REGISTRATION 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. ***Not applicable to El Paso dates.*** 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 which can be delivered virtually. 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

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GOOD MANUFACTURING PRACTICES

INSTRUCTOR: KERRY POTTER

COURSE DATES WILL BE OFFERED VIRTUALLY THROUGH LIVE INTERACTIVE SEMINARS

Jan 13 – 15, 2021 - Virtual (CST)

COURSE DESCRIPTION

This course covers the foundations of the regulations that control the manufacture and distribution of pharmaceutical, biologic and medical devices sold in the United States. CGMPs are defined for all Food and Drug Administration (FDA) Regulated products in Title 21 CFR 210/211. Application of the regulations will be discussed and examples provided throughout the course. Attendees will gain an understanding of how knowledge of the regulations facilitates efficient and cost effective production and problem resolution.

Each section of 21 CFR 211 (Current Good Manufacturing Practices [CGMP] for Finished Pharmaceuticals) will be covered interspersed with references from 21 CFR 600/610 (Biological Products: General) and 21 CFR 820 (Quality Systems Regulations). Although CGMP refers to 21 CFR 210/211 the other Parts (600 and 820) rely on Part 211 as well. In addition to the above, ICH, EU, and other comparisons will be made in order to provide a complete understanding of the regulations.

The course provides a complete overview of the industry requirements as specified by the FDA.

INSTRUCTOR CREDENTIALS

Mr. Kerry Potter is the founder of Summit Consulting and has more than 30 years' experience in the areas of project management of regulatory compliance systems, quality assurance and quality systems audits, design and presentation of regulatory training, employee development, GMP and documentation. He has been assisting pharmaceutical firms (domestic and non-domestic) in the areas of remediation and project management in quality systems, manufacturing controls and training functions for the past five years.

Kerry gained his pharmaceutical manufacturing experience during his 28-year career with Merck. His career spanned the areas of Quality Operations, Audits & Inspections, Laboratory, Human Resources, and Learning & Development. More specifically, his responsibilities included quality inspector, analytical chemist, quality motivation administrator, quality management of laboratory assessment, site GMP lead auditor, FDA Quality Management System manager, 5S coordinator, GMP trainer (annual, ongoing, new hire), OSHA regulations and Process Safety Management training, as well as internal and external public relations.

Kerry is a graduate of James Madison University in Harrisonburg, VA (B.S. in Chemistry). He has received qualifications and certifications in the areas of facilitation and training, including instructional design and competency-based curricula, and the ASQ Certified Quality Auditor. His past affiliations have included ASQ, ASTD, PDA, GMP-TEA, ASPI, and AQP.

WHO SHOULD ATTEND

This three-day course is designed for those who work in a current Good Manufacturing Practices (CGMP) environment (beginners to advanced professionals). It is designed for those whose roles and responsibilities require that they understand and apply CGMP quality principles to their job as related to product discovery, development, and/or manufacturing. It will benefit professionals who are new to industry, by presenting an overview of the important concepts in a logical and natural sequence so they can begin to understand GMP regulations and begin applying them effectively. The course is also designed to help both the "CGMP Intermediate" and the "CGMP Professional" by providing continuity from product development through facility construction and final product release. Understanding the 'why' of CGMP principles along with valuable insights and examples that will assist them in their quality decision-making, as well as, demonstrating ways to make their present systems more effective.

FIRST DAY

Section 1 - Introduction to the Regulations
- What are the GMPs
- Intro to the FDA
- Intro to the FD & C

Section 2 - Other Regulatory Agencies
- EU and other regulations
- Importance to our manufacturing

Section 3 - Organization and Personnel Roles and Responsibilities
- Department Roles/Functions
- Interactions
- Training
- Change Control

SECOND DAY

Section 4 - Facilities & Equipment
- Types of Facilities – Solid Dose, Aseptic, Biologic, API
- Facilities and Equipment – the role they play
- Flows – Material, Air, Personnel
- Lighting, Plumbing, & Containment/Contamination

Section 5 – Vendors and Materials Control
- Classification of materials according to function
- Material specifications
- Vendor Auditing- qualifying, and controlling suppliers and contractors
- Control of incoming materials
- Container Closure and other GMP functions
- What the regulations require for reduced testing

Section 6- Process Control: "Master Batch Records and Validation"
- The Validation Master Plan
- Review and Approval of Master Records
- Converting the Master Record to a Batch or History Record
- Predicate rules and Part 11 – What are they really
- Another new paradigm-Process Analytical Technology (PAT)

Section 7 - Packaging and Labeling
- Why is packaging and labeling is so important?
- Controlling Labels and other Printed Materials
- Examining and storing Packaging & Labeling Materials
- Controlling labeling operations

Section 8 - Validation (applying CGMPs)
- Qualification v. Validation
- Protocol Development
- Types of Validation
- Executions
- Final Reports

THIRD DAY

Section 9 - Laboratory Controls
- Sampling
- Analytical methods-Scientific Basis, Approval, & Validation
- Pharmacopeias
- Methods Validation Requirements
- Equipment Qualification Requirements
- Controlling Reagents & Reference Standards
- Laboratory Data-Notebooks, LIMS, & Disks
- Equipment Controls
- Using a Contract Laboratory

Section 10 - Product Release and Distribution
- QA Responsibilities in Product Release
- Why perform testing on finished products?
- Batch Record Review
- Recalls

Section 11 - Records – Reports – Investigations
- Storing Documents and Retains
- When Things Go Wrong
- Getting to the Root Cause

Section 12 – Wrap Up
- Discussion of Hot Topics
- Consent Decree Case Studies
- Questions & Answers