PAYMENT

$2150.00 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.

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.

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 128
Malvern, Pennsylvania 19355

http://www.CfPIE.com

CfPIE® The Center for Professional Innovation and Education, Inc.

COMPREHENSIVE OVERVIEW OF FDA REGULATORY COMPLIANCE FOR DRUGS & BIOTECH PRODUCTS

February 26 - 27, 2018 - Malvern, PA
July 30 - 31, 2018 - Boston, MA
November 1 - 2, 2018 - Malvern, PA

COURSE DESCRIPTION

This course is designed to provide participants with an understanding of the parameters for regulatory compliance, successful approaches to compliance, and meeting the concerns of regu-lators. Attendees will leave with a comprehensive set of tools for preparing regulatory initiatives, coping with challenges, and managing compliance.

Additional benefits of this class include:

- FDA authority and processes including 483s, Warning Letters, recalls, and other potential actions
- Update on FDA electronic submission procedures
- The benefits of a quality management system beyond the manufacturing environment

WHO SHOULD ATTEND

This course is designed to provide attendees with a strong foundation for understanding the regulatory requirements of the US FDA. The content is ideal for those looking for an introduction to regulatory compliance or who need a refresher on current compliance trends within the regulated environment.

Typical attendees include those in the following disciplines:

- Regulatory Affairs
- Manufacturing/Production
- Research and Development
- Quality Assurance & Control
- Development and preparation of submission material
- Laboratory operations

The course is ideal for new hires, as well as Managers, Directors, and Vice Presidents of Regulatory Affairs and Quality Assurance. All levels of experience will benefit from this course.

INSTRUCTOR CREDENTIALS

Glenda Guest is Vice President of Norwich Clinical Research Associates Ltd (NCRA). This full-service clinical CRO in upstate NY consults on study development, monitoring and analysis; clinical and data-management-department development; regulatory consulting; SOP consulting; GCP and clinical regulatory training/auditing services. NCRA has performed a number of FDA mandated third-party audits for companies against which an integrity hold has been applied – an experience that has allowed Ms. Guest to develop a solid understanding of CDRH expectations.

Since 2004 Ms. Guest has lectured and trained on such topics as medical device clinical research, FDA Inspection preparedness, using FDA Warning Letters to improve practices, 21 CFR Part 11 compliance, computerized systems in clinical trials, electronic medical records, the changing 510(k) environment and quality systems in clinical trials.

With 14 years of experience in regulated research involving medical devices and an extensive background in clinical CRO; Ms. Guest has a unique perspective on regulatory requirements for device development and market approval. Serving such medical device companies as Welch Allyn, NMT Medical and BSD Medical; Ms. Guest has worked with large and small manufacturers in both premarket approval and 510(k) realms. Consulting for a global clinical research professional society, she also co-developed a two-day advanced training course for device professionals.

Ms. Guest is a Registered Quality Assurance Professional in Good Clinical Practices through the Society for Quality Assurance.

LEARNING OBJECTIVES

Upon completion of the course attendees will:

- Understand the guidelines, philosophy and practical approach to FDA compliance
- Comprehend the key strategies to achieve compliance: use of outsourced assistance, internal audits, the drug development and approval process, Quality by Design, reliance on electronic submissions, remediation plans and proper FDA communication
- Have resources for reference and update of latest regulations

HOTEL INFORMATION

The Hilton LAX, Los Angeles, CA (CfPIE room rate of $152/night if booked 3 weeks in advance of the course date)

The Desmond Hotel & Conference Center, Malvern, PA (CfPIE room rate of $136/night if booked 3 weeks in advance)

The Club Quarters Hotel, Boston, MA (CfPIE room rate of $249/night if booked 3 weeks in advance)

The Berlin Hilton, Berlin, Germany (CfPIE 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.)

FIRST DAY

1. Introduction

- FDA delegated authority and powers
- FDA compliance: regulations, guidelines, internal agency controls
- FDA enforcement
  - 483s
  - Warning Letters
  - Consent Decrees
  - Seizure
  - Recalls

2. Interpreting Regulations

- Review of applicable regulations
- FDC ACT
- CFR
  - Establishing clear criteria
  - Establishing clear SOPs and policies
  - Managing the process

3. Audits and outsourcing

- Auditor qualifications
- Use of contract support
- Internal auditing procedures and schedule
  - Key critical audit areas
  - Audit expectations of site personnel
- Staff training

4. Management Oversight

- Quality Policy
- Management Review
- Escalation of issues to upper management
- Communication, decision making and transparency across management
- Resourcing

SECOND DAY

5. Navigating FDA

- Website Review
- Investigator Operations Manual
- Compliance Policy Guides and Program Manuals

6. Emerging Trends at the FDA

- New compliance issues
- Drug shortage crisis
- Counterfeit drug issues and growing concerns
- Biosimilar approval pathways

7. Drug Development and Approval Process

- Drug Development
  - QbD product development and design
  - Risk analysis
  - Post approval changes to process, methods etc.
- Regulatory Filings
  - Key elements of IND, NDA/ANDA applications and FDA expectations
  - Electronic CTD format and content, most submitted through ESG (Electronic Submissions Gateway)
- FDA Review and Approval Process
- Post Approval Submissions

8. Successful Approaches to Compliance

- Internal Auditing Procedure and Schedule
- Gap Analysis
  - Regulations, Guidances and Procedures
- Remediation Plan
  - CAPAs
  - Change Control Process
  - Assignment of resources to correct issues
- Training Procedure and Curriculums
- FDA communication
  - Direct communication (emails,phone calls)
  - Recalls
  - Post approval submissions – annual reports, ADE reporting

9. Summary

- Key Issues
- Questions and resources