

Registration Form

Offering # **0709-410**

Laboratory Analysis in Clinical Trials

September 24–25, 2007 • New Brunswick, NJ

Priority Code: **520**

(Please use this code when registering)

Dr. Mr. Ms. _____
First Name Last Name

Job Title _____

Company/Institution _____

Company Address _____

City _____ State _____ Zip _____

Tel: _____ Fax: _____

E-mail Address _____
(CFPA does not rent or sell e-mail addresses)

How did you learn about this course?

- Direct Mail Colleague Website Other

Tuition and Payment Methods

Early Registration (Save \$200) U.S. \$ **1240** / \$ **1180***
(Register and pay by July 30, 2007) (Group Discount)

Regular Registration U.S. \$ **1440** / \$ **1380***
(Group Discount)

Tuition payable in US funds net of all charges includes continental breakfast, luncheon, breaks and course notes.

Payment is due prior to course start date. If payment has not been received two weeks before the course, a credit card will be required to guarantee admittance.

*Group Discount is for two or more enrollments registering at the same time, from the same company, for the same course.

Send Invoice (POs must be received in advance of course)

Purchase Order # _____

Check (payable in U.S. funds to The Center for Professional Advancement)

Credit Card Visa MasterCard American Express

Card # _____ Exp. Date _____

Cardholder Name _____

Signature _____

4 Ways To Register

- Log on to www.cfpa.com
- Call: 732.613.4500
- Fax to: 732.238.9113
- Mail: **The Center for Professional Advancement (CFPA)**
P.O. Box 7077
East Brunswick, NJ 08816-0964

General Information

Discounts: Early registration discount requires payment at time of registration and before expiration or regular tuition will apply. Group Discount is for two or more enrollments registering at the same time, from the same company, for the same course.

Cancellations/Substitutions: All cancellations are subject to a \$150.00 processing fee. Applicants may cancel up to two weeks prior to the course start date for a refund. If less than two weeks, a credit will be issued that can be used towards a future course up to one year from the date of issuance. No refunds or credit will be issued for those who do not attend the scheduled course and/or cancel less than two working days before the start date. Substitutions are permitted at any time. If for any reason, CFPA decides to cancel this course, we are not responsible for airfare, hotel or other costs incurred by the registrant. Program content, schedule and instructors are subject to change without notice.

Confirmation Letters: Before each course begins, all registrants will receive written confirmation including detailed information regarding course location. If confirmation is not received two weeks prior to the course please contact us.

For our full terms and conditions, visit www.cfpa.com.

Accreditations



The Center for Professional Advancement has been reviewed and approved as an Authorized Provider (#640) of continuing education and training programs by the International Association for Continuing Education and Training (IACET). Continuing Education Units (CEU) will be awarded for participation in this course at a rate of 0.1 CEU per contact hour. 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 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; certificate will be mailed within six weeks. You will have an opportunity to evaluate your successful completion of these course objectives through a Learning Assessment. This offering is Program# 716-000-07-506-L04

Who We Are

The Center for Professional Advancement (CFPA) is the largest technical training organization in the world with a curriculum of approximately four hundred and fifty short courses. Since our founding in 1967, we have successfully trained nearly a half million people worldwide in subjects ranging from Chemistry to Engineering, from Pharmaceutical Technology to the Chemical Process Industries, and from R&D to Quality and Manufacturing.

Courses of Interest

- **ADME: Fundamentals of Absorption, Distribution, Metabolism and Elimination**
course id# 2077
- **Analytical Methods Validation for FDA Compliance**
course id# 1887
- **CMC Submissions in CTD Format**
course id# 1989
- **Early Stage Clinical Studies for Drugs and Devices**
course id# 2118
- **Good Clinical Practices (GCP)**
course id# 107
- **INDs, NDAs vs CTDs Global Regulations**
course id# 448
- **The GLP Study Director**
course id# 2136
- **Writing and Implementing Clinical Protocols**
course id# 772

The Center for Professional Advancement

P.O. Box 7077, East Brunswick, NJ 08816-7077

Phone: 732.238.1600 • Fax: 732.238.9113

E-mail: info@cfpa.com

www.cfpa.com

Register by July 30 and **SAVE \$200**

September 24–25, 2007
New Brunswick, NJ



Laboratory Analysis in Clinical Trials

How to Ensure Acceptability of
Laboratory Data in Clinical Studies

Course Topics Include:

- Regulatory Requirements
- Documentation
- Method Validation
- Communication:
Laboratories, Monitors & Investigators

Directed by:

David Long
Consultant

Long & Associates International Consulting Ltd.



