This course focuses on developing and implementing regulated computer systems with an appropriate level of documented evidence to satisfy FDA expectations. The course targets deliverable document content and how to avoid rework and unnecessary expense through a proactive approach. The core elements of a satisfactory computer validation program will be emphasized.

Topics to be discussed include:

- The regulatory expectations for computer validation
- Relevant FDA warning letters
- The tasks and deliverables expected for computer validation
- Why validation processes vary so much
- Strategies for practical, yet defensible computer validation
- Sops required for system operation and maintenance
- 21 CFR part 11 and its implications for common regulations
- An active discussion of part 11 examples and audience questions
- The implications of GAMP 5 on computer validation and how to transition from GAMP 4
- Auditing GXP computer systems and suppliers

ABOUT CfPIE

In a life sciences industry that has faced nearly $15 billion in fines and compliance-related settlements over the last several years, The Center for Professional Innovation & Education (CfPIE) is a better alternative for maintaining high standards, protecting industry reputations, and enhancing personal growth. Since 2001, we have embraced a singular goal—to provide the highest quality education to life science professionals. Today, as the global leader in quality life sciences training, we offer the largest range of course options for professional development in pharmaceutical, medical device, biotech, and skin/cosmetics disciplines. We are dedicated to enriching that reputation by conveying content relevant to the needs of individuals and organizations facing intense scrutiny in those highly technical disciplines.

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INSTRUCTOR CREDENTIALS

Dr. Raymond Miller is President of Miller Regulatory Consulting (MRC). His company focuses on compliance management and execution in computer system validation and technical services.

Prior to founding MRC, Mr. Miller co-founded Cetan Technologies, Inc. There, he served as Vice President and Chief Technical Officer; developing a practical, yet defensible approach to computer system validation and 21 CFR Part 11 compliance. He also provided primary regulatory oversight and training to consultants, created the firm’s product-development department and developed the first automation-assisted, nonintrusive computer-system validation testing.

In addition to this experience, he has also held senior-level computer-validation and information-systems positions with AAI, Alcon Labs and Mary Kay Cosmetics.

Dr. Miller received both his Ph.D. in Chemical Instrumentation and his M.A. in Analytical Chemistry from the University of Cincinnati. He received his B.S. in Chemistry from Florida Atlantic University.

WHO SHOULD ATTEND

This course is designed for Validation, Quality, IT, and Business personnel responsible for implementing and using regulated computer systems in the pharmaceutical, biotech and medical device industries. The course is of special value to personnel seeking experience with computer validation and issues associated with FDA regulated computer systems. The course is especially designed for attendees seeking a thorough introductory level of understanding, yet is also designed to be valuable to those with prior experience seeking to remain current with industry trends and approaches.

FIRST DAY

Computer Validation – General Overview
• Computer Validation fundamentals – a walk-through of a complete validation of a small example system
• Who needs to validate?
• What is Computer Validation?
  • Core principles
  • Brief history of computer validation
• Why is validation necessary and what regulations guide validation requirements?
• Review of the computer validation references in regulations and guidances:
  • 21 CFR Part 211
  • 21 CFR Part 810
  • 21 CFR Part 11
  • Annex 11: Computerized Systems
  • Guidance: Q7A GMPs for Active Pharmaceutical Ingredients
  • Guidance: General Principles of Software Validation
  • Guidance: Computerized Systems Used in Clinical Investigations
• When and how are systems validated?
• Review of key FDA Warning Letters related to computer validation

Computer Validation Process and Deliverables
• What is the SDLC (System Development Life Cycle) process?
• How does computer validation fit into the SDLC?
• What content must be covered?
• What are the expected tasks and deliverables?
• System/software specifications
• Requirements options and documentation
• How 21 CFR Part 11 applies to computer validation
• Design Qualification (DQ) and vendor selection
• Risk Assessment in computer validation
  • Where does it apply?
  • A walkthrough of the GAMP risk assessment process
• Validation Plans and Master Validation Plans
• Installation Qualification (IQ)
  • The five topics expected in IQ documents
• Operational Qualification (OQ) and Performance Qualification (PQ)
  • Testing strategies and level of detail
  • How much testing is enough?
  • Examples of effective test cases and system errors discovered
• SOPs required for system operation and maintenance
  • How they related to FDA Warning Letters
• Validation Summary Reportse

SECOND DAY

Overview of 21 CFR Part 11 (Part 11)
• Background and purpose of Part 11
• Overview of Part 11 (review regulation)
• Review of the Part 11 implications in regulations and guidances:
  • 21 CFR Part 58 GLP
  • 21 CFR Part 211 GMP
  • 21 CFR Part 312 GCP (IND)
  • 21 CFR Part 810 QSR
  • Guidance: Part 11 scope and application (September 2003)
  • Guidance: Computerized Systems Used in Clinical Investigations
  • Guide to the Inspection of Pharmaceutical Laboratories
• Review of Part 11-related FDA Warning Letters
• Discussion of example systems and the evaluation of Part 11 Compliance decisions
• Industry trends and approaches – the future of Part 11 issues
• Interactive discussion of Part 11 issues and concerns (bring your questions)
• Achieving and Maintaining Part 11 Compliance

GAMP-Specific Computer Validation Topics
• The industry guidance for Good Automated Manufacturing Practice (GAMP)
• How GAMP addresses the FDA’s expectations for computer validation
• GAMP 5 versus GAMP 4
• How to transition to GAMP 5 from GAMP 4
• A review of the supplementary GAMP guidances and where they apply

Auditing Computer Systems
• Auditing GxP computer systems
• Auditing suppliers of computer systems for GxP use
• Auditing developers for customized systems
• The general process for auditing computer systems
• Variations that can save time and money
• Review of an example audit checklist
• Primary areas of focus (what to look for)
• Examples of audit findings

Day 2 wrap-up