

## 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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Suite 295  
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<http://www.CfPIE.com>



## CLINICAL TRIAL DESIGN FOR MEDICAL DEVICES™

October 18 - 19, 2018 - Malvern, PA

April 3 & 4, 2019 - Boston, MA

## COURSE DESCRIPTION

Clinical studies are an integral part of the approval process for medical devices. While some devices may be approved with little or no clinical data, for others, manufacturers need to demonstrate, with safety and effectiveness data in the target population, that the product is safe for human use. This course offers an overview of the regulatory process for medical device applications, including medical device clinical trial design and implementation. Throughout, examples and case studies will help participants apply the concepts being covered.

## WHO SHOULD ATTEND

This two day course is designed for Medical Device professionals involved in clinical trials.

It is primarily designed to benefit the following disciplines and personnel:

- Clinical Affairs
- Medical Directors
- Regulatory Affairs
- Product Development
- Project Managers

## 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 consulting; 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.

### 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)

Club Quarters Hotels, Boston, MA (CfPIE room rate of \$230/night if booked 4 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 to Clinical Trials

- What is a clinical trial?
- Why are clinical trials performed?
- Types of clinical trials
- Differences between medical device, drug, and biologic trials

### Premarket vs. Post Market Clinical Trials

- What is a premarket clinical trial?
- Types of premarket clinical trials
  - Pilot (feasibility)
  - Pivotal
- What is a post market clinical trial?
- Types of post market clinical trials
  - Condition of Approval
  - Registry
  - Post Market Surveillance/522

### How Claims for Medical Use Impact Trial Design

- Intended Use
- Indications for Use
- Implied Claims
- Comparative Claims

### Protection of Human Subjects

- Declaration of Helsinki
- Informed Consent
- Ethical considerations

### Institutional Review Boards (IRB)/Ethics Committees (EC)

- Purpose
- Organization
- Responsibilities
- Records and reports

### US and EU Premarket Regulatory Requirements

- Significant vs. non-significant risk
- Sponsor and Investigator responsibilities
- Application contents
- Report of prior investigations/Investigator Brochure and regulatory manuals
- Additional requirements

### Changes during the Conduct of the Trial

- Supplemental applications
- IRB/EC review
- Informing patients

## Regulatory Reporting and Record Keeping Requirements

- Investigator and Sponsor records
- Investigator and Sponsor reports

## SECOND DAY

### Design of Clinical Study Protocols

- Study objectives
- Hypotheses, primary and secondary endpoints
- Specific study population
- Control groups
- Inclusion and exclusion criteria
- Sample size, selection of study sites, and investigators
- Randomization plan
- Treatment
- Subject compliance and monitoring
- Anticipated and unanticipated Adverse Effects
- Follow-up procedures
- Methods of analysis, including interim analysis
- Methods for collection and validation of data

### Preparation of Clinical Study Report

- Study objectives and design
- Specific study population
- Control groups
- Treatment
- Methods of analysis and evaluation of data
- Results
- Comparison of results to success/failure criteria
- Anticipated and unanticipated Adverse Effects
- Deviations
- Discussion of missing data and impact
- Method of statistical analyses
- Conclusions
- Appendices (e.g., Data Listings, CRFs)

