

Strategies for 21 CFR Part 11 Cost Effective Compliance Using a Risk-based Approach

Location: Your Computer **Offering #** 1007-710 **Priority Code:** 520

WHO SHOULD ATTEND

This course is designed for professionals in the pharmaceutical and medical device industries and those involved with clinical research within these areas. It will be especially beneficial to:

- IT Managers
- Managers of automated laboratories, automated manufacturing systems and automated clinical testing/analysis systems
- Regulatory/QA Managers and Directors
- Managers of computerized medical devices

LEARNING OBJECTIVES

Upon completion of this training, you will be able to:

- Outline the requirements of 21 CFR Part 11
- Discuss the risk-based approach to cost effective compliance with 21 CFR Part 11
- Apply the cost effective strategies to assist in your own Part 11 compliance

COURSE DESCRIPTION

The FDA requires that computer systems involved with the generation, processing, storage or analysis of regulated data conform to 21 CFR Part 11, which provides guidance for system validation; archiving and storage, audit trails, (optional) electronic signatures and data integrity.

This 90-minute **accredited** online training course provides an overview of the requirements of 21 CFR Part 11 and provides a strategy for cost effective compliance.

Module 1: Overview of 21 CFR Part 11

- Background of the regulation
- Cost as an access issue
 - Components of cost
 - Minimizing unnecessary regulatory burdens
- Major Components
 - System validation
 - Audit Trails
 - Archiving
 - (Optional) electronic signatures
 - Data integrity

Module 2: A Risk Based Approach to Cost Effective Compliance

- Risk as the defining characteristic
- A Multi-tier standard
- Low, Medium and High Risk situations
 - Full validation
 - Data integrity checks
 - Audit trails
 - Electronic signatures
 - Archiving with confirmation
 - Basic Validation
 - Bare bones validation

Module 3: A Strategy for On-Going Control of Computer Systems

- Risk factors
 - Frequency; severity
- Steps
 - Inventory of systems
 - Adoption of multi-tier plan
 - Categorization of systems
 - Progress toward compliance
- Summary; New developments
- Key issues

Question and Answer Session

For more information see reverse side →



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COURSE DIRECTOR

Dr. Sandy Weinberg, Associate Professor of Health Care Management (Regulation) at Clayton State University, part of the Georgia State University System; retired regulatory professional from the drug, device and vaccine industries.

Dr. Weinberg is teaching and researching Regulation and Biodefense. He is a consultant to the FDA regulated industries and is a former consultant to the FDA and other international regulatory agencies including Health Canada, NIH, CDC, EMEA and the Swiss Ministry of Health.

He has been a leader in the field of system validation for more than twenty years, and a practitioner in regulatory submissions, auditing, international liaison and biodefense vaccine development. Dr. Weinberg is the author of numerous books and articles, including *The GALP Regulatory Handbook*, *The Handbook of System Validation*, *Good Laboratory Practice Regulations*, and *The Handbook of Drug Regulatory Submissions*. His most recent articles include "Cost Effective Validation for LIMS" and "Conforming to Part 11 Regulations".

Dr. Weinberg is a member of the Board of the KEMA Registered Quality (ISO 9000 Certifier) in the United States and the Netherlands. Recently retired, Dr. Weinberg was Senior Director for Biodefense at GE Healthcare and Vice President of Tikvah Therapeutics; as well as an investor in and Board member of several international biomedical companies.

Working as a consultant, Dr. Weinberg provides auditing and advisory services in regulatory areas. Recent projects include the auditing and certification of a chromatography control system; a business development and fund raising project for a biodefense vaccine company; an Orphan Drug submission; and the validation of a Laboratory Information Management System. Much of Dr. Weinberg's practice is centered in the US, Western Europe and Israel.

TUITION AND REGISTRATION

TUITION* - **Single Rate: U.S. \$295.00 per person** **Group Rate: U.S. \$245.00 per person****

Register at www.cfpa.com. Enter **Course Offering #1007-710** into **Quick Jump**. To register use **Priority Code: 520**.

For Questions and Information call Customer Service at 732-613-4500.

Please Note: Multiple participants are not authorized to share access provided to a single registrant, a single dedicated seat license must be purchased for each individual. CfPA reserves the right to cancel access or collect the group rate payment if this requirement has been violated. Only registered participants will receive accreditation.

ACCREDITATIONS



The Center for Professional Advancement has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102. In obtaining this approval, The Center for Professional Advancement has demonstrated that it complies with the ANSI/IACET Standards which are widely recognized as standards of good practice internationally. As a result of their Authorized Provider membership status, The Center for Professional Advancement is authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards.

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COURSES OF INTEREST

- **An Overview of Documentation Requirements in FDA Regulated Industries—An Online Course**
course ID# 2325
- **Introduction To Pharmaceutical cGMP—An Online Course**
course ID# 2244
- **Pharmaceutical cGMP-Quality Systems—An Online Course**
course ID# 2245
- **Documentation Management and Control**
course ID# 1866

ABOUT ON-DEMAND:

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TERMS AND CONDITIONS

***Payment:** Tuition payable in US funds net of all charges. Payment is due at time of registration in the form of a credit card. Please contact CfPA's Customer Service for other payment options.

****Group Rate:** The Group Rate is for two or more enrollments, up to five registering from the same company at the same time. For groups of six or more, please contact Customer Service for group pricing.

Cancellations/No Show: "Live" - Registrants may cancel up to two working days prior to the course start date and will receive a letter of credit to be used towards a future course up to one year from date of issuance. No credit will be issued for no-shows and/or cancellations less than two working days prior to the course. : **"On-Demand"** - No refund or credit will be issued for no-shows and/or cancellations of on-demand training courses. CfPA is not responsible for any outside related costs incurred by registrant's cancellation.