10th Annual Device Research and Regulatory

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

Wednesday, April 6, 2016

12:00 - 12:20 Registration

12:20 - 12:30 Welcome

12:30 – 1:45 **Demystifying Medical Devices**
Donna Headlee, RN, BSN, CCRP, Program Co-Chairperson
This session will provide a basic overview of the regulations guiding medical device research and development. Topics include: FDA Regulations, risk categorizations of IDE studies, adverse event reporting, device classification, and marketing applications (PMAs, 510(k)s and HDEs).

1:45 - 2:30 **Significant vs. Non-Significant Risk – IRB Perspective**
Sarah Attwood, BSc, IntegReview IRB
IRBs require rationale for non-significant risk devices when submitted for review. However, what is the process for an IRB to review and agree on the risk assessment? Discussion on the process for determination and how an IRB handles any disagreement with a Sponsor's assessment

2:30 – 2:50 Break

2:50 - 3:35 **ISO 14155: Will it Change Like ICH E6 is Changing?**
Joy Frestedt, Ph.D., CPI, RAC, FRAPS
This presentation will include an international perspective on the conduct of clinical trials. We will consider differences in international standards and FDA regulations and how international standards play a part in medical device development globally. This talk will review the medical device international GCP standard for clinical trials (ISO14155). This standard mirrors the pharma GCP standard ICH E6. Because ICH E6 is being revised, the potential to need revisions to ISO 14155 will be discussed. Audience participation will be solicited to see how the ISO 14155 standard is working today in the field.

3:35 - 4:20 **Medical Device Case Study: Lessons Learned**
Donna Headlee, RN, BSN, CCRP, Program Co-Chairperson
This session will be an interactive session discussing aspects of FDA BIMO medical device investigational study inspections and lessons learned. Topics will include IDEs, PMAs, GCP and compliance strategies.

4:20 - 4:50 **Question & Answer Session**
Faculty will discuss current issues related to device research sourced from attendee questions submitted both before and during the program.

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

Day One: Thursday, April 7, 2016

7:30 - 8:00 **Registration and Continental Breakfast**

8:00 - 8:15 **Program Welcome**
Kathi Durdon, BA, MA, Director of Operations, CNY Biotech Accelerator
Attendees will be provided with overview of the program, its history and the importance of evaluations in driving development of subsequent programs.

8:15 - 9:00 **A Look at Today's 510(k)**
Heather Rosecrans, Executive Vice President, Medical Devices and Combination Products, Greenleaf Health, LLC
Ms. Rosecrans, former Director of the 510(k) program at FDA, will provide an update of the 510(k) program. The session will provide insight into how to best approach and work with the FDA

9:00 - 9 :45 **HDEs: Everything You Need to Know**
Elisa Harvey, DVM, PhD, Sr. Regulatory Consultant, CardioMed Device Consultants
This talk will present the basics of understanding HUDs, HDEs, IRB oversight, and off label use.

9:45 - 10:00 **Break**

10:00 - 11:00 **Introduction to Non-clinical studies: The importance of GLP to the Establishment, a Decision of "Reasonably Safe"**
Victoria Hampshire, VMD. Director, Capital Preclinical Scientific Research Consulting, Inc.
This talk will cover the fundamentals of regulatory review and the history from post WWII to the establishment of regulatory processes resultant in the GLP. It will explain why GLP is important to establishment of "valid scientific evidence" (Federal Food Drug and Cosmetic Act) and "reasonably safe for first in man".

11:00 - 12:00 **TPLC and the Life After Approval**
Lindsay K. Pack, Director of Regulatory Affairs-Drug Coated and Specialty Balloons, Spectranetics
Understanding and planning for the Total Product Life Cycle of your medical device is becoming increasingly more important. This talk will dive into some key areas of TPLC and how that might impact your IDE and PMA. We'll also go over the "life after PMA approval" and some tips for managing this process.

12:00 - 1:00 **Lunch**

1:00 - 2:00 **Monitoring Strategies and Clinical Trial Oversight in Medical Device Studies**
Andrea Gonzales, RN, MSN, Manager, Clinical Monitoring, Global Clinical Affairs
Monitoring strategies today increasingly utilize centralized and remote monitoring to focus on-site activities and overall clinical trial management. There are advantages and challenges in the implementation of each approach when providing oversight for medical device studies and achieving site compliance. Site logistics and requirements for successful study execution will also be reviewed.

