Strategies for Investigational & Marketed Products

Pharmacovigilance in Europe: Drug Safety

Course Description

The EU Clinical Trials Directive has provided Europe with its most comprehensive overview of clinical trial processes. At the heart of this revision was expedited (including electronic) and annual safety reporting. Furthermore, post-marketing surveillance in the new Creative Member State Europe has never been more detailed. Electronic safety reporting, new pharmacovigilance inspections, the role of the Qualified Person for pharmacovigilance, licensing agreements and safety data exchange, and the revised Volume IX are all new challenges that face multi-national companies. This course provides pharmacovigilance personnel with the tools to remain compliant, and the knowledge of what needs to be reported when and to whom.

Who Should Attend

- Clinical trials safety personnel responsible for multinational clinical trials, as well as safety personnel involved with global post-marketing safety responsibilities.
- Pharmacovigilance personnel involved in auditing of company compliance.

Instructor

Graeme Ladds

You Will Learn

- About the many safety requirements of the new EU Clinical Trials Directive
- The new, extensive pharmacovigilance inspections being conducted by the regulatory authorities, their findings, and the sanctions that can be imposed upon companies
- The detailed post-marketing safety requirements for companies with marketed products in Europe, for both generic and innovator companies

Interactive Exercises

- Hands-On Exercises
- Group Discussions

Course Outline

Day One: 8:00 a.m. – 5:00 p.m.

- Developing Company Core Safety Information – CIOMS III: Developmental Core Safety Information; what to include/exclude in DCSI/CCSI; EU and FDA differences; maintenance and development of CCSI
- Product Safety Reviews – Purpose & Function: The safety review committee; timing; record keeping; crisis management of serious safety findings
- Safety Reporting in Licensing Agreements: Types of agreements; regulations and audits of pharmacovigilance partners; establishing and monitoring safety reporting agreements
- Compliance and Drug Safety: Basic principles; measuring compliance; quality versus quantity in safety reports; ensuring future compliance
- The EU Qualified Person for Pharmacovigilance (EUQP PV): Legislation, training, roles and responsibilities
- Audits and Expectations: Audit preparations, records, findings, and recommendations

Day Two: 8:00 a.m. – 5:00 p.m.

- The EU Clinical Trials Directive: Principles and implications for safety reporting in global clinical trials; the SUSAR database; the EUDRACT database; the product dictionary database
- Reporting Requirements: Expedited reporting requirements of SUSARs under the directive; reporting of comparator and placebo reports; pre-clinical safety submissions; ICH E2A and E6 versus the directive; electronic safety reporting
- Writing Safety Information into the Investigator Brochure: Presentation and updating of safety information in the IB; pre-clinical data and relevance to the IB
- CIOMS VI & Safety Reporting: What, to whom, when, and why; post study SUSARs; the role of ethics committees; benefit-risk assessments
- Independent Data Monitoring Boards: Regulatory requirements, expectations, and composition; assembling an IDMB; EU initiatives on the role of the IDMB; IDMB findings and company responsibilities

Course Dates and Locations

August 26-27, 2008
Chicago, IL
Embassy Suites Hotel Downtown
Course #: SPVC0808
$1,495 by July 18
$1,695 after July 18

December 18-19, 2008
Philadelphia, PA
Renaissance Philadelphia Airport Hotel
Course #: SPVA1208
$1,495 by November 14
$1,695 after November 14

Registration

- ON-LINE: www.barnettinternational.com
- FAX or MAIL: Submit Registration Form (back cover) with Payment to Barnett Customer Service
For assistance, CALL (800) 856-2556

Registration includes Tuition, Networking Lunches, Refreshments, and all Educational Materials.
Team Discounts Available!

Hold This Course at Your Company! Call (800) 856-2556 for more information.

Accreditation: Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 15 hours (1.5 CEU) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will mail ACPE statements within three weeks of program completion. ACPE#: 778-000-05-027-L04-P. Released: 2/06.