basic for higher level personnel. Supervisors are encouraged to attend the programs with their employees to show support for the program, and to answer specific questions relating to their departmental operations.

## Company Background

### PharmaNet, Inc.

PharmaNet, Inc. was incorporated in the State of New York in 1989. PharmaNet specializes in the development and presentation of seminars, education programs and courses associated with the good manufacturing compliance requirements for the pharmaceutical and active pharmaceutical ingredients industries. PharmaNet also customizes and presents these courses and programs at the client's sites. PharmaNet, Inc. holds an Incorporation Certificate Filing Consent from the State of New York in accordance with section 216 of the New York State Education Law.

### Training and Education

Education programs offered by PharmaNet have been carefully selected to fulfill training and education needs in specific areas. Program selection and course contents are usually determined based on industry surveys which show that no similar programs, or programs with the same quality level, are being offered by other industry organizations. The main objective of our educational programs is practical and current application. We fulfill this objective by recruiting instructors who are recognized experts in their field of interest, with hands-on practical industry experience, and/or regulatory experience from their previous employment with the Food and Drug Administration.

### Quality of Training

The small size of our company and the limited number of programs that we offer allow us the opportunity to review each program carefully to ensure that the quality level exceeds industry standards. The typical overall ratings of our programs by our course attendees range between 1 to 2 (1=Excellent, 2=Very Good, 3=Good, 4=Average, 5=Poor).

# Good Manufacturing Practices (GMPs)

## GMP COMPLIANCE

- GMP Origin
- Reasons for Compliance
- Review the Major Requirements of Each Subpart
- The Five Major Objectives of GMP Compliance
- How to Comply With GMPs

Approx. Time: 90 min.  
Level: B  
Module: A-1

## GMP INTERPRETATIONS

- Basic Rules for Interpreting GMP Requirements
- FDA References for GMP Interpretations

Approx. Time: 45 min.  
Level: A  
Module: A-2

## GMP DOCUMENTATION AND SOP REQUIREMENTS

- Review Basic Elements for GMP Documentation
- Recommendations for Level of Details in SOPs
- Requirements for Second Person Checking
- Review the Interpretations for Selected GMP Records
- Discussion of Recordkeeping Deficiencies to Avoid

Approx. Time: 75 min.  
Level: B  
Module: A-3

## GMP REQUIREMENTS FOR STERILE PRODUCTS

- Basic Requirements for Sterile Products
- Environmental Requirements and Controls
- Aseptic Filtration
- Terminal Sterilization
- Depyrogenation
- Time Limitation
- Validation

Approx. Time: 2 hrs.  
Level: B  
Module: A-4

## STERILE DRUG PRODUCTS PRODUCED BY ASEPTIC PROCESSING cGMP

- Revised Guidance, 9/2004 - review of selected revisions
  - Environmental classifications, requirements and monitoring
  - Media fills
  - Isolators

Approx. Time: 30 min.  
Level: A  
Module: A-27

## ASEPTIC TECHNIQUES AND TRAINING

- Generation of Particulates
- Interruption of Laminar Flow
- Contamination Control
- FDA Guidance
- Cleanroom Behavior

Approx. Time: 45 min.  
Level: B  
Module: A-25

## GMPs FOR ACTIVE PHARMACEUTICAL INGREDIENTS: A COMPARATIVE REVIEW

- Departmental Responsibilities
- Second Person Checks
- Equipment Qualification
- Raw Material Control
- Productions, Packaging and Distribution
- Laboratory Controls
- Product Annual Review

Approx. Time: 60 min.  
Level: A  
Module: A-9

## GMP FOR EXECUTIVE MANAGEMENT

- GMP Objectives
- GMP Interpretations
- Current Compliance Issue
- FDA Expectations for Executive Management
- Management Responsibilities
- Management Support for Compliance

Approx. Time: 2 hrs.  
Level: A  
Module: A-10

\*There is an additional fee of \$1,000 for this module.

