Understanding & Implementing New EU Clinical Trial Regulation & GDPR

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

August 19 & 20, 2019 - Boston, MA

COURSE DESCRIPTION
This course focuses on understanding and implementing the requirements of the new EU Clinical Trial Regulation and how it differs from the previous EU Directive and other country’s requirements. The course covers all relevant topics associated with the Regulation, the reasons behind its replacement of the Directive and a review of methods for effective implementation. This course was recently updated to include the new EU General Data Protection Regulation which became mandatory May 2018. The course consists of lecture and interactive exercises to reinforce the learning.

Key Topics to be discussed:
- The current regulatory situation in relation to clinical trials in the European Union
- The purpose of the Clinical Trial Regulation & why it replaces the Directive
- Implementing the EU Clinical Trial requirements
- Understanding the impact the Regulation will have on running clinical trials
- A detailed explanation of the key differences between the EU Clinical Trials Regulation and FDA Regulations and ICH Guidelines
- The key differences between the EU Regulation and the requirements in China, India and Japan

WHO SHOULD ATTEND
This two-day training course will describe the new Regulation while focusing on implementation of its requirements. This course will be of value to clinical research professionals conducting clinical trials in the European Union either as stand alone or as part of a multi-national clinical study program. GCP and GMP requirements for the EU will be compared to those of the US. The course will also make comparison to China, India and Japan.

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.

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.

CfPIE also offers on-site courses for 10 or more attendees. Contact us at info@cfpie.com.

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
Malvern, Pennsylvania 19355 USA
610-648-7550

http://www.CfPIE.com
INSTRUCTOR CREDENTIALS

Michael A. Pierro is consultant to life sciences industries; building on over 35 years of pharmaceutical-industry experience to provide services in clinical-practice areas of SOPs, study management and monitoring, auditing and site qualification.

Mr. Pierro previously served as Director of Business Development, Consulting and Clinical Training for a large consulting firm. There, he was responsible for the development and implementation of SOPs, specialized training programs and related consulting services. His clients included pharmaceutical and biotechnology firms, CROs, university medical centers and the United States government.

Before this, Mr. Pierro was Director of Global Training for the Global Clinical Quality Assurance Department of Hoechst Marion Roussel (now Aventis). In this role, he directed all GCP, SOP and technical training activities within the company’s Drug Development Center and other sites throughout the world. In his other roles at the company; he served as a Senior CRA, Manager of Phase-IV Clinical Operations, Chairperson of the SOP Steering Committee and GCP Auditor. In addition, Mr. Pierro was involved in several NDA/SNDA preparations, filings and other reports to regulatory agencies.

LEARNING OBJECTIVES

Upon completion of this course you will have a working knowledge of the EU Clinical Trial Regulation requirements in the EU and how they differ with the US and Asian region requirements.

This course is designed to provide attendees with an understanding of:
- The regulatory requirements for conducting clinical trials in the European Union
- How to implement the Regulation and remain compliant
- How the EU Clinical Trial Regulation differs from the US FDA Regulations and ICH Guidelines

FIRST DAY

Background Information
- Clinical Trials pre-Directive
- Directive Development Timeline
- Overview of the clinical trial initiation process in the US

Describing The EU CT Directive
- Definition
- Purpose
- Scope
- Member states
- EU Regulatory organization & roles
- 2001/20EC 23 Articles: Requirements
- 2005/28/EC GCP Requirements
- 2003/94/EC GMP Requirements

Clinical Trial Differences Between the EU & US
- Major differences between US & EU requirements

Clinical Trial Application and Registration Process
Sponsor
- EudraCT application process
- CTA application contents
- CTA submission/revision Process
- CTA fee structure
- End of trial declaration

SECOND DAY

Ethics Committee Submission & Review Process
- Definition & role
- Responsibilities
- Sponsor submission/re-submission process
- Composition, functions, operations & procedures
- Documentation reviewed
- Approval process

Implementing the Directive
- GCP requirements
- GMP requirements

Safety Reporting Requirements
- Eudravigilence database
- SUSAR reporting requirements
- Reporting non-SUSARs
- Post marketing reporting requirements

Recent Initiatives & Future of the Directive
- Risk Based Monitoring
- Implementing Direct Data Entry
- Performance of Pharmacovigilance
- The Future of the Directive
  - 2010 Survey
  - Industry Feedback
  - Potential Changes

Course Review / Q & A

HOTEL INFORMATION

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<th>Location</th>
<th>Room Rate</th>
<th>Booking Period</th>
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<td>Hilton LAX, Los Angeles, CA</td>
<td>(CPEIE room rate of $167/night if booked 3 weeks in advance of the course date)</td>
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<td>The Desmond Hotel &amp; Conference Center, Malvern, PA</td>
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