

Clinical Testing Submissions

Location: Your Computer **Offering #** 0903-705 **Priority Code:** 520

WHO SHOULD ATTEND

This course is designed for professionals within the pharmaceutical and biologics industries who are interested in the planning and submissions of INDs. The training will be especially valuable to

- Regulatory personnel
- Directors, and VPs
- QA Managers
- Representatives of Contract Research Organizations (CROs)

LEARNING OBJECTIVES

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

- Discuss the quality issues critical to Clinical Testing
- Prepare for the Pre-IND Meeting
- Explain industry guidelines relevant to electronic IND process including e-forms and alternative means for submissions

COURSE DESCRIPTION

The FDA procedures for the clinical testing of drugs, potentially leading to the filing of an NDA or ANDA, are evolving rapidly. This 90-minute **accredited** program examines the steps involved in dealing with the FDA Pre-IND meeting and the procedures for electronic IND filing. Quality issues within the clinical arena will be addressed. Attention will be directed toward developing a plan for the pre-IND meeting and industry and FDA guidelines for electronic INDs.

Dealing with the FDA Pre-IND Meeting and Details of Electronic Filings

Module 1 : Quality Issues in Clinical

- Clinical Team pre-IND meeting with FDA
- Focusing on the important issues and meta-issues
- Evaluating research facilities and strategies
- Ethical issues
- Protection of the safety, rights of persons participating

Module 2: Prep for the Pre-IND Meeting

- Early interactions with FDA staff to help to prevent clinical issues from arising
- Selection of appropriate CROs and Investigators
- The Mock-Meeting: managing expectations
- Efficient use of FDA resources

Module 3: Electronic INDs

- Evolving process
- Industry guidance and FDA guidelines
- e-Forms
- Alternatives: paper, paper with electronic index, paper with hyperlinks

Question and Answer Session

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 #0903-705** 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.

For more information see reverse side ⇨



CfPA

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COURSE DIRECTOR

Carl A. Rockburne, Regulatory Consultant

Carl Rockburne is a regulatory consultant with extensive experience in the electronic IND (and other filings) systems. He has been involved in the field of system validation. Additionally, he was a full time consultant to GE Healthcare Fast Trak BioDefense program. A program designed to be a free standing entrepreneurial program within GE Healthcare.

Mr. Rockburne has also worked with small/ medium research & development companies in their search for vaccines for, including, small pox, avian influenza, Ebola, rift valley, botulinum. Mr. Rockburne is a Certified Regulatory Compliance Auditor to the biomedical industries. (Part 11; GMP; GLP; GCP etc. He is an expert on international clinical testing requirements, and has authored the international filings chapter for the *Guidebook to Drug Regulatory Submissions*, summarizing the requirements of Canada, Australia, Japan and the EMEA.

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.

WHO WE ARE

The Center for Professional Advancement (CfPA) is the largest accredited technical training organization in the world with a curriculum of approximately three hundred and fifty short courses in 18 industries including Pharmaceutical, Biotechnology, Medical Device, Chemical, Cosmetics, Food and more.

Since our founding in 1967, we have successfully trained nearly a half million people worldwide in topics ranging from basic and introductory concepts to new advances and cutting-edge technology, and current U.S. and European regulations. CfPA courses are offered in a variety of formats – Public offering, Client Site and Online- to fit you or your company's training needs

For more information visit our website at www.cfpa.com

COURSES OF INTEREST

- **21 CFR Part 11: Strategies for Cost Effective Compliance Using a Risk-based Approach–An Online Course**
course id# 2225
- **Best Practices in SAS Statistical Programming for Regulatory Submission**
course id# 2234
- **Best Practices in SAS Statistical Programming for Regulatory Submission: Understanding and Applying the QC Plan to Validate Summary Tables (FIRST in a Two-Part Series)–An Online Course**
course id# 2213
- **Clinical Testing Process**
course id# 2271
- **Computerized Systems Used in Clinical Investigations: the New FDA Guidance–An Online Course**
course id# 2184
- **Good Clinical Practices (GCP)**
course id# 107
- **INDs/NDAs/CTDs**
course id# 448

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 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.