The drug development process involves a series of lengthy steps that determine the degree of success for every drug brought to the market. Decisions made throughout the process affect every aspect of future development and impact heavily on commercialization strategies.

Included in the course content is an overview of the regulatory and pre-marketing steps that occur to ensure a successful launch. The course also covers sales planning and the commercialization decisions that affect the development of the drug.

Topics include:
- Basic concepts of drug discovery and testing
- Scientific, regulatory, and management framework for modern pharmaceutical development
- Pre-clinical study requirements and how information gathered is used for human clinical studies
- The four major clinical phases (1-4) in the drug development process and the rationale for each and an introduction to the special problems of each phase
- The economics of drug development
- Cost/benefit issues in clinical development
- Discovery and development milestones
- The IND Process
- The NDA Process
- FDA Interactions – Application review and approval process
- Patents and exclusivity
- AND MORE...

About CfPIE

Learn from the Leader

In a life sciences industry that has faced nearly $15 billion in fines and compliance-related settlements over the last several years, The Center for Professional Innovation & Education (CfPIE) is a better alternative for maintaining high standards, protecting industry reputations, and enhancing personal growth. Since 2001, we have embraced a singular goal—to provide the highest quality education to life science professionals. Today, as the global leader in quality life sciences training, we offer the largest range of course options for professional development in pharmaceutical, medical device, biotech, and skin/cosmetics disciplines. We are dedicated to enriching that reputation by conveying content relevant to the needs of individuals and organizations facing intense scrutiny in those highly technical disciplines.

Payment

$2650.00 per person (includes breakfast & lunch)

Early Bird Discount

If you register at least thirty days in advance you will receive a $200 discount on the course.

Additional Discounts

Contact us at 610-648-7550 or info@cfpie.com for information regarding partnership discounts or how your organization can become a partner with CfPIE.

Cancellation Policy

All cancellations must be in writing and are subject to a $350.00 cancellation fee. If cancellations are made more than 30 days prior to the course, a refund less the cancellation fee will be provided. If cancellations are made less than 30 days prior to the course, a voucher good for attendance at an upcoming course will be provided. The voucher, which can be used by the registrant or anyone else within his/her company, will be valued at the registration fee minus the $350.00 cancellation fee.

If a registered attendee does not cancel and fails to attend, neither a refund nor voucher will be issued. All course cancellations must be in writing and emailed sent to info@cfpie.com. Registrants are responsible for contacting the hotel and canceling their room reservations.

CfPIE reserves the right to alter the venue, if necessary.

Substitution Policy - Classroom Courses

Substitutions are accepted at no penalty with written notification from the original registrant in advance of course. All substitution requests must be in writing and emailed to info@cfpie.com.

CfPIE also offers on-site courses for 10 or more attendees. Contact us at info@cfpie.com.

How to Register

1. Go to http://www.cfpie.com
2. Go to “REGISTER HERE” and select your course.
3. Create an account and register for your course.

The Center for Professional Innovation & Education, Inc.
7 Great Valley Parkway
Suite 295
Malvern, Pennsylvania 19355

http://www.CfPIE.com

COURSE DESCRIPTION

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INSTRUCTOR CREDENTIALS

Michael A. Pierro is consultant to life sciences industries; building over 35 years of pharmaceutical-industry experience to provide services in clinical-practice areas of SOPs, study management and monitoring, auditing and site qualification.

Mr. Pierro previously served as Director of Business Development, Consulting and Clinical Training for a large consulting firm. There, he was responsible for the development and implementation of SOPs, specialized training programs and related consulting services. His clients included pharmaceutical and biotechnology firms, CROs, other sites throughout the world. In his other roles at the company; he served as a Senior CRA, Manager of Phase-IV Clinical Operations, Chairperson of the SOP Steering Committee and GCP Auditor. In addition, Mr. Pierro was involved in several NDA/SNDA preparations, filings and other reports to regulatory agencies.

LEARNING OBJECTIVES

This course provides an understanding of the interrelated activities throughout the drug development cycle and is designed for R&D, operations and/or marketing and sales management. This course serves as an introduction to the drug development process and will familiarize participants with the steps involved in developing a drug from Discovery to Commercialization. The course is often customized to address specific organizational, departmental or functional issues.

HOTEL INFORMATION

The Hilton LAX, Los Angeles, CA (CPPIE room rate of $167/night if booked 3 weeks in advance of the course date)

The Desmond Hotel & Conference Center, Malvern, PA (CPPIE room rate of $141/night if booked 3 weeks in advance)

Club Quarters Hotels, Boston, MA (CPPIE room rate of $255/night if booked 4 weeks in advance).

DoubleTree by Hilton London - Victoria (CPPIE room rate of £199.00/night if booked 4 weeks in advance)

09:00 – 09:30-Welcome
• Introductions
• Course Objectives
• Agenda Review

09:30 – 10:30-Drug Discovery
• Regulatory definition of a “drug”
• Types of drugs & how they are produced
• Approaches to drug discovery
• Patents
• Exercise # 1 Drug Discovery

10:45 – 12:00-Drug Development
• Challenges in drug development
• Drug Development Lifecycle
• Industry Perspective
• Non-Clinical Studies
  • GLP
  • Clinical Studies
  • The IND/IMPD
  • CDP
  • Phase I-IV
  • Exercise # 2 Drug Development

01:00 – 03:00-Drug Development (continued)

03:15 – 05:00-Drug Development (continued)

SECOND DAY

09:00 – 10:00-Good Clinical Practices
• Purpose & Principals
• The IRB/IEC
• Exercise # 3 GCP

10:00 – 12:00-Components of a Clinical Study
• Regulatory Requirements
  • History & Role
  • Key Players
  • Roles & Responsibilities
  • Documentation
  • Monitoring
  • Data Processing
  • Exercise # 4 Clinical Study

THIRD DAY

09:00 – 09:45-GMP
• Impact
• Commercial Manufacture
• GMP Controls
• Scale-up Issues
• Process Validation
• Exercise # 7 GMP

10:00 - 12:00-DDP Workshop
• Break into working groups
• Present findings

1:00 – 02:00 - Course Review

02:00 – 03:00-Wrap-up
• Final Q&A
• Course Evaluation