



CfPA

The Center for Professional Advancement

Accredited Technical Training Worldwide

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ON-DEMAND Online Training Course

Computerized Systems Used in Clinical Investigations: the New FDA Guidance

Location: Your Computer

Offering # 0711-721

Priority Code: 520

WHO SHOULD ATTEND

This online training course is important for those in the Pharmaceutical, Biotechnology and Medical Device Industries including:

- Study sponsors
- Clinical Investigators
- IT Professionals
- Data Management Centers
- Other Professionals Who Use or Design Computer Systems for Clinical Studies
- Contract Research Organizations (CROs)
- Institutional Review Boards (IRBs)
- Clinical Software Vendors
- Computer System Validators
- Project Managers
- Management

LEARNING OBJECTIVES

Upon completion of this online training course, participants will be able to

- Explain the basics of the new FDA Guidance for Computerized Systems Used in Clinical Investigations
- Describe how the new Guidance can be harmonized with EudraVigilance
- Design and utilize computer systems to support clinical studies in a more efficient manner
- Apply 21CFR Part 11 appropriately to Clinical Investigations

COURSE DESCRIPTION

This program will provide key insights and features of the new FDA Guidance. Attendees will learn what the FDA expects when you use computer systems for clinical studies, how 21CFR Part 11, (eRES) applies and how this can help to support the EudraVigilance requirements for the European Medicines Agency.

This is an important and **very timely** program that can help to better plan the more efficient and compliant use of computer systems to support clinical studies.

Module 1:

- Study Protocols
- SOPs
- Security

Module 2:

- Audit Trails
- Data Management
- Change Control

Module 3:

- Personnel
- EMEA Standards
- EudraVigilance Reporting

COURSE DIRECTOR

Philip E.Sax, Principal Consultant and President FDA Compliance Solutions

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.



The Center for Professional Advancement (CfPA) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Continuing Education Units (CEU) will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal sessions and submission of a course evaluation. The CEU rate is 0.1 CEU per contact hour; statement of credit will be mailed within six weeks. You will have an opportunity to evaluate your successful completion of these course objectives through **interactive question and answer sessions**. This offering is Program# 716-000-07-555-L04. If interested in ACPE credits, notify CfPA immediately upon completion of this course.

REGISTRATION

TUITION* - **Single Rate: U.S. \$99.00 per person** **Group Rate: U.S. \$99.00 per person****

Register at www.cfpa.com. Enter **Course Offering #0711-721** 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 olinettraining@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.