



6th Annual Device Research and Regulatory Conference

DEVICE BASICS Pre-Conference Workshop - Optional (Half-Day Workshop)

Program Chair and Presenter: Kathi Durdon, MA, CCRP, Manager of Clinical Operations, Welch Allyn

Program Co-Chair and Presenter: Donna Headlee, RN, BSN, CCRP

Wednesday, May 16, 2012 (Wednesday)

- 12:30 - 1:00 Registration
- 1:00 - 2:30 **Device Regulations**
This session will provide a basic overview of the regulations guiding research of medical device development and marketing. Topics will include FDA regulations, risk categorization, adverse event reporting, IRB submission of devices and device classifications.
- 2:30 - 3:00 **Medical Device Design and Development**
Did you ever have an idea for a device? We will follow an example of a device's design through ideation, prototype formative usability testing, and summative final design validation testing from the clinical research industry perspective. In particular, we will look at why the user – most often the nurse, physician, nurse assistant - is an integral partner in the design and development of medical devices.
- 3:00 - 3:30 Break
- 3:30 - 4:15 **Site Selection, Study Monitoring, Study Management in the Device Arena**
Are there differences between device and pharmaceutical clinical trials? What are the perspectives from the sponsor, the site and the CRO? What are some of the concerns that CRAs and monitors have when conducting studies? These and other issues will be discussed with the audience participation.
- 4:15 - 5:00 **Lessons Learned: Case Study Medical Device IRB Inspections**
Through discussion of a case study the presenter will introduce, explain, and discuss fundamental CDRH BIMO IRB inspections and their impact on the regulatory review process. Topics will include: IRB's role and responsibilities for the oversight of medical device studies, the IRB FDA/CDRH BIMO inspection process, regulatory and compliance trends in device clinical trials, and interactions of sponsors and investigators with an IRB.
- 5:00 - 5:30 Question and Answer

Device Research and Regulatory Conference (Two-Day Main Program)

Day One: Thursday, May 17, 2012

- 8:00 - 8:30 Registration and Continental Breakfast
- 8:30 – 8:45 **Welcome and Introduction to Device Research**
Kathi Durdon, MA, CCRP, Program Chair
- 8:45 – 9:45 **Premarket Notification 510(k) Update**
Marjorie Shulman, MBA, Acting Director, Premarket Notification Program, FDA
The 510(k) process is the regulatory pathway by which most medical devices go to market in the US. It is a classification process that determines if a device is substantially equivalent or not substantially equivalent requiring a Premarket Approval or DE Novo application. This talk will update attendees on any changes to the existing 510(k) Program.
- 9:45 – 10:45 **Development of a PMA Submission Strategy**
Nicole Wolanski, BS, Director, Premarket Approval Application Program, FDA/CDRH/ODE
This session will discuss concepts and strategies for successful submissions of CDRH premarket applications (PMA). Discussions will include contents of an application, interacting and meeting with the FDA, what to expect during the review process, and the impact of MDUFA III. The session will conclude with strategies/helpful hints for successful submissions.
- 10:45 – 11:00 Break
- 11:00 – 12:00 **Device Clinical Studies: Considerations for Evaluating Effectiveness**
Stephen P Rhodes, Senior Consultant, Medical Devices, Biologics Consulting Group, Inc.
Sponsors of device clinical trials face a number of challenges when designing and conducting a study that establishes the effectiveness of a device for a specific patient population. Health care reform has resulted in changes in coverage that have led some device companies to conduct effectiveness studies for devices that have been on the market for many years. Additionally, the agency has issued recent guidance on evaluating effectiveness in certain clinical trials. This presentation will focus on the considerations for conducting prospective, retrospective, post-market, and registry trials to support effectiveness.
- 12:00 – 1:00 Round Table Lunch Discussions (Lunch Provided)
- 1:00 – 2:00 **FDA's Perspective on Regulation of In Vitro Diagnostic Devices**
Tremel Faison, MS, RAC, SCT(ASCP), Regulatory Scientist, FDA
This presentation will cover basics of in vitro diagnostic device regulations as well as thoughts on current policies for laboratory developed tests, analyzing specific reagents, and drug/device co-development.

