COURSE FEE

$2150.00 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

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

BASIC GMP TRAINING FOR THE QC LABORATORY

COURSE DIRECTOR: STEVEN A. OSTROVE, PH.D.

COURSE DATES WILL BE OFFERED VIRTUALLY THROUGH LIVE INTERACTIVE SEMINARS

Jun 28 & 29, 2021 - CDT

Sep 27 – 29, 2021 - UK Time – 12-5 x 3 days

COURSE DESCRIPTION

Upon completion of this course, you will:

- Be conversant in the specialized language of laboratory compliance
- Be very familiar with the cGMPs and other regulations as they impact QC labs
- Know the current compliance “hot spots” that FDA and other regulatory authorities look for when inspecting QC labs
- Understand how to effectively deal with laboratory deviations and OOS results
- Have an understanding the what, how and why of laboratory equipment qualification and methods validation
- Understand how to properly prepare your QC lab for audits and inspections

INSTRUCTOR CREDENTIALS

Steven A. Ostrove, Ph.D., has been involved in the Bio-Pharmaceutical business for over 35 years and is an invited course leader, lecturer and guest speaker for both national and international conferences.

In 1999, he opened Ostrove Associates, Inc. (OAI) – a validation, compliance and regulatory-affairs consulting company – to provide consulting services to both major pharmaceutical/biotechnology companies and small, start-up companies. Previously, Dr. Ostrove worked as Senior Technical Specialist in the Technical Service Department of Pharmacia Biotechnology. He also served as Senior Director of Validation and Regulatory Affairs with a number of major design/build engineering companies.

In addition, Dr. Ostrove has also served as an adjunct professor of Pharmaceutical Engineering for Validation and Regulatory Affairs for the New Jersey Institute of Technology and as an adjunct professor of Biology for Kean College. He recently served as industry representative on an FDA advisory panel and as Acting Manager of Validation for a contract pharmaceutical/OTC manufacturer.

LEARNING OBJECTIVES

This course is intended to give participants a thorough overview and practical understanding of Current Good Manufacturing Practices for laboratory compliance including:

- General requirements for design and construction of analytical laboratories
- Calibration and Qualification of instrumentation and equipment
- Documentation, records-keeping and change control
- Management of reagents, test solutions and reference standards
- Personnel development and training

FIRST DAY

Regulations – Guidance's-Problems

Session 1 – Introduction to Laboratory GMPs

- Introduction
- Overview of CFR Title 21, Parts 58, 210 and 211, an abbreviation and acronym primer
- Differences between Part 58 and Part 211
- The Design of a Quality Control Laboratory:
  - Part 211 Subpart C: Buildings and Facilities
  - Utilities
  - Equipment and Instrumentation-Subpart D: Equipment

Session 2 – The GMP Laboratory

- The Essentials of CGMP compliance Laboratory Management-Subpart J: Records and Reports
  - Essential Documentation Sample management-Subpart E: Control of Components and Drug Product Containers and Closures
  - Good Documentation Practices (GDP)
- Stability
- Training

Session 3-When Things Go Wrong

- Using the guidance documents
- Deviations and test failures, Subpart F: Production and Process Controls
- Effective Investigations
  - A basic root cause analysis primer
- Corrective and Preventative Actions (CAPA)

SECOND DAY

Auditing – Validation-Improvement

Session 4-The Regulatory Inspection

- Planning, techniques, reporting and follow-up actions
- Self-Inspection and Self-Auditing
- Auditing external QC labs

Session 5-Laboratory Validation and Other Quality Concerns

- Analytical method validation
- Equipment Qualification Requirements
  - Qualification of QC lab equipment: D/I/O/PQ
  - Design Qualification
  - Installation Qualification
  - Operational Qualification
  - Performance Qualification
- System Suitability Testing: an essential component of lab compliance
- Calibration and maintenance of QC lab equipment
- 21 CFR Part 11 and the QC lab

Session6-The cost of non-compliance-Hot Topics

- Examples of Observation of non-compliances – FDA 483
- Top CGMP problems FDA sees in QC labs
- Warning Letters and current hot topics in lab compliance
- Improving operations
- Discussion Forum:
  - Question and Answer Period, Course wrap-up and conclusions
  - What are your top lab compliance challenges, issues, and problems?
  - Discussion of participant questions, problems, and issues