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**Device Basics - Preconference Workshop - maximum 4.5 CE Device Regulations - 2 day Conference - maximum 13 .25CE*

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SOCRA Course Series: 900

April 6 and 7, 2017
Chicago, IL USA

Chaparral Suites Scottsdale
5001 N Scottsdale Rd.
Scottsdale, AZ 85250

Hotel Phone: (312) 664-1100
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SOCRA's hotel room rate of **$169 (plus applicable taxes)** is available until March 7, 2016 or until the SOCRA room block is filled. You must mentions SOCRA to receive the room rate.

SOCRA®
FOR CLINICAL RESEARCH EXCELLENCE

11th Annual Device Research & Regulatory Conference

The Premier Conference for Device Professionals

April 6 and 7, 2017

Device Basics Preconference Workshop
April 5, 2017 (11:30 a.m. - 5:00 p.m.)

Scottsdale, AZ USA

Goal: This annual MEDICAL DEVICE conference, now in its 11th year, hosts a Pre-conference Half-day Workshop, "Setting the Stage," followed by a two-day Main Program, "Laying the Groundwork," and "Current Topics." Attendees will hear from and discuss issues with experts in the medical device research and regulatory fields. The Main Program presentations change each year to address prior year attendee topic requests, new technology, medical advances, as well as new or updates to regulations, standards and guidance – so you can attend year after year! Separate registrations allow you to elect to attend the Pre-conference Half-day Workshop and/or the Main Program.

Objective: The Pre-Conference Half-day Workshop "Setting the Stage" is designed to provide a comprehensive medical device regulatory overview and is a fundamental precursor to the Main Program. You will receive an overview of the regulations guiding device research, development and marketing applications from master presenter, Donna Headlee. Topics this year will also cover Premarket Approval, De Novo Program and Humanitarian Use Devices. An interactive Medical Case Study will give attendees an overview of the FDA inspection process.

Main Program – Day 1, "Laying the Groundwork"

Day 1 includes presentations and discussions to lay the groundwork for medical device research development, regulatory compliance, best practice process, and issue resolution. Presentations include:

- FDA Submission Insider Tips
- Clinical Data Requirements for FDA Submissions
- Study Budgets for Device Research
- Navigating the CDRH Web-based Resources
- Audit Management and Monitoring
- Corrective and Preventive Action Plans (CAPA) for Medical Device

Learning Objectives - Preconference Workshop – The participant will be able to:

- Discuss the FDA regulations that govern the administration of device research including risk categorization and device classifications.
- Describe Premarket Approval and De Novo Program attributes.
- Discuss the HUD/HDE marketing approval pathway for rare diseases.
- Comprehend FDA Bioresearch Monitoring Program inspection goals.

Learning Objectives – Main Conference - The participant will be able to:

- Discuss 510(k) process relative to submission requirements.
- Describe clinical data requirements for 510(k) submission for safety and effectiveness.
- Comprehend and promote best practice budget development and approval.
- Describe resources available through the FDA CDRH website.
- Apply audit management and monitoring to my organization's process and policy development.
- Discuss CAPA specific to medical device.
- Examine how digital health data will promote precision healthcare.
- Discuss OUS data submission to support US marketing applications.
- Explain global medical device reimbursement.
- Comprehend FDA proposal for LDT regulatory requirements.
- Discuss mobile medical devices.
- Actively discuss issues and topics germane to attendee roles and responsibilities.

Member Fee: $675 **Non-Member Fee: $750***

Optional ½ day Device Basics Workshop: $175

*** Non-Member Fees include a non- refundable one year SOCRA membership**

**** All fees are USD**

Register Online or Download a Registration Form at
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Device Research and Regulatory Conference

DEVICE BASICS

- Optional ½ Day Workshop -

Preconference Workshop

11:30 – 12:10 Registration & Welcome

12:10 – 1:40 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).

1:40 – 2:00 Break

2:00 – 3:00 Clarifying 513(g), De Novo and PMA Device Submissions
Joy Frestedt, PhD, CPI, RAC, FRAPS,
President and CEO, Frestedt Inc.

This presentation will cover the 513(g) and the FDA's response and fee structure for "a request for classification information." This session will also review the de novo reclassification process which has been getting a lot more use lately to ensure Class I and II medical devices are not automatically left in the Class III bucket which is assigned when no predicate is available. We will review the regulatory background and pathway/process for FDA approval of de novo applications. In addition, this session will review the processes for PMA submissions for Class III medical devices. Best practices and strategies will be shared for a successful submission for these three submission types.

3:00 – 4:00 FDA Approval of Humanitarian Use Devices
Eric Chen, MS, FDA Office of Orphan Product Development

Rare diseases collectively affect approximately 30 million Americans and more than 50% affect pediatrics. However, relatively few medical devices have been developed to specifically address the needs of patients with pediatric or rare diseases. The Humanitarian Use Device/Humanitarian Device Exemption (HUD/HDE) is a unique marketing approval pathway for medical devices targeting diseases affecting small patient populations. This presentation will discuss lessons learned from an analysis of HDE approvals, needs assessment of devices for rare diseases, FDA device initiatives for rare diseases, and other relevant work in this field.

4:00 – 4:45 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.

4:45 – 5:00 Question and Answer Session
Faculty
This session is an opportunity to discuss questions and answers related to the topics presented in pre conference. In addition, to highlight key points.

