

DEVICE BASICS

- Optional 1/2 Day Workshop -

Preconference Workshop

11:30 – 12:10 Registration & Welcome

12:10 – 2:00 Introduction to the Medical Device Regulatory Framework

Donna Headlee, RN, BSN, CCRP, Program Co-Chairperson

Ms. Headlee will provide a basic overview of the regulatory framework for medical device research and development. Topics include: Medical Device Regulations, risk categorizations of IDE studies, adverse event reporting, device classification, and marketing applications (PMAs, 510(k)s and HDEs).

2:00 – 2:20 Break

2:20 – 3:20 Sponsor-Investigator Trials: Developing and Managing an IDE

B. August Gwaffia, RN, IDE Manager

The National Institutes of Health and Lerdos Biomedical Research

This presentation focuses on IDE research that is initiated, conducted and sponsored by the investigator. From the perspective of a sponsor-investigator, Ms. Gwaffia will cover: the IDE application process, FDA decisions on IDE applications as well as sponsor-investigator requirements and responsibilities in IDE trials.

3:20 – 4:20 Sponsor-Investigator Trials: Coordinating Multisite IDEs

B. August Gwaffia, RN, IDE Manager

The National Institutes of Health and Lerdos Biomedical Research

Ms. Gwaffia will discuss IDE research that is initiated, conducted and sponsored by the investigator. This presentation will cover the coordination of working with multiple IRBs, PI's research coordinators and monitors for the implementation and conduct of sponsor-investigator research that spans across multiple sites.

4:20 – 5:00 Question and Answer Session

Main Conference Day One

8:00 - 8:30 Registration and Continental Breakfast

8:30 - 8:45 Program Welcome and Introduction

Kathi Durdan, MA, CCRP, Director, CNY Biotech Accelerator, Upstate Medical University, Syracuse, NY

8:45 - 9:45 HDST CITY KEYNOTE: The Promise and Complications of "Broad Consent"

Mark Barnes, JD, Partner, Ropes & Gray, LLP

The revised Common Rule created a new version of consent entitled "Broad Consent," meant to allow unrestricted future uses of identifiable data and biospecimens. The provisions for Broad Consent are complex and carry complications of such significance that few medical centers have adopted its use. Mr. Barnes' session will explore the history and meaning of Broad Consent, and will ask whether there are any circumstances in which its use is both practical and useful.

9:45 - 10:45 The 510(k) Program

Marjorie Shulman, MBA, Center for Devices and Radiological Health, Food and Drug Administration

Ms. Shulman will present an interactive session using real-life examples and databases searches to discuss how to determine if you need a 510(k), identifying a predicate and how to prepare the submission. In addition, discussion of general and special controls and utilization of FDA Guidance Documents and Standards associated with the device.

10:45 - 11:05 Break

11:05 - 12:05 Lessons Learned: De Novo Classification Pathway

Donna Headlee, RN, BSN, CCRP, Program Co-Chairperson

The De Novo process provides a pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device. This presentation will provide an introduction to the De Novo pathway and identify best practices to optimize the use of the program, through a case study discussion.

12:05 - 1:00 Lunch (Provided)

1:00 - 2:00 The Types of Device Trials, Billing and Reimbursement

Kelly M. Willenberg, DBA, RN, CHRC, CHC, CCRP, Manager, Kelly Willenberg & Associates

Ms. Willenberg will explore the types of device trials including Category A and B, IDEs. Ms. Willenberg will discuss how you know what to bill to a payer and what you should expect to be reimbursed. Understand what you need to do to make sure your patients in research trials do not end up financial liabilities that they do not know about.

Day One (Continued)

2:00 - 3:00 Expanding Access to Medical Device for Patients: Expanded Access Program, Early Feasibility Study Program and the Breakthrough Devices Program

Donna Headlee, RN, BSN, CCRP, Program Co-Chairperson

The average time from medical device concept to marketing approval has been reported as three to seven years. If alternative treatments are not available, this is problematic for patients with serious or life-threatening diseases. Expanded access permits patients with life-threatening conditions who are not eligible to participate in clinical trials to receive investigational devices before formal product approval. Ms. Headlee will provide an overview of multiple programs at CDHR that enable patient access to important devices, which address unmet medical needs. This presentation will introduce the Expanded Access Program, the Early Feasibility Study Program, and the Breakthrough Devices Program.

