2-day In-person Seminar:

Safety Reporting in Clinical Trials for Drugs, Biologics and Medical Devices

San Diego, CA  
July 14th & 15th, 2016  
9:00 AM to 6:00 PM

Harold Thibodeaux

Research Investigator, Stiefel

Harold Thibodeaux is a medical research scientist with in vivo pharmacological experiences in both academia and biopharmaceutical industry. During his prestigious career the focus of Mr. Thibodeaux's research efforts has been on the efficacy of cardiovascular drugs most notably Hypertension, Myocardial Infarction, Focal Ischemia (Stroke), Beyond Advair Pulmonary Research and topical antibiotics. Optimal therapeutic benefits were the goal in all of these projects but cardiovascular safety to provide safer medicines to patients was a priority. Mr. Thibodeaux transitioned into the pharmaceutical industry when he joined the Cardiovascular Department of Genentech in 1990, as a technical lead with the Second Generation

Overview:

The Food and Drug Administration's Center for Drug Evaluation Research, Center for Biologics Evaluation and Center for Devices and Radiological Health are responsible for the approval of drug products, biologics and medical devices industries. This seminar begins with outlining the structural role of the FDA and a brief introduction to the Food, Drug and Cosmetic Act (the ACT) and how the FDA uses it to enforce the regulatory requirements during the drug, biologics and medical device approval process. Additionally, this seminar will highlight safety, which is in the FDA's mission statement, by guiding participants on how to develop a data safety monitoring plan and when it is important to use a Data Safety Monitoring Board.

Price:

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<th>Price: $1,495.00</th>
<th>(Seminar for One Delegate)</th>
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<td>Register for 5 attendees</td>
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<td>Price: $4,485.00 You Save: $2,990.0 (40%)*</td>
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**Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.**
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AGENDA:

**Day One**

**Lecture 1:** Introduction to the FDA, Food, Drug and Cosmetic Act - Regulations and Guidance
- Role, Structure and Operations of the FDA
- Good Clinical Practice (GCP) in Clinical Trials
- Regulatory Agencies Involved in Clinical Development of Drug Products

**Lecture 2:** Establishing and Importance of a Clinical Trial Safety Monitoring Plan
- Data Safety Monitoring Plan (DSMP) and Data Safety Monitoring Boards (DSMB)
- Who Requires What in Clinical Trials
- What is the Best Way to Monitor Your Clinical Trial
- Primary List of the Required Contents of DSMP

**Lecture 3:** Outline of Various Safety Management Practices Employed in Clinical Trials
- Data Safety Monitoring Boards (What are they and when are they necessary)
- Data Monitoring Committees
- Institutional Review Boards (IRB) and Ethical Review Committees
- Investigator brochure
- Safety Assessment Committees

**Lecture 4:** The Importance and Training Requirements for Safety Monitors for a Successful Clinical Trial
- General Information about a Clinical Monitor
- Duties in Specific Phases of Clinical Development
- Compliance Training on Good Clinical Practice (GCP), FDA Regulations and Guidelines
- Knowledge Specific to Site Study (SOPs, Protocols, Investigational Product)
- Site Specific Safety Monitoring

**Lecture 5:** The Process in the Establishment of an Adverse Event Database
- Background
- Targeted Data Collection - Recommendations
- Circumstances in Which Targeted Data Collection Maybe Appropriate
- Method for Target or Selection Collection of Safety Data
- When Comprehensive Data Collection is Really Needed
- Types of Data That Should be Collected

**Day Two**

**Lecture 1:** The Procedures and Requirements for Filing and Updating IND Safety Reports
- General Information about Investigational New Drug (IND) and Investigational Device Exemption (IDE)
- Mandatory Safety Reporting (IND - Initial and Follow up Reports)
- Monitoring the Safety Database and Submitting Safety Reports
- Submitting an IND Study
- Safety Reporting for Requirements for BA/BE Studies
- Review of Safety Information

**Lecture 2:** Comprehensive Discussion on IDE Safety Reports with Medical Devices
- General Information on an Investigational Device Exemption (IDE)
- Mandatory Medical Device Reporting
- Responsibilities of Investigator-Sponsor Safety Reports in Clinical Trials
- Reporting Requirements for Manufacturers
- Reporting Requirements for Investigators
- MedSun: Shining a Light on Medical Products Safety

**Lecture 3:** Safety Reporting for IND Annual Safety Update and Development Safety Update Report (DSUR)
- General Principles
- Relationship of DSUR to the Periodicity Safety Update Report
- Durations of DSUR Submissions
- Responsibilities for Preparing and Submitting a DSUR
- Guidance on Contents of a DSUR
- Significant Findings from Clinical Trials During the Reporting Periods

**Lecture 4:** Troubleshooting Safety Events with Site Principle Investigators to Ensure Study Quality
- Background Information - FDA Guidance
- Overview of Clinical Investigator Responsibilities
- Supervision of the conduct of the Clinical Investigator
- Protecting the Rights, Safety and Welfare of Study Subjects
- Reporting Timeframes
- Types of Reportable Events
- Protocol Deviation - Major and Minor ones.

**Lecture 5:** How to Prepare for an FDA Audit for Safety Management Practices
- Discuss legal obligations of FDA audits and Food Drug and Cosmetic Act
- Suggestion as to the steps clinical sites take to prepare for the FDA Inspector
- Bioresearch Monitoring or BIMO Inspection
- What is Form FDA 482?
- FDA inspection procedures
- Post-inspection procedures and importance of Form FDA 483
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Kindly get in touch with us for any help or information.
Look forward to meeting you at the seminar
GlobalCompliancePanel

Group Participation

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What You will get

1. Learning Objectives
2. Participation certificates
3. Interactive sessions with the US expert
4. Post event email assistance to your queries.
5. Special price on future purchase of web based trainings.
6. Special price on future consulting or expertise services.
7. Special price on future seminars by GlobalCompliancePanel.
8. Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
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