## GMP REQUIREMENTS FOR CALIBRATION AND MAINTENANCE

- GMP Requirements
- Recommendations for Program Implementation
- Calibration and Maintenance Records

Approx. Time: 90 min.  
Level: B  
Module: A-16

## GMP REQUIREMENTS FOR BUILDINGS AND UTILITIES

- Basic GMP Review
- Requirements for Facilities
- Requirements for Systems and Utilities (HVAC, dust collection, compressed air, water)

Approx. Time: 60 min.  
Level: B  
Module: A-20

## LABEL CONTROLS

- Master Label Controls
- GMP Requirements for Packaging and Labeling
- GMP Compliance Interpretations for Labeling Controls
- Proposed GMP Revisions for Cut Labeling

Approx. Time: 60 min.  
Level: B  
Module: A-5

## COMPLIANCE REVIEW FOR CHANGE CONTROL PROGRAM

- FDA Expectations and Compliance Issues
- Basic Elements
- Documentation Requirements
- Evaluation of Changes

Approx. Time: 45 min.  
Level: A  
Module: A-24

## U.S. VS. BARR LABORATORIES

- Laboratory Retest Policy
- Manufacturing Controls
- Failure Investigations
- Cleaning Validation
- Manufacturing Process Validation

Approx. Time: 45 min.  
Level: A  
Module: A-15

## FDA COMPLIANCE/INSPECTION TRENDS AND ISSUES (WITHIN PREVIOUS TWO YEARS)

- Drug Recalls
- FDA Compliance and Enforcement Trends
- FDA Inspection Programs and Trends
- CBER Enforcement and Inspection Trends (where available)
- Recent GMP Interpretations (where available)
- New/Proposed Regulations and Guidance

Approx. Time: up to 3 hrs.  
(based on a selection of topics)  
Level: A  
Module: E-9

\*There is an additional fee of \$1,000 for this module. Requests for this module should be confirmed at least one month prior to presentation.

## Clinical Supplies and Research & Development

### GMP REQUIREMENTS AND COMPLIANCE ISSUES FOR CLINICAL SUPPLIES

Approx. Time: 90 min.  
Level: A  
Module: A-6

- FDA Inspection Policy
- GMP Applications to Clinical Supplies
- GMP Interpretations for Clinical Supplies
- Change Control and Reporting
- Bio-Sample Retention Requirements

### DEVELOPMENT AND TECHNOLOGY TRANSFER REPORTS

Approx. Time: 75 min.  
Level: A  
Module: A-11

- FDA Recommendations
- Preparation and Contents of Development and Technology Transfer Reports

### GOOD DOCUMENTATION PRACTICE AND COMPLIANCE REVIEW FOR RESEARCH AND DEVELOPMENT

Approx. Time: 90 min.  
Level: A  
Module: A-19

- Development and Technology Transfer Supports
- Good Research and Development Documentation Practices
- Good Science Systems and Practices
- Research and Development Support for FDA Pre-approval Inspection

## Part 11 and Other FDA GMP Initiatives

### ELECTRONIC RECORDS AND ELECTRONIC SIGNATURES - MARCH 20, 1997

Approx. Time: 3 hrs.  
Level: A  
Module: A-23

- Comprehensive review of the regulations and interpretations for each subpart
- Includes module A-28

### PART 11 GUIDANCE - ELECTRONIC RECORDS AND SIGNATURES

Approx. Time: 30 min.  
Level: A  
Module: A-28

- Part 11 Guidance 8/2003
- FDA Enforcement Discretions for Selected Areas

### PROCESS ANALYTICAL TECHNOLOGY (PAT)

Approx. Time: 20 min.  
Level: A  
Module: D-20

- Definitions and Scope
- Principles and Tools
- PAT Implementation Plans

## FDA Inspections

### FDA ORGANIZATION, INSPECTION AUTHORITY AND INSPECTION PROCEDURES

- FDA Field Office Responsibilities
- FDA Investigator Training and Qualifications
- FDA Inspection Authority and Jurisdiction
- FDA Inspection Program
- FDA Procedures, Tactics and Follow-up

Approx. Time: 75 min.

Level: A

Module: E-4

### PREPARATION FOR AND HANDLING FDA INSPECTIONS

- Establishment of Company Policy and Procedures
- Logistics and Document Organization
- Personnel Training
- FDA Escort Team Qualifications
- Escort's Handling of Inspection and Responsibilities
- Discussion with Management (Exit Interview)

Approx. Time: 75 min.

Level: A

Module: E-7

### FDA INSPECTIONS: DOs AND DON'Ts

- Basic Inspection Behaviors
- Answering Questions
- Reviewing Records with the Investigator
- Volunteering Information
- Recommendations

Approx. Time: 60 min.

Level: B

Module: E-8

### PREPARATION FOR AN FDA PRE-APPROVAL INSPECTION (PAI)

- FDA Pre-approval Inspection Program
- Preparation for the PAI
- Preparation for the PAI: Organization and Strategy
- Handling the PAI Inspection
- DOs and DON'Ts for the PAI

Approx. Time: 60 min.

