

Effectively Managing CROs

Location: Your Computer Offering # 0905-703 Priority Code: 520

This course
presented by
CfPA in
conjunction with



and

PFQ

WHO SHOULD ATTEND

This online training will benefit professionals in the pharmaceutical industries who manage Contract Research Organizations (CROs) who have been contracted for any projects involved in the process of new product development. Programs involving: Pre- and Non- Clinical Studies, Clinical Trials in Phases 1, 2, 3, 3b and 4, and Manufacturing require continuous management expertise in order to bring these programs to successful completions. The course will be especially valuable to:

- Managers who are responsible for overseeing programs contracted to CROs in the non and pre-clinical, clinical and manufacturing areas
- Vice Presidents, Directors and Administrators responsible for all programs necessary to bring new pharmaceutical products to market on time and within budget
- CRO personnel who work with Sponsors who are developing pharmaceutical products in order to understand the expectations and demands based on their contractual agreements

LEARNING OBJECTIVES

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

- Describe the basic legal requirement and confidentiality concerns within the CRO/Sponsor relationship
- Explain the accountabilities of the CRO to the Sponsor and the responsibilities of the Sponsor to the CRO
- Give examples of problem solving techniques when facing project failures and regulatory compliance issues

COURSE DESCRIPTION

This 90-minute **accredited** online training course will detail the procedures and skills needed for Sponsors who develop pharmaceutical products, drugs, biologics or devices, how to successfully manage CROs. This course will guide the learner in how to manage and collaborate with CROs to best achieve the objectives of each project assignment. Each area in the process of new pharmaceutical product development will be addressed as to the responsibilities of the Sponsor and CRO obligations in conjunction with, SOPs, GLPs, GCPs, and GMPs. Recommendations and contingency plans for handling project failures, program lags, and non-compliance of global agency regulations will be presented. Topics to be covered:

Module 1:

- Confidentiality
- Legal Requirements
- Managing Pre-Clinical CROs
- Managing Clinical CROs

Module 2:

- CRO/Sponsor Responsibilities
- SOPs
- Assuring Data Collection
- CRO-Sub-Contractors

Module 3:

- Sponsor/CRO Communications
- Co-Monitoring
- Managing Regulatory Compliance
- Managing GMPs

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 #0905-703** 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.



CfPA

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PO Box 7077, East Brunswick NJ 08816
Phone 732-238-1600 • Fax 732-238-9113

www.cfpa.com

COURSE DIRECTOR

Richard A. Guarino, M.D., President, Oxford Pharmaceutical Resources, Inc.

Richard A. Guarino, M.D. is President of Oxford Pharmaceutical Resources, Inc., a consulting organization specializing in the planning, implementing and submitting of INDs, NDAs and CTDs. Dr. Guarino also has 25 years of experience in new drug applications, in marketing launches, advertising, and FDA liaison.

Dr. Guarino was formerly the President and CEO of Oxford Research International Corp., one of the largest CROs in the United States. Besides serving as an adjunct professor at Fairleigh Dickinson University, he was a former Director of Clinical Research at Sandoz Pharmaceutical Inc., now Novartis, and held the position of Vice President/Medical Director at Revlon Healthcare Group. He has been acclaimed for his book, *New Drug Approval Process*, now in its 4th edition. It is the first book ever written to guide and recommend ways to expedite global new drug approval process while following all the requirements of the Code of Federal Regulations and EU Directives.

Dr. Guarino is a member of many professional societies and associations including the New Jersey and New York Academies of Medicine, The Royal Society of Medicine, the Columbus Citizens Foundation, the Presidential Advisory Cabinet at Fairleigh Dickinson University, the Lupus Erythematosus Foundation, the Cystic Fibrosis Foundation and the Columbus Foundation, Drug Information Association (DIA), Association of Clinical Research Professionals (ACRP), and Academy of Pharmaceutical Physicians and Investigators (APPI).

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.

ABOUT WILEY-BLACKWELL

Wiley-Blackwell was formed in February 2007 as a result of the acquisition of Blackwell Publishing Ltd. by John Wiley & Sons, Inc., and its merger with Wiley's Scientific, Technical, and Medical business. Together, the companies have created a global publishing business with deep strength in every major academic and professional field. Wiley-Blackwell publishes approximately 1,400 scholarly peer-reviewed journals and an extensive collection of books with global appeal. For more information on Wiley-Blackwell, please visit www.blackwellpublishing.com or <http://interscience.wiley.com>.

COURSES OF INTEREST

- **Auditing and Inspecting Preclinical Research for GLP Compliance**
course id# 1774
- **CMC Submissions in CTD Format**
course id# 1989
- **Effective Tools in Selecting a CRO**
course id# 2296
- **INDs, NDAs vs CTDs Global Regulations**
course id# 448
- **Non-Clinical Drug Safety Evaluation and Drug Development**
course id# 1153
- **Selecting and Managing CROs**
course id# 2032

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.

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