CFPA

The Center for Professional Advancement
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40
YEARS
1967-2007

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Who Should Attend

This course is for professionals involved in analytical activities as part of clinical trials. The course is designed for:

- Persons working in laboratories performing analysis of biological samples from clinical trials
- Monitors or investigators involved in clinical trials
- Persons involved in assessing or selecting clinical laboratory facilities to perform analysis
- Quality Assurance personnel

Participants may come from the pharmaceutical industry, government institutions, hospitals, academic organizations or contract facilities.

Learning Objectives

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

- Implement an internal set of guidelines for running analytical phases of clinical trials
- Operate laboratory analysis in a way that is acceptable to the regulatory authorities
- Establish documents that will achieve traceability of laboratory activities and thus guarantee the credibility of your results

Course Description

Good Clinical Practices (GCP) does not provide detailed requirements regarding the conduct of laboratory activities in clinical trials. Therefore, laboratories have applied their own standards to such work drawing from relevant guidance in other publications, for example ICH in relation to method validation, GLP relating to preclinical studies and other quality systems such as ISO standards. At the core of this course is a collection of basic scientific and management principles that, if applied, will ensure the credibility of laboratory data.

This course draws together information to provide a set of principles for laboratories dealing with blood chemistry, haematology or analysis of test drugs in biological matrices, which will ensure that the data stands up to scrutiny.

Practical applications of principles are given maximum priority in this course through the high level of interactive, dynamic, problem solving workshops. These mirror situations that the participants are actually involved in. Solutions to the workshops require the application of good practices in areas of regulatory science where guidelines have been unspecified or unaddressed. The presenters recognize that many courses can provide information, but information can only be turned into knowledge through the depth of understanding that comes from sharing experience and exchanging ideas. This is why a workshop approach is so valuable.

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COURSE OUTLINE

first day

8:00 a.m.: Registration/Continental Breakfast

8:30–5:00 p.m.:

Topics covered:

- Introduction and overview
- Principles of Quality Management
- Regulatory requirements
- Organization and control of work
- Facilities
- Equipment: qualification and maintenance
- Documentation: SOPs, Protocols & Methods
- Sample management & Chain of custody

Workshops:

- Developing usable and useful SOPs
- Sample transfers, to and within the laboratory

second day

8.30–5.00 p.m.:

Topics covered:

- Method validation
- Data recording & data management
- Reporting
- Archiving
- QA

Workshops:

- Dealing with communication between laboratories, monitors and investigators
- Reliability of third party data
- Case studies dealing with analytical/management problems

Client Site

Training at your site and at your convenience. For further information, please contact **Client Site** Programs: Direct Dial (USA) +1/732.238.1600, ext. 4549; or fax +1/732.238.9113; or E-mail clawrence@cfpa.com.

Online Training Now Available

A NEW way to experience our accredited training, easily access the knowledge you need through the Internet. For a list of upcoming courses visit www.cfpa.com/onlinetraining.

Course Director

David Long worked for Rhône Poulenc Health Division (now Sanofi-Aventis) in Quality Assurance (QA) for over twenty years where he gained considerable experience in all three Good Practice disciplines, GLP, GCP and GMP. When he left Rhône-Poulenc he was Senior Director R&D worldwide for Quality and for Process Improvement. Mr. Long has since worked for CHIMEX, a manufacturing subsidiary of the L'Oreal group and also runs his own consultancy company.

Mr. Long has always shown a keen interest in promoting professional QA activities. He was a founding member and President of the French QA Society and a founding member and President of the European QA Federation. He was also the founder and Chief Editor of the Quality Assurance Journal, an international scientific journal specifically addressing subjects of interest to R&D and QA personnel.

He has lectured and trained widely and has been an active participant in developing training in Good Practices and QA, working with a number of international groups including the OECD and the WHO. His latest contribution through the WHO has been in the co-authoring of a set of guidelines for research performed upstream of the regulatory scene, called "Quality Practices in Basic Biomedical Research".

Additional Faculty

Philip Withers is an independent consultant to the pharmaceutical industry. He was Director of Quality Assurance at MDS Pharma Services in France and has been involved in preclinical and clinical QA for over 25 years. Philip is a member of the organizing committee of SoFAQ, the French QA group, past chairman of the multi-site working party and representative to EQAS the European QA association. He has presented many papers at international QA meetings and has been involved for many years in developing a variety of training programs internationally. Philip is also a member of the editorial board of The Quality Assurance Journal.

Course Location

This course will be held in the **Hyatt Regency** located in New Brunswick, New Jersey. A limited block of rooms in the hotel will be held for our registrants until four weeks before the course. Participants must, however, make their own reservations; the cost of hotel accommodation is not included in the course fee. Hotel information will be included with your acceptance. To receive **CFPA's** rate and room block, be sure to mention that you will be attending one of our courses. For reservations call 800.233.1234; outside U.S. call 732.873.1234.