Main Conference Day One

7:30 - 8:00 Registration and Continental Breakfast

8:00 - 8:15 Program Welcome and Introduction
Kathi Durdon, BA, MA, CCRP, Director of Operations for the Central New York (CNY) Biotech Accelerator, Program Chairperson

8:15 - 9:15 FDA Submissions: Insider Tips, Tricks & Timelines
Allison Komiyama, PhD, RAC, Principal Consultant, AcKnowledge Regulatory Strategies

What does an FDA submission look like? What's the best way to get my device approved/cleared as fast as possible? Specifically you will learn about the different types of FDA submissions and how to figure out what you should submit for your specific medical device.

9:15 - 10:15 Device "Clinical Trial" Regulatory Submission (The hows and whys for Clinical Trial and Other Data Needed in 510(k) Submissions)
Joy Frestedt, PhD, CPI, RAC, FRAPS, President and CEO, Frestedt Inc.

Clinical data is needed for a 510(k) when bench or animal testing raises clinical questions or the benefit:risk analysis differs from the predicate device. Clinical data for the 510(k) submission should indicate no significant differences exist between the subject device and the predicate devices (esp. for safety and performance when used as indicate).

10:15 - 10:35 Break

10:35 - 11:35 The Budget Deep Dive for Device Research
Patricia Ames, Ph.D., CCRC., CAPM, Market Director of Research, Abrazo Clinical & Translational Research Institute

This session will delve deeply into strategies that research sites can use to develop a study budget by exploring costs analysis, Fair Market Value, reimbursement, and negotiation. Budget implications for studies after enrollment has begun are also discussed. This session is intended to be an interactive exploration of best practices.

11:35 - 12:05 FDA Resources for Medical Device
Donna Headlee, RN, BSN, CCRP, *Program Co-Chairperson*

12:05 - 1:00 Lunch

1:00 - 2:00 Audit Readiness
Erika Stevens, MA, Senior Managing Director, FTI Consulting
Audit readiness remains a top priority among research organizations. The opportunity to manage and monitor audits throughout the research administration enterprise enables safeguards that can reduce audit findings. The process for audit management and monitoring involves the following steps: Document gathering Identifying appropriate stakeholders, reporting, and regulations review. This session describes audit readiness for research audits. Conducting an in-depth analysis of risk for audits is gained by exploring regulatory agency opinions (HHS-OIG, FDA, DOJ, etc.).

Day One (Continued)

2:00 - 3:00 Corrective and Preventive Action Plans (CAPA) for Medical Device
Athena Thomas-Visel, MA, MEngr, RD, CCRP, RQAP-GCP, PMP, CQA,
Cliq Solutions
This presentation will discuss how to develop and implement an effective corrective and preventative action plan. We will also outline how to conduct a root cause analysis, determine the necessary corrective and preventative action needed to be taken, and efficiently communicate the plan in your response.

3:00 - 3:15 Break

3:15 - 4:15 Panel Discussion

Patricia Ames, Ph.D., CCRC., CAPM, Market Director of Research, Abrazo Clinical & Translational Research Institute

Joy Frestedt, PhD, CPI, RAC, FRAPS,
President and CEO, Frestedt Inc.

Erika Stevens, MA, Senior Managing Director, FTI Consulting

Athena Thomas-Visel, MA, MEngr, RD, CCRP, RQAP-GCP, PMP, CQA,
Cliq Solutions

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 On the Intersection of Genomics, Technology and Precision Healthcare
Kenneth S. Ramos, MD, PhD, Interim Dean, College of Medicine – Phoenix, The University of Arizona, College of Medicine-Phoenix

Advances in genomic science and technology development have revolutionized the type of health data that can be collected real time in order to improve the quality of healthcare. This presentation will highlight advances in the digital era that provide relevant health-related data that inform clinical decision making and that guide complex clinical care platforms in academic medical centers.

9:00 – 10:00 Studies for FDA marketing applications conducted OUS
Lindsay K. Pack, BSE, Director, Regulatory Affairs,
The Spectranetics Corporation

There are many programs for conducting studies in the US, but sometimes it still makes sense to conduct some studies outside the US. When you intend to use data collected outside the US to support a US marketing application, there are multiple things to plan for and consider. During this session we'll talk through what to do to be successful conducting an international study for US submission.

10:00 - 10:20 Break

10:20 - 11:20 Medical Device Reimbursement
Stephen Hull, MHS, Health Policy, Johns Hopkins; BA, Colgate University, Hull Associates, LLC

This session will provide an in depth overview of medical device reimbursement in major global markets.

11:20 - 12:20 LDTs (Lab Development Tests): Past, Present, Future
Wendy Schroeder, RN, BSN, CCRC, CRCP,
Schroeder Clinical Research Consulting, LLC

LDTs have evolved from simple, single analyte reporting such as a sodium or potassium value to multi-analyte assays that report disease risk scores to next generation sequencing of large gene panels. CLIA certification is a requirement for laboratories to bill government payors for LDTs, but CLIA oversight is limited to an assurance that testing procedures are controlled. FDA proposes to classify LDT risk similar to the risk stratification of medical devices and regulate LDTs as medical devices.

12:20 - 1:10 Lunch

1:10 - 2:10 Mobile Medical Devices: Regulations, Examples, and Possible Controversy
Jonathan C. Young, PhD, CIP, CCRP, Senior IRB Consultant, Rush University Medical Center

This talk will go over regulations and guidance related to mobile medical devices. Examples will then be given, which will include mobile apps. Finally, some mention will be given to possible risks or controversy that may arise from the use of such devices.

2:10 - 3:10 Research and Regulations Jeopardy Challenge
Donna Headlee, RN, BSN, CCRP, *Program Co-Chairperson*

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

3:10 - 3:40 Question & Answer Session and Discussion

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