



# CfPA

The Center for Professional Advancement  
Accredited Technical Training Worldwide  
PO Box 7077, East Brunswick NJ 08816  
Phone 732-238-1600 • Fax 732-238-9113

## ON-DEMAND Online Training Course

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

Location: Your Computer

Offering # 0811-701

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

### COURSE DIRECTOR

Dr. Sandy Weinberg, Independent Consultant to FDA Regulated Industries and former consultant to the FDA, Health Canada, NIH, CDC, EMEA, and the Swiss Ministry of Health

### 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.

### REGISTRATION

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

Register at [www.cfpa.com](http://www.cfpa.com). Enter **Course Offering #0811-701** 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.

### ABOUT ON-DEMAND:

Our pre-recorded on-line training courses are available for viewing at your convenience at your computer. Register for a CfPA on-demand course, your registration will be processed within two (2) business days, after payment and registration are complete you will receive an email from [olinetraining@cfpa.com](mailto:olinetraining@cfpa.com) with your password to access the on-demand course. You will have two (2) business days to view the course. You **MUST** complete all polls and the course evaluation to receive your accreditation certificate for this course.

### 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.