GOOD CLINICAL PRACTICES (GCP) & RISK BASED MONITORING - UNDERSTANDING AND IMPLEMENTING CURRENT GLOBAL REQUIREMENTS

INSTRUCTOR: MICHAEL R. HAMRELL, PH.D.

October 21 – 23, 2019 - Boston, MA

This GCP training course is designed to provide individuals with an in-depth understanding of the clinical research process, the roles and responsibilities of key players, as well as regulatory requirements. The course consists of lecture and exercises designed to focus on the practical implementation of the GCP requirements. 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 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

Dr. Michael R. Hamrell is the President of MORIAH Consultants, a Regulatory Affairs/Clinical Research consulting firm located near Los Angeles, CA. He has worked in drug development, clinical research and regulatory affairs for over 30 years. He has worked in pharmaceuticals, contract research, government, and biotech industries, in domestic and international regulatory affairs and clinical research. Dr. Hamrell also worked in the Division of AIDS in NIAID at the National Institutes of Health, and as a reviewer in the Center for Drug Evaluation & Research at the Food and Drug Administration (FDA), in the Divisions of Antiviral Drug Products, Oncology Drug Products, and Bioequivalence.

Dr. Hamrell spent a number of years doing basic research, first as a Research Fellow at Duke University and later as an Assistant Professor of Pharmacology at the McGill University Cancer Center. Dr. Hamrell has a Ph.D. degree in Pharmacology from the University of Southern California and a B.S. in Biochemistry from the University of California, Los Angeles. Dr. Hamrell has received numerous awards for his research, teaching and professional work and is recognized in Who’s Who. Dr. Hamrell also holds an appointment as Adjunct Professor of Molecular Pharmacology and Toxicology at the University of Southern California School of Pharmacy, as Adjunct Associate Professor at the Massachusetts College of Pharmacy & Health Sciences, the School of Nursing at the University of Southern California, and Adjunct Assistant Professor at George Washington University School of Medicine, Clinical Research Program.

HOTEL INFORMATION

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

The Desmond Hotel & Conference Center, Malvern, PA (CfPIE room rate of $199.00/night if booked 4 weeks in advance)

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

FIRST DAY
9:00am – 9:30am-Intro & Review of Agenda
9:30am – 10:30am-The Drug Development Process
  • Overview of Development
  • Phases of clinical development
  • Exercise
10:45am – 12:00pm-Good Clinical Practice (GCP)
  • Principals of GCP
  • Role of IRB/IEC, sponsor, investigator
  • Exercise
1:00pm – 2:00pm-Regulations
  • History of Regulations
  • 21 CFR, EU Directive
  • ICH Guidelines
  • Role of Regulatory Agencies
  • Overview of differences in GCP between US, EU, India, China, Japan
  • E Source Documents
  • E TMF
  • Exercise
2:00pm – 3:00pm – IND/IMPD
  • Definition
  • Composition
  • Types of INDs & IMPDs
  • Review & amendment process
  • Exercise
3:15pm – 4:30pm-IRB/IECs
  • Description, composition & role
  • Study review and approval process
  • Exercise
4:30pm-5:00pm-Recap, Questions and Answers

SECOND DAY
9:00am – 10:30am-Informed Consent
  • Elements
  • Process
  • Common errors
  • Review, approval, amendments
  • Exercise
10:45am – 11:30am-Monitoring Simulation
  • Definition
  • Types of monitoring visits & tasks
  • Role of the Study Monitor
  • Risk Based Monitoring
  • Exercise
11:30am – 12:30pm-Adverse Events
  • Definitions
  • Documenting
  • Reporting
  • Exercise
1:00pm – 2:45pm-Drug Accountability
  • Definition
  • Managing clinical supplies
  • Compliance
  • Exercise
2:45pm – 3:30pm-Fraud & Misconduct
  • Maintaining accurate records
  • How to detect fraud in case report forms and clinical trial materials
  • Misleading data and results
  • Examples of fraud
3:45pm – 4:30pm – Fraud (continued)
4:30pm – 5:00pm – Recap
  • Questions and answers

THIRD DAY
9:00am – 9:30am-Post Drug Approval
  • Reporting requirements
  • Phase IV
9:30am – 10:30am-Monitoring Simulation
  • CRF Review
  • SDV
  • Review & Discussion of Monitoring Simulation
10:45am – 11:45am-Electronic Systems and Data Management
  • Complying with 21 CFR Part 11
  • FDA guidance on electronic systems
  • Issues with electronic data capture, CRFs and medical record systems
11:45am – 12:30pm-Preparing for FDA Inspections
  • Preparing for the visit
  • FDA criteria for selecting sites for inspection
  • Source documentation: How much is enough?
  • Common GCP deficiencies
  • Review potential roadblocks of non-compliance
  • Recent BIMO inspection results
  • Identifying potential problems early
1:30pm – 2:30pm – Collecting, Managing and Reporting Clinical Study Data
  • Computerized clinical data management
  • CRFs vs. eCRFs
  • How much clinical data is enough
  • Making sure your records and reporting are accurate
2:30pm – 3:00pm-Course Review
3:00pm – 3:45pm-Recap
  • Questions and Answers
  • Course Evaluation