This course is designed to provide participants with an understanding of the parameters, approaches, and concerns of FDA inspectors, and the tools for preparing, coping, and managing those inspections in pharmaceutical, biologics, and device facilities.

Additional benefits of this class include discussion of:

- FDA authority and process including 483s, Warning Letters, recalls, and other potential actions
- The FDA inspection process and approach
- Device Master Records requirements
- The use of a mock audit and outside certifying audit
- Required documentation, format, and archive
- How to respond to inspection and audit results
- Parallel process from the EMEA, TGA, PMDA, and other international regulatory agencies
- A chance to actively learn from fellow participants and an instructor who brings 30 years of practical regulatory experience to a lively combination of lecture, discussion, and exercises

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.

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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.

FDA INSPECTIONS - WHAT REGULATORS EXPECT AND HOW TO PREPARE

INSTRUCTOR: KERRY POTTER

November 18 & 19, 2019 - Boston, MA
Mar 19 & 20, 2020 - Malvern, PA
Jul 20 & 21, 2020 - Boston, MA
Nov 9 & 10, 2020 - Los Angeles, CA

Go to http://www.CfPIE.com
INSTRUCTOR CREDENTIALS
Mr. Kerry Potter is the founder of Summit Consulting, Inc. He has more than 30 years of experience in project management, regulatory compliance systems, quality assurance, quality systems audits, regulatory training, employee development, GMP and documentation.

During the past 10 years, Kerry has provided consulting, training and mentoring services to several pharmaceutical firms in the United States and Europe through regulatory remediation activities (e.g. Consent Decree, Warning Letters), training and training systems development, documentation control, and project management.

Mr. Potter gained his pharmaceutical-manufacturing experience during his 28-year career with Merck. His experience spanned quality operations, audits/inspections, laboratory, human resources, and learning & development. His responsibilities included quality inspector, analytical chemist, quality motivation administrator, laboratory quality-management assessment manager, GMP lead auditor, FDA quality-management system manager, SS coordinator, GMP trainer, OSHA regulations trainer, process safety management training, and internal and external public relations management.

Mr. Potter received his B.S. in Chemistry from James Madison University. He has received qualifications and certifications in quality auditing, facilitation and training – including instructional design and competency-based curricula. His past and current affiliations include ASQ, ASTD, PDA, GMP-TEA, ASPI and AQP.

WHO SHOULD ATTEND
This is a practical, hands-on course designed to provide pharmaceutical, biopharmaceutical, biologics and medical device professionals with the information and tools they require to prepare for and manage an FDA inspection. The course is ideal for Managers, Directors, and Vice Presidents of Regulatory Affairs and Quality Assurance.

HOTEL INFORMATION
The Hilton LAX, Los Angeles, CA (CPIE room rate of $167/night if booked 3 weeks in advance of the course date)
The Desmond Hotel & Conference Center, Malvern, PA (CPIE room rate of $141/night if booked 3 weeks in advance)
Club Quarters Hotels, Boston, MA (CPIE room rate of $215/night if booked 4 weeks in advance).
DoubleTree by Hilton London - Victoria (CPIE room rate of £199.00/night if booked 4 weeks in advance).

FIRST DAY
Introduction
- Participant goals, issues and questions: a flexible framework to assure that everyone leaves with the information they need
- FDA Inspections: authority, guidelines, internal agency controls
- Strategies for copies with FDA inspections

The Inspection Process
- Systems and traditional inspection approaches
- Establishing clear SOPs and policies
- Managing the process
- Device issues: engineering, quality control, and the Device Master Record (DMR)
- Common 483s and warnings

MOCK AUDIT (workshop): Case Study of a Manufacturing Facility Inspection: Systems Inspection
- FDA inspection questions
- Documentation
- CAPA: corrective and preventive actions
- OOS: “Out of Specification” prevention and response

Legal Issues
- Executive responsibility and vulnerability
- Management review
- Staff training
- FDA authority and powers process

An audit perspective of the MVP

SECOND DAY
FDA Inspection Checklist: Do’s and Don’ts
- Documentation preparations
- Hosting investigators
- What not to say
- Key roles and players
  - Responses to the inspections
  - Initial response
  - Challenge
  - Dispute

Emerging Issues
- Part 11 Signatures and records: latest interpretation, 483s
- Signature authentication
- Archiving
- Audit trails
- QbD product development and design: latest interpretation, 483s
- Process Analytical Technology (PAT)
- Design space
- Risk analysis
- Special device issues
  - Engineering
  - DMR
  - Testing
- Other emerging 483 issues

MOCK AUDIT (workshop): Case Study-GMP Audit Medical Device
- FDA inspection questions
- Documentation
- CAPA: corrective and preventive actions
- OOS: Out of specification: prevention and response
- The DMR

Uses and Limits of Internal Audits
- Fear factor
- Inside versus outside
- Checklist
- A model of successful audits
- A model for FDA inspections

SECOND DAY cont.

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