Company branding and layout with content.
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

10:00 – 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

10:45 – 12:00 - Components of a Clinical Study
- Regulatory requirements
- History & Role
- Key Players
- Roles & Responsibilities
- Documentation
- Monitoring
- Data Processing
- Exercise # 3 GCP

10:45 – 12:00 - Components of a Clinical Study (continued)

01:00 – 02:30 - The NDA/CTD
- Definition & Contents
- Process
  - Submission, Review & Approval
- Exercise # 5 NDA/CTD

02:45 – 05:00 - Post Approval
- Sales Training
- Role of Marketing
- Marketing Strategy
- Promotional Advertising
- Post Marketing Compliance
- AE Reporting
- Exercise # 6 Post Approval

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

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

09:00 – 10:00 - 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

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.

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, universities, 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.

HOTEL INFORMATION
The Hilton LAX, Los Angeles, CA (CPIE room rate of $152/night if booked 3 weeks in advance of the course date)
The Desmond Hotel & Conference Center, Malvern, PA (CPIE room rate of $136/night if booked 3 weeks in advance)
Club Quarters Hotels, Boston, MA (CPIE room rate of $230/night if booked 4 weeks in advance).
The Berlin Hilton, Berlin, Germany (CPIE room rate of Standard Single Room is €179.00 and Double Occupancy is €199.00 inclusive of VAT and Breakfast if booked 4 weeks in advance.)