Level: A

Module: E-10

### INTERNATIONAL INSPECTIONS

- FDA Organization and Field Office Roles
- FDA Inspection Guidance and Manuals
- Inspection Authority, Procedures and Coverage
- FDA Forms, Sample/Records Collections
- Discussion with Management
- Inspection Report

Approx. Time: 75 min.

Level: A

Module: E-12

\* If a topic of interest is not included in the program listing, we may be able to develop a customized program to meet your needs.

## Comprehensive Courses

### CGMP: INTERPRETATION AND APPLICATION

Pharmaceutical GMP requirements, as specified in 21CFR211, are general and subject to interpretation. The FDA stated that the GMP was intentionally written as such to allow the pharmaceutical industry the flexibility to apply the GMP in a manner appropriate for each specific operation. To keep pace with the rapid technological advances in the industry since the 1978 GMP revision, the FDA has been supplementing the GMP with interpretive guides, guidelines and policy statements to keep it current and to ensure its applicability to current industry operations and practices.

This course will focus on the FDA's current interpretation of the GMP regulation with an in-depth review of the agency's regulations, guidances, inspection guides, compliance policy guides, compliance programs, proposed rules, publications and policy statements. Each section of the GMP regulations is reviewed along with the FDA's interpretations of that section. An integral part of this course is the intensive class work to enhance the interpretation and practical application of the GMP requirements.

#### LEARNING OBJECTIVES

This course will provide the attendees with a practical understanding of the GMP regulations. They will be familiar with the available FDA documents and references that are essential for GMP interpretation, and the compliance and legal impact behind each of these references. The attendees will learn how to effectively use the FDA documents and references to provide an official interpretation of GMP requirements, and interpret and apply GMP regulations to specific operations and unique situations. This practical knowledge and understanding of the GMP regulations will provide the attendee with the skills to effectively communicate and negotiate with the FDA on GMP compliance issues.

#### WHO SHOULD ATTEND

This is an essential course for professionals who are responsible for GMP Compliance and Auditing, Quality Assurance and Regulatory Affairs. Production and support personnel, as well as those who need to interact with the FDA on GMP compliance issues, would benefit significantly from this course.

#### COURSE OUTLINE

- ◇ Review of GMP Regulations, FDA Publications and Other Sources of GMP Interpretations
- ◇ Basic Techniques for GMP Interpretation
- ◇ GMP Interpretation by Subpart with FDA References
  - ⇒ GMP Preamble
  - ⇒ FDA Guidances
  - ⇒ ICH Guidelines (where applicable)
  - ⇒ FDA Inspection Guides
  - ⇒ FDA Compliance Programs
  - ⇒ FDA Compliance Policy Guides
  - ⇒ FDA Inspection Guides
  - ⇒ Other FDA Publications; e.g. FDA cGMP notes
- ◇ Review of FDA Inspectional Observations and Warning Letter Citations
- ◇ Class Exercises on Practical Application and Interpretation of GMPs

Approx. Time: 3 days

Level: A

Module: S-1

Instructor: John Y. Lee

## BATCH RECORD REVIEW AND INVESTIGATIONS

This course concentrates on the practical applications of GMP and FDA compliance requirements, from the batch record review process to final batch disposition. It begins with practical instructions and techniques for conducting a technical batch record review and identifying batch related discrepancies. The course then shifts to the follow-up investigation of discrepancies noted from batch production and testing and the decision making process for the final disposition of the batch (i.e., release, reject or rework).

The course lecture provides the attendees with technical knowledge and understanding of the compliance requirements, and “how-to” instructions for batch record review and follow-up investigations. This is achieved by focusing on the interpretation of the GMPs and FDA requirements, using FDA references, industry practices, FDA-483 citations and “real-life” experiences. The knowledge acquired from the lecture is, then, applied to class workshops to enhance the practical skills for conducting batch record reviews, identifying significant discrepancies, conducting the necessary follow-up investigations and making the appropriate decision for batch disposition.

All topics and workshops in this course include examples for sterile and non-sterile products.

### LEARNING OBJECTIVES

This course will teach the attendees how to perform a technical review of batch records to detect hidden compliance and quality problems. They will also acquire the skills to conduct the appropriate follow-up investigation and make the final decision or recommendations.

