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

**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.

**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.

**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.
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

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, Guidelines 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