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 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 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

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 sent to info@cfpie.com.

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

GOOD LABORATORY PRACTICES (GLP) FOR NONCLINICAL LABORATORY STUDIES

Feb 24 – 26, 2020 - Malvern, PA
Jun 15 – 17, 2020 - Los Angeles, CA
Oct 5 – 7, 2020 - Boston, MA
**INSTRUCTOR CREDENTIALS**

Dr. Kenneth Cleaver is a highly regarded GLP consultant with over 20 years of industry experience. Since 2001, Dr. Cleaver has taught GLP courses and consulted for a variety of organizations. These include Medtronic, M.D. Anderson Cancer Institute, Exxon-Mobil, Hewlett-Packard, Vertex Pharmaceuticals, and Phillips Oral Care. His experience covers such disciplines as basic research, drug re-formulation, medical device development, contract laboratory testing and environmental studies.

In addition to his role as a CfPIE Course Instructor, Dr. Cleaver is the Director of CfPIE’s GLP Facility Certification Program, which provides clients with the documentation they need in order to prove to the world that their facilities and quality systems are fully GLP compliant.

Prior to 2001, Dr. Cleaver served as Vice President of Product Development for Novadel (formerly Flemington Pharmaceutical). Before this, he was a consultant with Medical Development Quality Associates and directed the Quality Assurance Unit at Oread Laboratories – a CRO specialized in distribution, metabolism and excretion of drug substances in various animal species. He has also overseen toxicology studies in mice, rats, guinea pigs and dogs for such clients as Upjohn Laboratories, Marion Laboratories, Bristol-Myers Squibb and Burroughs-Wellcome.

Dr. Cleaver received his Ph.D. in Pharmaceutics and M.A. in Organic Chemistry from Temple University. He received his B.S. in Chemistry from Albright College.

**REGISTRANT INFORMATION**

Each person attending a course will be asked to set up an Attendee Profile Account during the registration process. Accounts are a new feature on our website. Creating an Account helps you view your order history and manage your training programs.

If you are registering for others, please set up an Account in the Attendee’s name. If you are registering more than one person, you’ll need to set up a separate account for each Attendee.

**HOTEL INFORMATION**

<table>
<thead>
<tr>
<th>Hotel Information</th>
<th>Room Rates</th>
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<tbody>
<tr>
<td>The Hilton LAX, Los Angeles, CA (CfPIE room rate of $167/night if booked 3 weeks in advance of the course date)</td>
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<tr>
<td>The Desmond Hotel &amp; Conference Center, Malvern, PA (CfPIE room rate of $141/night if booked 3 weeks in advance)</td>
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<tr>
<td>Club Quarters Hotels, Boston, MA (CfPIE room rate of $255/night if booked 4 weeks in advance)</td>
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<tr>
<td>DoubleTree by Hilton London - Victoria (CfPIE room rate of £199.00/night if booked 4 weeks in advance)</td>
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**LEARNING OBJECTIVES**

By the end of this three-day course, attendees will have a strong understanding of the fundamental compliance requirements for current Good Laboratory Practices, and will be able to apply compliance protocols in all efforts aimed at generating regulated data for evaluation by the US FDA, USEPA and regulatory agencies overseas. All participants will gain a fundamental understanding of the basis of the regulations and the necessity of rigorous implementation. Special attention will be given to incorporating proactive thinking and a robust compliance regimen in all scientific matters. The consequences of non-compliance will be examined, including a thorough review of examples of previous FDA inspectional findings.

**FIRST DAY**

**Section 1: Introduction: The GLPs**

- Historical perspective & development
- Role and philosophy of the FDA
- Role of other federal agencies
- FDA regulations/guidelines/policies
- International GLP, ISO and harmonization
- When you need GLP and when you don’t

**Section 2: The Regulations – 21 CFR 58**

- Subpart A – General Provisions
- Subpart B – Organization & Personnel
- Subpart C – Facilities
- Subpart D – Equipment
- Subpart E – Testing Facility Operations
- Subpart F – Test & Control Articles
- Subpart G – Protocol
- Subpart J – Records/Reports
- Subpart K – Disqualification

**Section 3: It Starts at the Top – Organization, Management & Documentation**

- Organization and management structure; regulatory implications; involvement of personnel from a wide variety of functions
- Requirements for training of staff and documentation of such training; certification for employees, job competency standards, job descriptions, continuing education programs and annual refreshers
- Notebooks: Maintaining a laboratory notebook--do’s and don’ts: patent law and regulatory constraints; changes in US law for foreign inventors; electronic signatures, batch records and documents, electronic submissions
- SOPs: Writing, approval and dissemination of Standard Operating Procedures (SOPs); training of personnel; change control
- Logbooks and maintenance records
- Qualification (installation, operational and performance) and validation of key equipment, apparatus and computer programs

**SECOND DAY**

**Section 4: Implementing GLPs**

- Conducting a GLP audit and what it can tell you
- Basic elements of a quality system
- Writing & implementing SOPs
- The role of the Quality Unit
- GLPs in a mixed-GxP environment
- GLPs for the smaller organization or independent investigator

**Section 5: Study Director**

- Roles of the Study Director
- Protocol Development
- Subject Matter Expert
- SOPs and Study Method Development
- Validation Judge
- Study Reports and Amendments
- Archiving of Laboratory Data
- Role in Regulatory Inspections

**Section 6: Quality Assurance**

- Master Schedule
- Management’s Representative in the Laboratory
- SOP System Manager
- Auditor
- Conducting Audits
- Documentation Expert
- Manager of the Archives
- Role in Regulatory Inspections

**Section 7: Regulatory Inspections**

- Review of available guidance documents and regulatory resources
- The FDA GLP Inspection Program
- Foreign inspections
- Responsibilities for compliance
- Review & analysis of FDA inspectional findings

**Section 8: GLP Inspection Observations (Workshop)**

- Determine who was responsible for Observations

**Section 9: Emerging Issues**

- FDA Challenges
- Harmonization of worldwide practices
- Quality System inspection techniques
- Quality by Design
- Likely revisions to GLP

**THIRD DAY**

**Section 4: Implementing GLPs**

- Conducting a GLP audit and what it can tell you
- Basic elements of a quality system
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