### WHO SHOULD ATTEND

This course is intended for Production, Quality Assurance and Compliance personnel who are responsible for making batch record entries and performing reviews and compliance investigations. This course is suitable for both entry-level batch record reviewers and compliance personnel, as well as advanced-level personnel, including supervisors and managers.

### COURSE OUTLINE

- ◇ GMP Requirements for Batch Records
- ◇ Recommendations for Reviewing Batch Records
- ◇ Training Batch Record Reviewers
- ◇ Variance/Deviation/Non-Conformity Systems
- ◇ Compliance Requirements for Follow-up Investigations
- ◇ Evaluation of Investigation Findings
- ◇ Review Examples of Investigation
  - ⇒ Laboratory out-of-specification test results
  - ⇒ Dissolution test failure
  - ⇒ Sterility test failure
  - ⇒ Labeling and product reconciliation discrepancies
  - ⇒ Labeling and product mix-ups
- ◇ Compliance Issues for Product Reprocessing/Rework
- ◇ Preparing the Investigation Report
- ◇ Class Workshop: Variance/Deviation/Non-conformity Classification
  - ⇒ When to classify and document an “event” as a Deviation/Variance/Non-conformity
- ◇ Class Workshop: Batch Record Review
  - ⇒ Recognizing batch record discrepancies and GMP compliance deficiencies
  - ⇒ Identifying the potential causes for the follow-up investigation
- ◇ Class Workshop: Conducting an Investigation
  - ⇒ Investigating an LAL failure in water-for-injection system
  - ⇒ Investigating a content uniformity failure

Approx. Time: 2 ½ days

Level: A

Module: S-2

Instructor: John Y. Lee

## GMP COMPLIANCE AUDITING

Although quality and compliance auditing is not specifically required by drug GMPs, it has been an integral element of many pharmaceutical operations. The FDA has always expected self-audit programs and has criticized companies for failing to conduct such audits. This course will discuss some of the practical and proven techniques for conducting effective audits of various pharmaceutical operations, to identify the critical deficiencies associated with GMP compliance and product quality.

### LEARNING OBJECTIVES

Attendees will gain practical knowledge in establishing an effective GMP compliance audit program and auditor training program. They will learn practical skills for conducting GMP compliance audits, and know what to look for when conducting audits of various pharmaceutical operations. They will be familiar with the audit tools that are available to them. Attendees will also have a chance to review and discuss current GMP compliance issues.

### WHO SHOULD ATTEND

This course is intended for professionals who are responsible for GMP Compliance and Auditing, at both the beginner and advanced levels. Production and Quality professionals will benefit by learning the potential problem areas so that appropriate actions can be taken. Regulatory professionals who are responsible for FDA inspections and contact should also attend.

### COURSE OUTLINE

- ◇ Compliance Audit Program
  - FDA/GMP Requirements and Audit Focus for Contractors
- ◇ FDA/GMP Requirements and Audit Focus for Contractors
- ◇ Auditor Training and Audit Tools
- ◇ General Compliance Auditing
  - ⇒ Raw material control
  - ⇒ Weighing and dispensing
  - ⇒ Manufacturing controls
  - ⇒ Packaging and labeling controls
  - ⇒ Calibration and maintenance programs
  - ⇒ Quality Assurance programs
- ◇ Auditing Chemical/Biological APIs
- ◇ Auditing Validation and Qualification Studies
- ◇ Auditing Purified Water Systems

Approx. Time: 2 days

Level: A

Module: S-4

Instructor: John Y. Lee

## GMP COMPLIANCE AND AUDITING FOR STERILE PHARMACEUTICALS

This course reviews and interprets the current FDA compliance requirements for the production and control of sterile pharmaceuticals, and discusses the practical techniques for conducting an effective and efficient audit.

The topics selected for this course include the GMP compliance requirements for various aseptic processing controls; a compliance and technical review of aseptic filtration, lyophilization technology, and HVAC and WFI systems; and the current compliance issues for isolator technology, media fill, and microbiological environmental monitoring.

### LEARNING OBJECTIVES

This course will provide the attendees with the GMP compliance and technical knowledge to evaluate the controls for sterile pharmaceuticals and ensure compliance with FDA requirements.

### WHO SHOULD ATTEND

This course is intended for Compliance Auditors, Quality Assurance and Production professionals. Regulatory Affairs and Research and Development professionals involved in the support for sterile pharmaceuticals should also attend.

