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 and NDA Process
- FDA Interactions – Application review and approval process
- Patents and exclusivity
- The rationale of government regulations and how they affect the development process
- The relationship between the Code of Federal Regulations and ICH GCP
- Designing optimal clinical trials
- Drug labeling, marketing, and pharmacoeconomics studies
- Project management cross functional teams during the development process

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.

How to Register

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

COURSE FEE
$2,650.00 PER PERSON

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 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.
INSTRUCTOR CREDENTIALS

Michael A. Pierro is consultant to life sciences industries; building on 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, university medical centers and the United States government.

Before this, Mr. Pierro was Director of Global Training for the Global Clinical Quality Assurance Department of Hoechst Marion Roussel (now Aventis). In this role, he directed all GCP, SOP and technical training activities within the company’s Drug Development Center and 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.

WHO SHOULD ATTEND

Designed for employees who need an understanding of the drug development process, this course provides a detailed picture of the complex and highly interrelated activities of the development cycle for drugs and biologics, from discovery to a successful commercialization. The training will be beneficial for anyone involved in the R&D process. It can also be customized for marketing & sales personnel who need to understand that actions taken during the development process have a significant effect on sales and marketing strategies.

FIRST DAY

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

SECOND DAY

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

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

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

10:00 – 10:30–Components of a Clinical Study
• Regulatory Requirements
• History & Role
• Key Players
• Roles & Responsibilities
• Documentation
• Monitoring
• Data Processing
• Exercise # 4 Clinical Study