Clinical Trials for Medical Devices: Design and Development

Course Description
This course addresses the practical issues in the design of medical device trials and protocol development, as well as broader issues related to clinical trial design and interaction between FDA and sponsors to provide clear direction to support marketing of the medical device.

Who Should Attend
- Staff from medical device manufacturers or Contract Research Organizations (CROs) who will be involved in the design of clinical trials and have responsibility for protocol development.
- Project Managers who have little or no clinical trial experience.
- Project Team Leaders who will be designing clinical trials.
- Clinical, Regulatory, and Development Staff who would like to learn how to design a clinical trial program.
- Investigators who would like to learn how to design a clinical trial and about protocol development.

Instructor
Douglas E. Albrecht, B.S.N., C.C.R.A.

You Will Learn To
- Address the ethical considerations involved in conducting clinical trials
- Strategically plan for successful clinical trials
- Develop trial objectives and hypothesis testing
- Develop protocols in accordance with regulations
- Evaluate basic statistical issues relating to sample size
- Distinguish and utilize assessment instruments

Interactive Exercises
- Ethical Issues • Case Studies: Improving Clinical Trials
- Control Groups • Rationale Evaluation
- Protocol Modification • Sample Size • Study Objectives

Course Outline

Day One: 8:30 a.m. – 5:00 p.m. ___________
- Historical Overview: Overview of the regulatory process and general ethical considerations
- Device Regulations pertaining to Device Trial Design and Development: “Least Burdensome” approach in the USA; Europe; Japan; “Rest of World”
- Impact of ICH on Device Trials and Development: Principles of ICH/GCP
- Investigational Plan: Strategic planning; risk analysis; clinical operations; regulatory planning: marketing considerations
- Trial Design Considerations: Definitions; types; randomizing; blinding or masking; outcomes

Day Two: 8:30 a.m. – 5:00 p.m. ___________
- Trial Design Considerations, continued: Investigator selection
- Protocol Structure and Format: Sections and sub-divisions
- Populations: Inclusion/exclusion criteria; cultural considerations
- Determining Sample Size; Statistical Power: Qualitative and quantitative endpoints, equivalence, rare events; single group
- Objectives and Hypothesis Testing: Null vs. alternative hypothesis; Type I and Type II errors; single vs. multiple objectives; statistical concepts for non-diagnostic devices and diagnostic tests (IVD)

Course Dates and Locations

July 29-30, 2008
San Francisco, CA
Hilton San Francisco
Course #: SMMF0708
$1,495.00 by June 20
$1,695 after June 20

December 2-3, 2008
Chicago, IL
Embassy Suites Hotel Downtown
Course #: SMMC1208
$1,495.00 by October 24
$1,695 after October 24

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 CEUs) 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#: 778-000-08-002-L04-P. Released: 12/08.