### COURSE OUTLINE

- ◇ Sterile Product Processing Controls
- ◇ Sterilization Parameters: Practical Applications of F, D & Z Values, Including Class Exercises
- ◇ Designing, Validating and Revalidating Sterilization Cycles
- ◇ Environmental Requirements for Clean Rooms
- ◇ Microbiological Monitoring for Sterile Operations
- ◇ Disinfection and Sanitization (D&S) Programs
- ◇ Aseptic Filtration
- ◇ Media Fill: Validation Requirements and Recommendations
- ◇ Water-for-injection System
- ◇ Lyophilization Technology
- ◇ Isolators

Approx. Time: 2 ½ days

Level: A

Module: S-5

Instructor: John Y. Lee

## GMP COMPLIANCE FOR QUALITY CONTROL LABORATORY OPERATIONS

This course reviews the GMP requirements, and their interpretation and application to quality control chemistry and microbiology laboratory operations. The topics include the essential laboratory systems, programs and procedures, the current GMP compliance issues, and the FDA's expectations for laboratory systems and controls.

### WHO SHOULD ATTEND

This course is intended for the Quality Control, Quality Assurance and Compliance professionals who are directly involved with laboratory operations, or responsible for the compliance and auditing of laboratory systems and controls. The information in this course may be beneficial for Regulatory Affairs professionals who are responsible for FDA submissions.

### COURSE OUTLINE

- ◇ USP Interpretations
- ◇ Laboratory Walk-through Inspection Coverage
- ◇ General GMP Requirements and Laboratory Controls
  - ⇒ Samples, reagents and reference standards
  - ⇒ Instrument calibration, maintenance, qualification and logbooks
  - ⇒ Investigations and change control
  - ⇒ Personnel qualification and training
  - ⇒ Stability program
  - ⇒ Raw material reduced testing program
  - ⇒ Retention sample program
- ◇ Microbiology Laboratory Controls
  - ⇒ Media control and media growth promotion, sterility testing, methods validation
- ◇ Laboratory Procedures and Documentation
  - ⇒ SOPs, raw data, electronic records
- ◇ Laboratory Data Integrity Case Studies
- ◇ Analytical Methods Validation
- ◇ Laboratory OOS: Investigation and Retesting

Approx. Time: 2 days

Level: A

Module: S-6

Instructor: John Y. Lee

## CGMP INTERPRETATIONS AND APPLICATIONS FOR BPCs AND APIs

This course supplements the “cGMP Interpretation and Application” course with the review of the current FDA requirements and expectations, and the interpretation and application of GMPs (21CFR211) for the production and control of Bulk Pharmaceutical Chemicals (BPCs) and Active Pharmaceutical Ingredients (APIs). The review and interpretations are based on published FDA and ICH guidelines and guidance documents. The main focus of this course is a comparative analysis of the published GMPs in 21CFR211 with the required and proposed GMPs for BPCs and APIs, to identify the additional GMP requirements, and the flexibility and exemptions of 21CFR211, for application to BPCs and APIs.

### LEARNING OBJECTIVES

The course participants will gain the knowledge and skills to differentiate and effectively apply the GMP requirements for the production and control of BPCs and APIs, with the support of published regulatory references.

### WHO SHOULD ATTEND

This course is intended for all Quality Assurance, Laboratory, Compliance, Production and Regulatory Affairs professionals. This course is also beneficial for professionals who support the BPC/API operations (e.g., Engineering, Purchasing and Materials Management).

### COURSE OUTLINE

- ◇ Review, interpretation and comparative analysis of CGMPs (21CFR211) for BPCs and APIs.

Approx. Time: 1 day

Level: A

Module: S-8

Instructor: John Y. Lee

## VALIDATION QUALIFICATION COMPLIANCE REQUIREMENTS

This course reviews the GMP compliance requirements for validation and qualification, and the latest FDA interpretations of these GMP requirements and issues. This course also reviews current compliance issues, such as revalidation and requalification, qualification of existing equipment, and provisions for validation/qualification matrixing and bracketing. The topics for review and discussion include process validation, installation and operation qualifications, validation documentation, cleaning validation and computer validation.

A class exercise on process validation is included to enhance the practical focus and application of this important compliance requirement.

### LEARNING OBJECTIVES

The objectives of this course are to provide the attendees with an updated review of the latest GMP requirements and FDA interpretations for validation and qualification, and practical recommendations for the most effective and efficient methods to achieve a satisfactory level of compliance.

