

## 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](mailto: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](mailto: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](mailto:info@cfpie.com).

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CfPIE also offers on-site courses for 10 or more attendees. Contact us at [info@cfpie.com](mailto: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>



## COMPREHENSIVE OVERVIEW OF FDA REGULATORY COMPLIANCE FOR MEDICAL DEVICES™

February 5 - 6, 2018 - Malvern, PA

September 17 - 18, 2018 - Malvern, PA

## COURSE DESCRIPTION

This course discusses the FDA's regulatory authority for approving medical devices prior to marketing and the compliance programs used in enforcing its authorities during the manufacture and post-marketing reporting systems. It also provides FDA strategies towards inspections of manufacturing sites, and compliance actions that may result from these inspections. The course provides the attendees with the most important regulatory resource materials needed to understand agency policies and enforcement actions.

Issues to be covered include:

- Structure of the FDA and current FDA regulatory compliance practices- how to work with FDA investigators
- The regulatory approval process – “what the FDA is looking for” in 510ks, PMAs and other pre-approval applications
- The scope of FDA's compliance programs, policies and potential enforcement actions
- Discussion of post-marketing notification and reporting programs
- Strategies for development of an in-house compliance program for GMPs which ensure successful inspectional outcomes
- Recent FDA enforcement statistics

## WHO SHOULD ATTEND

This training course has been developed for those who are involved with ensuring regulatory compliance for medical devices. The course is primarily geared towards those who are new to industry or require a basic understanding of medical device regulatory compliance issues. The training may be of interest to industry veterans who need refresher training on these topics.

## INSTRUCTOR CREDENTIALS

Glenda Guest is Vice President of Norwich Clinical Research Associates Ltd (NCRA). This full-service clinical CRO in upstate NY consults on study development, monitoring and analysis; clinical and data-management-department development; regulatory consulting; SOP consult-ing; GCP and clinical regulatory training/auditing services. NCRA has performed a number of FDA mandated third-party audits for companies against which an integrity hold has been applied – an experience that has allowed Ms. Guest to develop a solid understanding of CDRH expectations.

Since 2004 Ms. Guest has lectured and trained on such topics as medical device clinical research, FDA Inspection preparedness, using FDA Warning Letters to improve practices, 21 CFR Part 11 compliance, computerized systems in clinical trials, electronic medical records, the changing 510(k) environment and quality systems in clinical trials.

With 14 years of experience in regulated research involving medical devices and an extensive background in clinical CRO; Ms. Guest has a unique perspective on regulatory requirements for device development and market approval. Serving such medical device companies as Welch Allyn, NMT Medical and BSD Medical; Ms. Guest has worked with large and small manufacturers in both premarket approval and 510(k) realms. Consulting for a global clinical research professional society, she also co-developed a two-day advanced training course for device professionals.

Ms. Guest is a Registered Quality Assurance Professional in Good Clinical Practices through the Society for Quality Assurance.

## LEARNING OBJECTIVES

This course is specifically focused on the law, regulations and policies set by the FDA for the pre-market approval, manufacture and post-marketing compliance of medical devices. The course content is designed to provide an in-depth understanding of the paths to obtaining agency approval; how the FDA performs inspections; the type of controls, systems and documentation they expect to see in place; and the variety of outcomes from each inspection. The course also covers the remedies available to show inspectors that manufacturing processes are in full compliance with quality system requirements.

## HOTEL INFORMATION

The Hilton LAX, Los Angeles, CA (CfPIE room rate of \$152/night if booked 3 weeks in advance of the course date)

The Desmond Hotel & Conference Center, Malvern, PA (CfPIE room rate of \$136/night if booked 3 weeks in advance)

The Club Quarters Hotel, Boston, MA (CfPIE room rate of \$249/night if booked 3 weeks in advance)

The Berlin Hilton, Berlin, Germany (CfPIE room rate of Standard Single Room is €179.00 and Double Occupancy is €199.00 inclusive of VAT and Breakfast if booked 4 weeks in advance.)

## FIRST DAY

### Introduction

- Objectives
- Seminar overview

### Introduction to FDA

- FDA organization and key departments
- Regulatory procedures manual
- Compliance program – compliance policy guides and other documents
- Regulatory history for devices
- Regulations and applicable guides

### Product Approval Processes

- Classification of the device is key
- Premarket notification
- Premarket approvals
- De Novo Reclassification
- Investigational clinical studies

### FDA Reporting Systems

- Registration and listing
- US vigilance system-MedWatch
- Corrections and removals

### Compliance System

- Types of programs
- Inspectional operations manual
- Inspectional outcomes

### Enforcement Tools and Actions

- Types of actions
- Warning letters, civil money penalties and criminal penalties

### Enforcement Statistics

- Review and discussion of warning letters and other enforcement actions

### Question and Answer Session

## SECOND DAY

### Quality System Orientation – 21 CFR 820

- QSR scope, definitions and requirements
  - Key elements – Management responsibilities, design controls, production & process controls, non-conformances and CAPA, controls of documents and records
- ISO 13485 comparison to QSR

### Quality System Inspection Technique (QSIT)

Approach  
Objective  
Key subsystems

### Quality Risk Management

ISO 14971

### Do's and Don't's

Risk areas you want to avoid  
Staying away from red flag areas

### Why Systems Fail

### Question and Answer Session