Day One (continued)

- 2:00 – 2:45 **The Roles and Responsibilities of the IRB in Device Research**
Wendy Lloyd, LPN, BA, CCRP, CIP, Regulatory Compliance Analyst, Vanderbilt Medical University
Ms. Lloyd will discuss what is included in the Investigator's submission to the Institutional Review Board (IRB) prior to, during, and at the conclusion of the research. She will discuss the roles and responsibilities of the IRB regarding review of device research. What happens in the event that the IRB disagrees with the risk determination will be discussed.
- 2:45 – 3:00 Break
- 3:00 – 3:45 **ISO 14155:2011: Are You Compliant?**
Joy Frestedt, PhD, RAC, CCTI, FRAPS, President and CEO, Frestedt Incorporated
In this session, attendees will understand the key requirements of ISO 14155:2011; describe practical steps recommended for conducting medical device clinical trials in the European Union (EU). and list at least 3 responsibilities for conducting clinical trials for medical devices in the EU.
- 3:45 – 4:30 **PMA Case Study and Lessons Learned**
Donna Headlee, RN, BSN, CCRP
This session will be an interactive discussion of the premarket application (PMA) review process and the impact of quality data on the review. A case study scenario will be used to highlight key points, considerations, and strategies.
- 4:30 – 5:00 **Question and Answer Session / Discussion**

Day Two: Friday, May 18, 2012

- 8:00 – 8:30 Registration and Continental Breakfast
- 8:30 – 9:15 **Tips for Effective Communications in ANY Situation**
Thomas G. Goodwin, BA, President, Thomas Goodwin Communications, Inc.
Whether talking about our research, protesting an FDA decision, or reporting device-related effects, it is important that we are understood by our audience in the way that we intend. This session will explore proven tips and techniques for maximizing our ability to be understood -- and not misunderstood -- by those who do not share our perspective.
- 9:15 – 10:00 **Innovation and Human Factors; Somewhere in the Diagnosis is a Person**
Suzanne Abate Gunter, RN, BSN, MBA, Senior Manager, Medical and Scientific Affairs, Welch Allyn, Inc.
Innovation with the human experience in mind. What do we need to think about? What are the outcomes? What are the unintended consequences?
- 10:00 – 10:15 Break
- 10:15 – 11:15 **Conducting Research to Support Device Development**
Stephen B. Wilcox, PhD, FIDSA, Principal, Design Science
Research methods employed to optimize usability and safety of medical devices are different from those typically used in clinical research. These methods involve careful observation to determine current procedures and use environments, application of technical information, and usability testing of prototypes and early production devices. The presentation will describe these methods, emphasizing how validity is achieved and how the results are reported.
- 11:15 – 12:15 **Integrating Clinical Trials into the Design Process**
Richard A. Vincins, CQA, RAC (US, EU), Vice President, QA, Emergo Group
Many organizations try to determine when their clinical trials are to be performed within the design and development process with many either starting too early or too late. The presentation will provide strategies to successfully initiate and maintain the clinical trial process throughout the development process. We will discuss various ways that clinical data can be accumulated during the validation stage. After product launch, it is important to continue clinical trial follow-up, as well as initiate post market surveillance and post-launch design review.
- 12:15 – 1:00 Round Table Lunch Discussions (Lunch Provided)
- 1:00 – 2:00 **Risk Management for Devices**
Loretta K. Dorn, RN, BSN, CRNI, CQM/OE, Associate Director Clinical Development, Baxter Healthcare
This presentation will review the process for assessing risk in medical device clinical research.
- 2:00 - 3:00 **Special Considerations for Device Monitoring**
James Mahoney, CCRC, CRA, Senior Clinical Research Associate, D-Target, a Premier Research Group
There are special considerations that must be taken in medical device monitoring. To ensure scientific integrity of a medical device study, in addition to the safety of the subjects and progression of the investigation, the following should be considered: US device-specific regulations, including 21 CFR 812, 50, 54, and 56; items unique to device clinical trials such as device accountability, storage of devices, device malfunctions, and procedural information (equipment, intra-operative data); and device-related effects (ADE, SADE, UADE).
- 3:00 – 3:15 Break
- 3:15 – 4:15 **Reporting Device-Related Effects**
Sarah Zanon, MS, Senior Clinical Project Manager, D-Target, a Premier Research Group
Recording and reporting adverse events and device effects that occur during a medical device clinical trial in order to ensure subject safety and to establish product efficacy will be the main topic. Information gathered from the FDA, in addition to European and international standards, to define device-related effects will be presented. Also, US recording and reporting requirements will be discussed, breaking down the responsibilities of the investigator and the sponsor.
- 4:15 – 4:45 **Question and Answer Session / Discussion**