3:00 - 4:00 Panel Discussion

This panel discussion will allow attendees an opportunity to query regulatory experts as an open interchange of hot topics, compelling questions, and day-to-day issues.

Day Two

7:30 - 8:00 Registration and Continental Breakfast

8:00 - 9:00 Clinical Evidence for Regulatory Purposes: IDEs and Real World Evidence

Joshua Ghetta, Lead Medical Device Reviewer, Center for Devices and Radiological Health, Food and Drug Administration

9:00 - 10:00 Utilization of Real World Evidence in Cardiac Lead Post-Approval Studies

Angie Rock, MBA, CCRP, Senior Manager, Clinical Research Group, Biotronik, Inc.

A collaboration consisting of the Food and Drug Administration (FDA), Industry, Academia, Heart Rhythm Society and American College of Cardiology have worked collectively to seek more efficient approaches to fulfilling FDA Condition of Approval Post-Approval Study requirements through the use of Real World Evidence as part of the Electrophysiology Predictable and Sustainable Implementation of National Registries (EP-PASSION) project. Ms. Rock will provide an overview of the collaboration, BIOTRONIK's approach and early success using Real World Evidence for registry studies.

10:00 - 10:20 Break

10:20 - 11:20 Medical Device Industry Trends - 2020 and Beyond

Allyson Hein, Medical Device Industry Lead, Clarkston Consulting

As businesses look to 2020 and beyond, the pace of change in the medical device industry is only expected to increase. Evolving technological and digital capabilities coupled with a shifting regulatory landscape and advancing patient expectations are driving new trends in the industry with profound impacts to how medical device makers plan, operate, and commercialize their products. While presenting unique challenges to long-held business models, these trends open new opportunities to better engage patients, enter new markets, and grow the business. This session will explore these trends and their impact to the industry and its future.

11:20 - 12:20 A Former FDA Manager Spills the Beans on Making Quality Compliance Easier

Bryant Headley, BA, MS, Sr. Director of Regulatory Affairs and Executive Government Liaison, MasterControl

Quality compliance can be easy—take a former FDA manager's word for it. Most medical device firms tend to establish overcomplicated processes, but simplification is actually the key to effective compliance. The Medical Device Single Audit Program (MDSAP) is the most important signal to device firms of the need to simplify compliance. MDSAP is now required in Canada, while the FDA will accept MDSAP audit reports as a substitute to routine inspections. Whether you are complying with MDSAP or individual regulatory bodies, there are two major things to keep in mind when it comes to quality management and compliance.

12:20 - 1:20 Lunch (Provided)

1:20 - 2:20 Cultural Considerations in Global Clinical Trials Management

Joy Beeler, MPH, CCRP, ACRP-CPM, Clinical Trials Project Manager, Lerdos Biomedical Research, Inc.

Join Ms. Beeler for a discussion of cultural aspects to consider when implementing and conducting clinical research studies internationally. Ms. Beeler will offer experience-based recommendations for addressing some concerns that may impact project timelines, protocol procedures/logistics, and interactions between site and sponsor staff.

2:20 - 3:20 Navigating a Clinical Trial Through the United Kingdom: It's a Little More Than Tea and Crumpets

Jonette Hodge, MSN, RN, CCRP, Senior Management, Clinical Affairs, Wright Medical

Ms. Hodge will discuss the experience and knowledge gained through navigation through the many steps and systems within the UK NHS, NIHR, CINR, HRA, Ethics. The presenter will also describe the advantages of data collection in the UK, as they collect data already, are avid researchers, and discuss the budgeting process, as if your study is a deemed a portfolio study in the NHS, there is additional funding for research sites. This includes the fact that PI's are not paid, as they are employees of the NHS and it only adds to the non-bias in your data collection.

3:20 - 3:30 Question & Answer Session and Discussion

This interactive session will allow the participants to discuss issues related to medical device investigational studies.

For more details and to Register Visit www.socra.org or call 800-762-7292

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