## PAYMENT

$2650.00 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 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.

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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.
7 Great Valley Parkway
Suite 295
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http://www.CfPIE.com

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# CLINICAL TRIAL PROJECT MANAGEMENT FOR PHASE 1 THRU PHASE 4: BEST PRACTICES

**COURSE DIRECTOR: KAY MONROE**

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December 9 – 11, 2019 - Boston, MA

Sep 16 – 18, 2020 - Malvern, PA

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## COURSE DESCRIPTION

Efficient and effective management of clinical trials can significantly impact the time, scope and budget for the development of a drug. Project managers must understand the development process and the key aspects of all phases of Clinical Development in order to act, react and adapt to change when the program moves forward and new data is acquired. Successful completion of Phase 1 and Phase 2 clinical trials are key project milestones to achieving proof of concept for any new drug. Phase 3 clinical trials are critical to gain regulatory approval for the market and Phase 4 allows expansion and extension of the indication for a drug. This course focuses on the best practices for developing and managing these trials within GCP guidelines and FDA regulations.

The course will discuss the challenges associated with clinical trials run outside the United States and identify key differences, common pitfalls, and cultural differences. Guidance for the how-to as well as problem-solving for specific situations such as slow enrollment, high screen failures, or issues with data quality will be provided. The course is interactive and designed to allow for the exchange of ideas between peers in addition to learning from the instructor.

## INSTRUCTOR CREDENTIALS

Kay Monroe is Acting Executive Director of Zagaya. This non-profit – specializing in Malaria – works to bring innovative technologies to the problems of global health in the developing world.

Ms. Monroe has spent over 25 years with biotechnology and pharmaceutical companies around the world; working on global project teams from Research through Phase IV and introducing Project Management Offices into several companies. She has extensive experience in product lifecycles and the creation of submission documents. In addition, she has sourced both items and processes for pharmaceuticals, biologics and devices.

Ms. Monroe has held positions as Vice President of Operations, Project Management and Quality Assurance in companies such as Lundbeck, Synarc and Genentech. She has extensive experience in the start-up environment with such companies as Cerus, Dynavax and Amyris.

Ms. Monroe received her Bachelors of Science in Animal Science from UC Davis and her MBA from Golden Gate University.

## WHO SHOULD ATTEND

This course is an overview designed for those in the Pharmaceutical and Biotech industries who will manage or direct projects within their functional area related to Clinical Trials. It will also benefit those who need an understanding of industry specific and project management best practices that should apply to their project. This course also applies for current project managers and others who may have cross-functional project management responsibilities.

## HOTEL INFORMATION

**The Hilton LAX, Los Angeles, CA** (CfPIE room rate of $167/night if booked 3 weeks in advance of the course date)

**The Desmond Hotel & Conference Center, Malvern, PA** (CfPIE room rate of $141/night if booked 3 weeks in advance)

**Club Quarters Hotels, Boston, MA** (CfPIE room rate of $255/night if booked 4 weeks in advance).

**DoubleTree by Hilton London - Victoria** (CfPIE room rate of £199.00/night if booked 4 weeks in advance)

## FIRST DAY

**Drug Development and Project Management**

- Overview of the Drug Development Process
- The History of Project Management

**Overview of Clinical Phases – What are they?**

- Phase 0 or Exploratory INDs
- Phase 1
- Phase 2 (a/b)
- Phase 3 (a/b)
- Phase 4
- Investigator Sponsored Studies

**Clinical Development Tools**

- Target Product Profile (TPP)
- Clinical Development Plan (CDP)
- Protocol templates
- Clinical Plan (CP)
- Core Data Sheet or MIRS (Messages, Issues, Responses, Supporting Documentation)

**Regulations Governing Clinical Research**

- Brief History of the FDA

## SECOND DAY

**Regulations Governing Clinical Research (cont'd)**

- FDA, EMA, MHAA
- Good Clinical Practice (GCP)
- International Conference on Harmonization (ICH)
- Who is responsible? Sponsor, Monitor, Investigator

**Ethics and Warning Letters**

- What they tell you and how can you apply those lessons?

**Study Conduct**

- Timelines
- Budgets
- Risk Assessment
- CROs and Outsourcing

## THIRD DAY

**GlobalTrials**

- Working in China and India
- Working in the Developing World
- Common Issues to address – Culture, Language, Time Zone

**Life Cycle Management**

- Keeping your Drug Portfolio alive
- Extending Patent Life
- Line Extensions, Re-Purposing, Re-Branding
- Fraud and Misconduct

**Team Conduct**

- High Performing Teams
- Team Roles and Responsibilities
- Communication, Negotiation & Conflict
- Team Dynamics and Leadership

For more information about On Site Courses or our GLP Facility Certification, please see www.cfpie.com or write Info@cfpie.com for more information.