

COURSE FEE

\$2650.00 PER PERSON

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.
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<http://www.CfPIE.com>



PHARMACEUTICAL ROOT CAUSE ANALYSIS OF FAILURES & DEVIATIONS - DEVELOPING AN EFFECTIVE CAPA STRATEGY

COURSE INSTRUCTOR: KERRY POTTER

**COURSE DATES WILL BE OFFERED
VIRTUALLY THROUGH LIVE INTERACTIVE
SEMINARS**

May 3 – 5, 2021 - CDT

Aug 11 – 13, 2021 - CDT

Nov 8 – 11, 2021 - UK Time – Noon to
17:00 (4 days)

COURSE DESCRIPTION

Inadequate failure investigations continue to be a major GMP deficiency cited during routine and for-cause regulatory inspections. This course highlights FDA and EU regulations and how to successfully approach a failure investigation and engage in subsequent root cause analysis.

The primary objective of this course is to recognize the value of conducting proper root cause analysis and documenting failure investigations. Emphasis is placed on the application and practical, hands-on aspects of how to facilitate root cause analysis. Additionally, the course will provide attendees with the principles and techniques involved in identifying failures and deviations, categorizing problems, assigning responsibility and tracking team activities.

Additional benefits of this class include:

- Learn not just from the Director, but tap into the knowledge of your peers: Participants will have the opportunity to anonymously submit their challenges, problems, and issues for classroom discussion. Ample time is provided to address specific problems and questions of individual participants
- Explore the use of brainstorming, process mapping and regulatory resources
- Participants will also have the opportunity for one-on-one consultation with the Course Director during course breaks and in the evenings

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, 5S 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.

LINKEDIN: <https://www.linkedin.com/in/kerry-potter-4749b04>

FIRST DAY

Course Introduction and Expectations

Regulatory Expectations for Investigations

- FDA (21 CFR and Guidance Documents)
- EU (Eudralex, Volume 4)
- ICH
- FDA 483s and Warning Letters
- Landmark case

Investigation Process Overview

- Purpose, basics and sources (types and categories) of investigations
- Elements of a thorough investigation process (Discovery through Closeout)
- Classification levels
- Investigation planning, action items and documentation
- Company culture

Skills and Tools of an Effective Investigator

- Characteristics and techniques
- Reading and documentation practices
- Technical writing

SECOND DAY

(Re) Introduction to Root Cause Analysis (RCA)

- Principles of root cause analysis
- Why root cause analysis is difficult
- Methodology of root cause analysis

Defining the Deviation

- The problem statement
- Active listening and interviewing
- Process mapping
- Brainstorming tools
- “Is/Is Not” technique

Identifying Root Cause

- 5 Whys
- Relations Diagram
- Ishikawa diagrams (Fishbone)
- Fault Tree Analysis vs. Failure Modes and Effects Analyses (FMEA)
- Challenges

THIRD DAY

Corrective and Preventive Actions (CAPA)

- What is the CAPA System
- Definition and regulatory interpretation
- Identifying and writing of corrective actions
- Abuses of the CAPA system
- Discuss robustness and effectiveness review

Management of the investigation

- Members of the Investigation Team
- CAPA management/team

Members of the Investigation Team

- Culture
- Compliant document extensions and interim reports (justification)
- Management communication and notification
- Metrics and trending
- Interim controls, timetables and other reports
- Policy and Standard Operating Procedures
- Escalation action assessment
- Common barriers and solutions
- Investigator training

Wrap Up and Review



GLP FACILITY CERTIFICATION FROM CFPIE.
WRITE INFO@CFPIE.COM FOR MORE INFORMATION.

