

# On-Site and Remote Internet GMP Training

21 CFR 211 ◇ FDA Requirements ◇ GMP Compliance Trends

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## Key to Training Levels

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

## About PharmaNet, Inc.

PharmaNet, Inc.<sup>®</sup> was incorporated in the State of New York in 1989, and re-incorporated in the State of Nevada in 2010. We specialize in the development and presentation of training modules and courses associated with the FDA Good Manufacturing Practices (GMP) regulations and compliance requirements for the pharmaceutical and active pharmaceutical ingredients industries. Our GMP compliance training modules and courses are meticulously selected to fulfill FDA training and education requirements to assure drug product quality and GMP compliance.

The primary objective of our GMP training modules and courses focuses on the practical and current application of GMP regulations and FDA requirements, and we achieve this objective by recruiting instructors who are recognized experts with hands-on practical industry and/or enforcement (FDA) experience. The GMP training module and course contents are selected based on our reviews, which show that no similar GMP training programs, or programs with the same level of quality, are offered by other industry organizations. Our training modules and courses include official FDA published references, and FDA-483 and FDA warning letter citations to emphasize the related GMP regulations and requirements.

PharmaNet, Inc.<sup>®</sup> customizes and presents these training modules and courses at the client's site and via Internet live-streaming.

## Quality of Training

The small size of our company and the limited number of training 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 rating of our training programs by our course attendees ranges 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 GMP Subpart (A-K)
- 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 the GMP Regulations
- FDA Published References for GMP Interpretations

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

### GMP DOCUMENTATION AND SOP REQUIREMENTS

- Review the Basic Elements for Good Documentation Practices
- Controls for Raw Data
- Requirements for Personnel Identification and Second Person Checking
- Data Integrity
- Recordkeeping Deficiencies to Avoid
- Recommendations for SOPs
- Significance and Consequences of Poor Recordkeeping and Documentation

Approx. Time: 90 min.  
Level: B  
Module: A-3

### DATA INTEGRITY

- FDA Enforcement Statistics
- FDA Inspection Techniques
- FDA & MHRA Guidances and Suggestions
- Data Integrity Compliance Issues
- Examples of Recent FDA Warning Letter Citations

Approx. Time: 2 hrs.  
Level: A  
Module: A-29

### GMP REQUIREMENTS FOR CALIBRATION AND MAINTENANCE

- GMP Requirements
- Recommendations for Program Implementation
- Calibration and Maintenance Procedures and Records
- Change Control for Maintenance
- Equipment Requalification

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

### GMP REQUIREMENTS FOR BUILDINGS AND UTILITIES

- GMP Regulations Review
- Requirements for Facilities
- Design 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 Compliance Interpretations for Labeling Controls
- GMP Requirements for Packaging and Labeling Operations
- GMP Interpretations for Labeling GMP Revisions (March 2012)

Approx. Time: 75 min.  
Level: B  
Module: A-5

## Good Manufacturing Practices (GMPs)

### COMPLIANCE REVIEW FOR CHANGE CONTROL PROGRAM

- FDA Expectations and Compliance Issues
- Essential Elements for Change Control Program
- Documentation Requirements
- Review and Evaluation of Proposed Changes

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

### GMP REQUIREMENTS FOR STERILE PRODUCTS

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

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

### GMP COMPLIANCE ISSUES FOR ASEPTIC PROCESSING

- Review New and Controversial FDA Requirements and Interpretations for Aseptic Processing
  - ⇒ Facilities Design
  - ⇒ Raw material Controls
  - ⇒ Production Controls
  - ⇒ Equipment Control and Maintenance
  - ⇒ Environmental Monitoring
  - ⇒ Sterilization Validation
  - ⇒ Media Fill Validation
  - ⇒ Isolator and RABS
  - ⇒ Aseptic Processing GMP Compliance Issues