### WHO SHOULD ATTEND

This course is suitable for professionals with a basic or advanced knowledge of GMP/FDA requirements and compliance issues for validation and qualification. The course will benefit Quality professionals with responsibility for validation compliance and auditing; and Validation, Engineering and Production professionals with responsibilities for the execution of the validation/qualification, and the preparation of related records.

### COURSE OUTLINE

- ◇ GMP Review and Interpretations for Validation and Qualification
  - ⇒ Current GMP and FDA requirements
  - ⇒ Performance qualification versus process validation
  - ⇒ Interpretation and application of commissioning, design qualification, FAT and SAT
  - ⇒ Conditions and limitations for retrospective and concurrent validations
  - ⇒ Objective and preparation of master validation plans and related records
  - ⇒ Worst-case, and bracketing and matrixing
  - ⇒ Current compliance issues
- ◇ Preparing the Validation/Qualification Protocols
- ◇ Compliance Requirements for Installation Qualification
- ◇ Compliance Requirements for Operation Qualification
- ◇ Compliance Requirements for Process Validation
- ◇ Compliance Requirements for Computer Validation
- ◇ Compliance Requirements for Cleaning Validation
- ◇ Preparing the Validation/Qualification Report

Approx. Time: 2 days

Level: A

Module: S-9

Instructor: John Y. Lee

## INTERNATIONAL GMPs: MEETING U.S. AND EUROPEAN REQUIREMENTS

Multinational manufacturing supply chains require an understanding of the similarities and differences between the European Union and the United States GMP requirements and expectations. Applying this knowledge becomes critical in designing, implementing, maintaining and auditing systems required to meet both U.S. and EU GMPs. Compliance is a business need. This course provides an in-depth interpretation and application of the U.S. and the EU GMPs by comparing and contrasting regulations and expectations for both non-sterile and sterile drug products. Current expectations and hot topics are also discussed. The role of ICH Q7a for Active Pharmaceutical Ingredient GMPs is also explored from the U.S. and EU perspectives. Practical applications, technical background, validation, regulatory compliance issues and key differences in inspection approach are some of the areas covered from both the U.S. and the EU perspectives.

### LEARNING OBJECTIVES

The goal of the course is to provide a comprehensive understanding of the differences and similarities between the U.S. and the EU GMPs in a way that will be useful for Quality, Production, Technical and Support personnel to apply within their areas of responsibility.

### WHO SHOULD ATTEND

This course is intended for Quality Assurance, Compliance, Regulatory Affairs and Production personnel responsible for implementing, operating, or approving compliance and quality programs to meet international GMP requirements. It is suitable for both entry-level as well as supervisory or managerial staff.

### COURSE OUTLINE

- ◇ Non-Sterile Drug Products
  - ⇒ Framework for U.S. and EU GMPs
  - ⇒ U.S. and EU GMPs - compare and contrast
  - ⇒ Interpretation and application of GMP requirements
  - ⇒ Inspection focus and compliance issues from U.S. and EU perspectives
  - ⇒ Qualified Persons, validation and selected topics
  - ⇒ ICH Q7a overview and application from U.S. and EU perspectives
- ◇ Sterile Drug Products
  - ⇒ U.S. and EU GMPs for sterile products - compare and contrast
  - ⇒ Interpretation and application of U.S. and EU GMPs (sterile)
- ◇ Regulatory Compliance Update
  - ⇒ Inspection focus and compliance issues
  - ⇒ Inspection process and strategies for success
  - ⇒ Update on regulatory compliance initiatives
  - ⇒ European Pharmacopoeia/USP

Approx. Time: 2 days

Level: A

Module: S-10

Instructor: John Grazal

## PRODUCT ANNUAL REVIEW WORKSHOP

This workshop begins with a review of the GMP requirements, GMP interpretations, FDA expectations and common GMP compliance problems associated with the product annual review program required by 211.180(e).

The workshop participants, working in small groups and using examples and data provided by the course instructor, will discuss the practical and effective methods for performing a product annual review. These include the selection, collection and organization of the critical information and data to perform the review; the development of specific instructions on “how to” perform the required trending for each section of the product annual review (e.g., analytical data, complaints, investigations and deviations, etc.); and “how to” prepare, and what information to include, in the product annual review report.

Each workshop participant will receive a written procedure with the necessary details on “what to” trend and “how to” trend, to ensure the performance of an effective and efficient product annual review. This written procedure will provide the critical information and details to guide the participant in the preparation of a company SOP on product annual review. Each participant will also receive an example of a product annual review report that outlines the necessary information to meet GMP requirements and FDA expectations.

