SAN FRANCISCO
EVENTS LIST

The EU Clinical Trial Regulation + EU Filings & Registrations

Date : Feb 14, 2018 - 09:00 AM - Feb 15, 06:00 PM

Event URL : http://www.sfbayeventslist.com/events/the-eu-clinical-trial-regulation-eu-filings-registrations-feb-2018

Organizer : GlobalCompliancePanel

Venue : Hilton Zurich Airport

Location : 1 Main St,
Los Angeles , CA, US, ZIP: 00000

This course covers the requirements for conducting Clinical Studies across the EU via the requirements of the EU Clinical Trial Directive and the impending changes coming to the EU through the EU Clinical Trial Regulation (for Drugs, Biologics & Combination Products). The course also covers recent updates on EU-GCP associated with the new regulatory framework, the highlights of the new EU Pharmacovigilance Directive, as it relates to studies and helpful tips into working with the European regulators. Additionally, the seminar will cover the impending changes coming with the EU Parliament passage of the EU Clinical Trial Regulation, which will affect all trials conducted across the EU [new and ongoing].

This course covers the various licensing methods (for Drugs, Biologics & Combination Products) by which applicants can file for product licenses (Marketing Authorizations) in one or multiple Member States [and EEA], as well as fully across all Member States of the European Union. This course specifically outlines and discusses the structure of the regulatory agencies at the EU-level and across specific Member States. Course content will explain which procedures are available for which products and then will follow the license processing steps for each pathway.

Learning Objectives / Key Topics:

Attendees will leave the Course clearly understanding the requirements under the current Directive. In addition, this Course has been updated to provide participants with competitive insight into:

- How the EU and individual countries within Europe interact
- Which registration procedure to use
- How regulations effect product development strategies
- Pricing issues - Coordinated filing vs. Individual filing
- Understanding the concerns/issues of European Regulatory Personnel
- How to negotiate with the regulators
- Information necessary for effective submissions
- Strategies for streamlining the registration application process for faster approval
- The advantages and disadvantages of various registration procedures
- How to efficiently initiate trials.....first patient, first visit
- How to link the strategy of Country Selection to an ultimate EU Licensing Plan
- Efficiently implementing studies via project teams and CROs at the National and multi-state level
- How to stay compliant.....What can make the difference in your data passing Regulatory scrutiny
- Related area-GCP and PV-reporting updates
- EUCTD and EUCTR vs. FDA IND Regulations
- Impending Changes of the EU Clinical Trial Regulation and timing for Implementation

Day 1 Schedule

EU Clinical Trial Directive / New EU CT Regulation

Lecture 1:

Overview of the EU and EU Regulatory Structure

Lecture 2:

Overview of the EU Clinical Trial Directive, the 2007 Pediatric Legislation

---

Lecture 3:

Impending Changes of the EU Clinical Trial Regulation

Lecture 4:

Clinical Trials in the EU

- Phases of a clinical trial
- Start-Up and Application Processes
- Ethics Committee and Competent Authority Review Process
- Trial Protocol and Management
- GCP and GMP Compliance
- Labeling Requirements

- Fees

Lecture 5:

End of a Clinical Trial

Lecture 6:

How Changes of the new Clinical Trial Regulation will affect Sponsors

Day 2 Schedule

European Filing & Registration Procedures

Lecture 1:

EU Agency Regulatory Structure

Lecture 2:

Registration Options

Lecture 3:

Company Strategy- Linking Clinical Trials & Marketing Authorization Applications

---

Lecture 4:

Balancing Strategy and Long Term Regulatory Cost & Maintenance

---

Lecture 5:

Registration Procedures

- Member State Procedures
- Mutual Recognition Procedure
- Centralized Procedure

Lecture 6:

Abridged Applications

- Similar Products & Devices
- Request for Extensions
- Use of Expert Reports

Lecture 7:

Generics, Orphan Drugs, Biologics and Combination Products

Lecture 8:

Variations

- Changes Concerning Manufacturing Aspects (Product & Process)
- Labeling & Packaging Leaflet Requirements
- EU Commission Regulations

Lecture 9:

Decision Making Process

- Scope
- Check-in Procedure
- Internal Commission
- Consultation
- Industry's Ability to Impact?- Involvement & Timing
- Standing Committee Participation
- Favorable Standing Committee Opinion
- Non-Favorable Opinion ?- Process & Timing

Lecture 10:

Review of Regulatory Authorities

- International, Regional, and Local laws applicable for each European Union Nation

---

Lecture 11:

Member State Analysis of Applicable Regulations At All Levels With Practical Examples of How the Regulations Are Applied

- Legislative Process
- Objectives of the Rules Governing Medicinal Procedures
- Regulatory Framework
- New Products, Requirements, & Procedures

Lecture 12:

Political Implications of The Regulations

- Compare/Contrast EMA and the FDA procedures

Lecture 13:

How and When to Influence the Regulatory Process

- Effective Monitoring Activity
- Association vs. Individual Company Involvement & Intervention
- The Regulatory Negotiation Process
- Effective Approaches
- The Do's and Don'ts of Regulatory Involvement

Lecture 14:

How to Use Regulations / Regulatory Contacts to Your Advantage

- Check-in Procedure
- Internal Commission Interactions
- Procedures within each regulatory office, contacts, etc.
    - Product Development Strategy
- Business Impact Within and Outside the EU
- Professionalism in Regulatory Lobbying

Lecture 15:

Maintaining Your License: Renewals

Lecture 16:

Helpful Websites

Lecture 17:

Glossary of Terms

Robert Russell

President, RJR Consulting, Inc.

For the past 9 years, Bob has been President of RJR Consulting, Inc. The company assists the pharmaceutical, medical device and biotech industries in understanding and complying with International Regulations affecting compliance, new product development, manufacturing and quality assurance. RJR has offices in Columbus, OH, Washington, DC, Brussels, Belgium with exclusive affiliates across Asia and Latin America. Bob has 28 years of past industry experience

as a CMC specialist, R&D Director and Global Director of Regulatory Affairs for Merion Merrill Dow pharmaceuticals and Cordis-Dow medical devices. He has a BS / MS degree in Chemistry.

Please contact Marilyn Turner: Phone: +1 929 900 1853 Email: marilyn.turner [a] nyeventslist.com for registrations

Event Categories :