Approx. Time: 60 min.  
Level: A  
Module: A-27

### ASEPTIC TECHNIQUES

- Aseptic Area Personnel Behavior and Movements
- Maintaining Uni-directional Airflow
- Sanitization/disinfection Requirements
- Aseptic Gown and Gloves Controls
- Aseptic Area Access Control

Approx. Time: 60 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

## Good Manufacturing Practices (GMPs)

### U.S. vs. BARR LABORATORIES

- Laboratory Retest Policy (OOS)
- Manufacturing Controls
- Failure Investigations
- Cleaning Validation
- Manufacturing Process Validation

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

### FDA COMPLIANCE AND ENFORCEMENT TRENDS AND ISSUES

- Warning Letter Statistics
- Critical GMP Deficiencies
- Recurring GMP Deficiencies
- Critical and Major GMP Compliance Issues
- FDA's Focus Areas
- FDA Foreign Inspection Compliance Statistics
- Recent GMP Interpretations (when available)
- New/Proposed Regulations and Guidance (when available)

Approx. Time: 2 to 3 hrs.  
(based on 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 to allow for updates and customization.

### GMP FOR EXECUTIVE MANAGEMENT

- GMP Objectives
- GMP Interpretations
- Current Compliance Issues and Trends
- Responsible Corporate Officer (RCO) Doctrine
- FDA Expectations for Executive Management
- Management Responsibilities
- Management Support for Compliance

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

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

## 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
- FDA Pre-approval Inspection (PAI) Focus

### DEVELOPMENT AND TECHNOLOGY TRANSFER REPORTS

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

- GMP Application
- 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

- GMP Application
- Development and Technology Transfer Supports
- Good Research and Development Documentation Practices
- Good Science Systems and Practices
- Laboratory Reference Standard Controls
- Research and Development Support for FDA Pre-approval Inspection (PAI)

## Part 11

### 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

- Review of Part 11 Guidance, August 2003
- FDA Enforcement Discretions for Selected Areas

## FDA Inspections

### 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)
- Post Inspection FDA-483 Response

Approx. Time: 75 min.

Level: A

Module: E-7

### FDA INSPECTIONS: DOs AND DON'Ts

- Basic Inspection Behaviors
- Answering FDA Questions
- Presenting Records to the FDA Investigator
- Inspection Participation 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: Organization and Strategy
- Handling the PAI Inspection

Approx. Time: 60 min.

Level: A

Module: E-10

**NOTE:** 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 written 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, guidances and policy statements to maintain its currency, and to ensure its applicability to industry technology and practices.

This course will focus on the FDA's current interpretation of the GMP with an in-depth review of the agency's regulations, guidances, inspection guides, compliance policy guides, compliance programs, publications and policy statements. Each section of the GMP regulations is reviewed along with the FDA's interpretations for 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 of 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 the 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 and documentation deficiencies. The course then shifts to the follow-up investigation of discrepancies 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 and warning letter citations, and “real-life” experiences. The knowledge acquired from the lecture is, then, applied to class exercises to enhance the practical skills for conducting batch record reviews and classifying discrepancies.

All topics and batch record review exercise 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 routine and hidden compliance and quality problems. They will also acquire the skills to conduct the appropriate follow-up investigation, and make the final decision or recommendation for batch disposition.

### WHO SHOULD ATTEND

This course is intended for Production, Quality Assurance and Compliance personnel who are responsible for making batch record entries, and performing records 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
- ◇ 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
- ◇ 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

Approx. Time: 2 days

Level: A

Module: S-2

Instructor: John Y. Lee

## GMP COMPLIANCE AUDITING

Although quality and compliance auditing is not specifically required by FDA 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 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
- ◇ 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 essential GMP compliance requirements for sterilization and aseptic processing controls, facilities and equipment design, and technical information .