### LEARNING OBJECTIVES

To provide the course participant with the practical knowledge of the GMP and FDA requirements for a product annual review program; and the necessary practical skills to perform a product annual review that will meet FDA compliance requirements and ensure product quality.

### WHO SHOULD ATTEND

This workshop is intended for the professionals who are responsible for supervising, performing, supporting, training or auditing the product annual review program.

Approx. Time: 1 day

Level: A

Module: S-11

Instructor: John Y. Lee

## A REVIEW OF CLEANROOMS AND CONTROLLED ENVIRONMENTS

### COURSE DESCRIPTION

Following good contamination control principles is critical to achieving product quality. There are currently over 40,000 standards in the field of contamination control. These standards cover cleanrooms in both the industrial and healthcare marketplace. Understanding of the standards and how they apply to the daily operations of your cleanroom and your process is the focus of this in-house course. Pharmaceutical, Biologics, Medical Devices, and associated industries have related but different requirements depending on the class of cleanroom, product and process risks, countries of export, etc. Gowning will be discussed in detail and gowning demonstrations will be presented for both sterile and non-sterile gowning. Sanitization methods will be demonstrated for wall, floors, doors and work stations.

This in-house course will provide an in-depth review of the practices required to achieve the level of product quality.

### COURSE OUTLINE

- ◇ Review of basic contamination control definitions
- ◇ Review of design basics
- ◇ People – a source of contamination
- ◇ Gowning and garment selection criteria
  - ⇒ Material testing and acceptance
  - ⇒ Gowning sequence
  - ⇒ Gowning qualification and certification
- ◇ Cleaning and sanitization
  - ⇒ Tools and equipment
  - ⇒ Methods of cleaning and sanitization
  - ⇒ Frequency determination
  - ⇒ Disinfectant selection and qualification
- ◇ Admittance of items into the controlled and classified environments
- ◇ Environmental Monitoring
  - ⇒ Comparison of monitoring regulations – EU and USA
  - ⇒ Determination of locations for monitoring
  - ⇒ Investigation of excursions

### LEARNING OBJECTIVES

This course will provide the attendees a practical understanding of cleanrooms and controlled environment operations. The students will become familiar with specific standards and the applications of these documents to their industry. This knowledge of cleanrooms and controlled environments will give the students a better understanding of the sources of contamination and how contamination can be controlled and/or eliminated. This basic knowledge can be applied to resolving CAPA and investigational issues and can assist in the determination of risk.

Approx. Time: 2 days

Level: A

Module: S-10

Instructor: Anne Marie Dixon

## Course Instructor

### PROFESSIONAL EXPERIENCE

<b>Executive Director</b> Pharmaceutical Compliance Associates North Massapequa, New York	8/91- Present
<b>Director, Quality Assurance</b> Altana, Inc. Melville, New York	3/88 - 8/91
<b>Quality Assurance Manager</b> Organon, Inc. West Orange, New Jersey	4/85 - 3/88
<b>GMP Compliance Associate</b> Ortho Pharmaceutical Corporation Raritan, New Jersey	12/83 - 4/85
<b>Consumer Safety Officer (Investigator)</b> U.S. Food & Drug Administration East Orange, New Jersey	10/77 - 12/83

### TECHNICAL EXPERIENCE

Extensive GMP auditing experience in active pharmaceutical chemicals (API) and finished pharmaceuticals, with specialization in pre-approval inspection (PAI) audits and sterile products.

Active involvement in the design, renovation and validation of sterile and non-sterile pharmaceutical facilities.

Designed validation studies, prepared validation documents and coordinated validation projects for sterile and non-sterile operations.

Developed and organized Quality Assurance operations and programs including batch record review, product annual reviews, documentation control, quality assurance investigation, auditing, vendor qualification, GMP and technical training, validation, product stability, complaint investigations, etc.

Developed and presented training programs for line personnel, supervisors and management on topics of GMP compliance, validation, quality assurance programs and sterilization science.