2:00 - 3:00 **Prerequisites, Documentation and Regulatory Requirements for Initiation of a Pivotal Clinical Trial for Left Ventricular Assist Device (LVAD) (s) in the US**
David Munjal, Ph.D., RAC, M.Sc, Ph.D., President, CRC Global Services, LLC
This session will discuss prerequisites, documentation, regulatory, statistical and strategic considerations for initiation of a multi-center pivotal human clinical trial with an example of an implantable LVAD. Adequate preparation and balancing innovation versus safety and effectiveness will bring results that will later help in preparation and submission of regulatory reports and documents for the FDA. Successfully enrolling patients and completion of the trial followed by statistical and risk-benefit analyses of data to prepare clinical module report for submission to the FDA will be discussed.

2:45 - 3:00 **Break**

3:00 - 4:00 **Panel Discussion – Day 1 Presenters**

Day Two: Friday, April 8, 2016

7:30 - 8:00 **Registration and Continental Breakfast**

8:00 - 9:00 **The Role for 3D Printing to Advance Healthcare Education and Clinical Outcomes**
Katherine A. Barsness, MD, MS, Ann and Robert H. Lurie Children's Hospital of Chicago, Northwestern University Feinberg School of Medicine
The Presenter will review relevant background on 3D printing for manufacturing, provide insight for current healthcare applications of 3D printing and discuss opportunity to expand role of 3D printing to improve patient outcomes.

9:00 – 10:00 **Collaboration in Medical Device Clinical Trial Innovation and Reform**
Stephanie Christopher, MA, CCRC, Program Manager, Medical Device Innovation Consortium (MDIC)
Innovation in medical device clinical trials and regulatory science has the potential to improve the safety and effectiveness of medical device products being introduced into the market and yield earlier access to beneficial innovative technologies for U.S. patients. The Medical Device Innovation Consortium's Clinical Trial Innovation and Reform project focuses on innovations in clinical trial design and early feasibility studies in the U.S. that hold promise for introducing new methods to regulatory science that will benefit all medical device companies. By defining, cataloging and testing possible solutions, industry, non-profits and government can work together to create a clinical trial environment flexible enough to evaluate the latest in medical device technology, while still maintaining rigorous safety and efficacy data standards.

10:00 - 10:15 **Break**

10:15 - 11:15 **Managing Subject Recruitment for Difficult Trials**
Adam Chasse, President, Chasse Clinical Consulting, LLC
Difficult clinical trials require not only a robust recruitment plan, but also a management approach that allows for quick diagnosis of what isn't working and informed approaches to adapting the plan accordingly. This session will focus on what type of information sites, CROs, and Sponsors should quantify, track, and analyze throughout a study, as well as actions to be taken to fix problems and/or sustain good performance. Real-life examples of tools, management approaches, and results will be discussed.

11:15 - 12:15 **21 CFR 50.24 Exception from Informed Consent Requirements for Emergency Research**
David Appleby, MPH, Director, Clinical Affairs and Biostatistics, Zoll
This session will discuss Zoll's experience in meeting the requirements of 50.24 as well as emergency research in both IDE and post-market studies.

12:15 - 1:00 **Lunch**

1:00 - 2:00 **Monitoring Skills: Soft and Hard**
Tammy Clark, MPH, Clinical Projects Manager, NxStage Medical, Inc.
Abstract: This session will discuss the ins and outs of a polished monitor. A monitor needs to be task oriented and people oriented. To be successful, a monitor needs more than an understanding of the CFR codes including sponsor and investigator responsibilities. Examples of prepping for a monitor visit, on site monitoring, and follow up experiences involving lessons learned will be provided and open to discussion.

2:00 - 2:15 **Break**

2:15 - 3:15 **Medical Device Jeopardy**
*Donna Headlee, RN, BSN, CCRP*Often investigators believe that creating a "registry" is not associated with conducting clinical trials. Abstract: This session will be an interactive competitive session discussing aspects of the medical device TPLC and lessons learned. Topics will include IDE, PMAs and GCP and compliance strategies.

3:15 - 3:45 **Question & Answer Session and Discussion**