### LEARNING OBJECTIVES

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

### WHO SHOULD ATTEND

This course is intended for Compliance Auditors, and 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; Facilities and Equipment Design
- ◇ Aseptic Gowning and Aseptic Techniques
- ◇ Sterilization Parameters: Practical Applications of F, D & Z Values, Including Class Exercises
- ◇ Designing, Validating and Revalidating Sterilization Cycles
- ◇ Clean Rooms
  - ⇒ Design and classification, HEPA filter testing
  - ⇒ Particulate monitoring, air pressure differential, air flow
- ◇ 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 and Restricted Access Barriers (RABS)

Approx. Time: 2.5 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
- ◇ Analytical Methods Validation
- ◇ Laboratory OOS: Investigation and Retesting

Approx. Time: 2 days

Level: A

Module: S-6

Instructor: John Y. Lee

## VALIDATION AND 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.

### 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 studies, and the preparation of related records.

### COURSE OUTLINE

- ◇ GMP Review and Interpretations for Validation and Qualification
  - ⇒ Current GMP and FDA requirements
  - ⇒ Process validation and performance qualification: US/EU
  - ⇒ 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
- ◇ FDA Process Validation Guidance Revision (Jan. 2011): Review of selected topics
- ◇ Preparing the Validation/Qualification Protocols
- ◇ Compliance Requirements for Installation Qualification
- ◇ Compliance Requirements for Operation Qualification
- ◇ Compliance Requirements for Process Performance Qualification (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

## 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 Henderson, Nevada	8/91- Present
<b>Director, Quality Assurance and Quality Control</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 (Div. J&J) 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 ingredients (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, and deviation/OOS investigations.

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

- ◆ "Checklist for Computer Software Validation," *Pharmaceutical Technology*, February 2014.
- ◆ "Change Management: Common Failures and a Checklist for Improvement," *Pharmaceutical Technology Europe*, May 2010.
- ◆ "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.
- ◆ "FDA Compliance Issues For Cleaning Validation," *STP Pharma Pratiques*, 10(5): 292-295, September-October, 2000.
- ◆ "Documentation Requirements for Preapproval Inspections," *Pharmaceutical Technology*, 17(3):154-164, March, 1993.
- ◆ "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.
- ◆ "GMP Compliance for Clinical Packaging," *Pharmaceutical Manufacturing*, 2(9):34-38, September, 1985.

## Course Instructor

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

## Fee Schedule

### SELECTED TOPICS

#### FEES

- ◆ Each Day: **\$14,300.00**
- ◆ One-day program includes up to six and one-half hours (6.5) hours of lecture/training. Additional hours or part thereof - **\$2,250/hour**.

### COMPREHENSIVE COURSES

#### FEES

- ◆ CGMP: Interpretation and Application:  
3 days, **\$42,900**
- ◆ Batch Record Review and Investigations:  
2 days, **\$28,600**
- ◆ GMP Compliance Auditing:  
2 days, **\$28,600**
- ◆ GMP Compliance and Auditing for Sterile  
Pharmaceuticals:  
2.5 days, **\$35,750**
- ◆ GMP Compliance for Quality Control Laboratory  
Operations:  
2 days, **\$28,600**
- ◆ Validation and Qualification Compliance Requirements:  
2 days, **\$28,600**
- ◆ A Review of Cleanrooms and Controlled Environments:  
2 days, **\$28,600**

### TRAVEL CHARGES AND TRAINING REQUIREMENTS

- ◆ Fees do not include travel and related expenses for course instructor.
- ◆ Domestic travel charge (including Canada)  
**\$350.00 per hour**
- ◆ International travel charge (excluding Canada)
  - \* Western Europe/Mexico:  
per week or part thereof: **\$5,800**
  - \* Far East/South America:  
per week or part thereof: **\$8,700**
- ◆ Meeting site, audio/visual equipment, and lunch and refreshments for attendees to be provided by client.
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- ◆ Attendance is limited to no more than thirty-five (35) participants per training session. There is a charge for each additional participant.
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