### COURSES AND LECTURES

Course director, symposium chairman, moderator and speaker for professional organizations:

- ▽ PharmaNet, Inc.
- ▽ Parenteral Drug Association
- ▽ The Center for Professional Advancement
- ▽ Pharm-Tech Conference
- ▽ Medical Manufacturing TechSource
- ▽ American Society for Microbiology
- ▽ Technomics
- ▽ Institute for Applied Pharmaceutical Science
- ▽ InfoScience
- ▽ Technical Seminars

### PROFESSIONAL AFFILIATIONS

- ▽ Founder of the GMP Compliance Network
- ▽ Former Vice President of the North Jersey Chapter of ISPE, and the GMP Education and Training Association
- ▽ Member of the Parenteral Drug Association

### EDUCATION

- ▽ Fairleigh Dickinson University  
Teaneck, New Jersey  
M.B.A. Pharmaceutical Studies,  
1991
- ▽ New York University  
New York, New York  
B.A. Biology, 1976

## PUBLICATIONS

- ◆ "Product Annual/Quality Review: US/EU Comparative Analysis and Interpretations," *Pharmaceutical Technology*, 32(3): 88-104, March, 2008.
- ◆ "Good Laboratory Practice (GLP) Regulations: Interpretation Techniques and Review of Selected Compliance Issues," *Drug Information Journal*, 40(1): 33-38, 2006.
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- ◆ "Validation Organization and Documentation," *Pharm Tech Japan*, 9(2):151-161, February, 1993.
- ◆ "Recent Trends in Process Validation," chapter in *Pharmaceutical Process Validation*, Marcel Dekker, Inc., New York, 573-586, 1993.
- ◆ "Validation Terminology and Concepts," *Pharm Tech Japan*, 8(9):7-16, September, 1992.
- ◆ "Sterilization Control and Validation for Topical Ointments," *Pharmaceutical Technology*, 16(3):104-110, March, 1992.
- ◆ "Product Annual Review," *Pharmaceutical Technology*, 14(4):86-92, April, 1990.
- ◆ "Investigating Sterility Test Failures," *Pharmaceutical Technology*, 14(2):38-43, February, 1990.
- ◆ "Validating an Automated Filter Integrity Test Instrument," *Pharmaceutical Technology*, 13(10):48-56, October, 1989.
- ◆ "Security for Pharmaceutical Audit Reports," *Pharmaceutical Production TechSource*, 4(6):3, June 1989.
- ◆ "Auditing an Aseptic Filtration Process," *Pharmaceutical Technology*, 13(2):66-72, February, 1989.
- ◆ "Environmental Requirements for Clean Rooms," *Bio-Pharm*, 1(7):40-43, 1988 reprinted 2(2):42-45, February, 1989.
- ◆ "GMP Compliance for the Lyophilization of Parenterals: Part II," *Pharmaceutical Technology*, 12(11):38-42, November, 1988.
- ◆ "GMP Compliance for the Lyophilization of Parenterals: Part I," *Pharmaceutical Technology*, 12(10):54-60, October, 1988.
- ◆ "Essential Elements for Establishing and Performing an Internal GMP Audit," *Pharmaceutical Manufacturing*, 3(2):18-21, February, 1986.

## Course Instructor

John Grazal

Mr. John Grazal is the Senior Director of the Global Compliance Management Group at AstraZeneca in Wilmington, Delaware. He has over 25 years of experience in the pharmaceutical industry with technical, managerial and executive responsibilities in the Quality and Compliance arenas.

John has spent a significant part of his career in Europe and continues to have close involvement with European and FDA inspections on both sides of the Atlantic. He is a frequent presenter in both Europe and the US serving as conference chairman, moderator, course instructor and speaker for the Pharmaceutical Drug Association, International Society for Pharmaceutical Engineering, PharmaNet, Inc., David Begg and Associates and numerous other organizations. John is also active in a number of industry organizations and working groups.

### EDUCATION

Florida Institute of Technology  
M.S. Systems Management

Michigan State University  
B.S. Microbiology and Public Health

## Course Instructor

Anne Marie Dixon

Anne Marie Dixon is the Managing Partner of Cleanroom Management Associates, a consulting firm that specializes in competitive benchmarking, training, and auditing of clean and aseptic operations and management.

She has been actively engaged in the field of contamination control for over two decades with extensive experience in the areas of training, technical writing, strategic consulting, facility start-up, construction protocols and process optimization.

Anne Marie was the first woman to be elected President of the *IEST* and was appointed to the position of FELLOW in 1998. She is the first recipient of the James P. Agalloco Award for Excellence in Training and is an active member of the *PDA*, *IEST*, *ISPE*, *ASQ*, *SSA* and *AMA*. She is also an ISO 9000 trained auditor. She is the head of the U.S. Technical Advisory Group - TC 209 and represents the USA on the ISO Technical Committee 209 on *Cleanrooms and Associated Controlled Environments*.

### EDUCATION

University of Illinois