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 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.

COMPREHENSIVE OVERVIEW OF FDA REGULATORY COMPLIANCE FOR DRUGS & BIOTECH PRODUCTS

November 18 & 19, 2019 - Malvern, PA
May 18 & 19, 2020 - Los Angeles, CA
Nov 19 & 20, 2020 - 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 regulators. 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
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 (CPPIE room rate of $167/night if booked 3 weeks in advance of the course date)
The Desmond Hotel & Conference Center, Malvern, PA (CPPIE room rate of $141/night if booked 3 weeks in advance)
Club Quarters Hotels, Boston, MA (CPPIE room rate of $255/night if booked 4 weeks in advance).
DoubleTree by Hilton London - Victoria (CPPIE room rate of £199.00/night if booked 4 weeks in advance)