

# SoCRA - 18th Annual Conference

## *Pre-Conference Seminars*

**Thursday, September 24 - 1:00 to 5:00PM**

### **How to Prepare for an FDA Audit**

**Steven Steinbrueck, MPH, President**, Stonebridge GCP Consulting, Inc.

Discussion and workshop addressing FDA (Food and Drug Administration) perspectives and the regulations regarding adherence to protocol, records management, patient rights, drug and product management and record keeping, and regulatory issues related to an FDA audit. This workshop will educate the attendee in Good Clinical Practice requirements and the FDA audit expectations, in order to prepare for an FDA GCP audit. This interactive workshop will provide the following: A brief introduction to the FDA; Overview of clinical research, including the Federal Regulations covering clinical research and clinical investigator obligations; Discussion on Trial Site Roles and Responsibilities; Explanation of the FDA's Bioresearch Monitoring Program, focusing on the Clinical Investigator inspection; Insight on understanding the FDA GCP inspection: Who is the FDA auditor? What makes FDA suspicious? Common FDA inspection findings at the clinical site audit; Specific examples of FDA-483 observations; FDA inspection strategy .001

### **IRBs and the Informed Consent Process**

**George D'Addamio, PhD, President**, PharmConsult Inc

Initial and continuing ethical review by institutional review boards (IRBs) or independent ethics committees (IECs) and the informed consent process are the cornerstones for protecting the human research subject. Regulations establish requirements clinical research professionals must follow, and the International Conference on Harmonization Good Clinical Practice Guideline provides guidance on complying with national or regional regulations. Dr. D'Addamio will discuss the regulatory requirements for IRBs and the informed consent process, challenges in obtaining informed consent, and challenges in keeping pace with technologically-evolving clinical research. Lessons learned from past experiences and regulatory enforcement actions taken to strengthen the systems for protecting the research subject will be discussed. .002

### **Clinical Research Administration, Budgeting, Contract Negotiation and Finance: A Site's Perspective**

**Bryan Soronson, MPA, BS, FACMPE, CRA, Senior Administrator**, University of Maryland Hospital

**Lisa Benson, BS, CCRP, Director of Grants & Sponsored Programs, Dept. of Research**, Connecticut Children's Medical Center

This session will discuss the elements of a clinical trial protocol, budget and contract and the impact of these elements on the conduct of a trial. The administrative and financial aspects of the trial will be covered with special emphasis on the study administration, effective budget development and management and contract negotiations. This session will be interactive with participation from attendees to include developing and negotiating the study budget. .003

### **GCP 101 for Sites - New Study Coordinator Workshop**

**Jacqueline Busheikin, CCRP, RN, Independent CRA**, Jana Research

In an effort to enhance quality assurance at academic institutions, private practices or government-supported sites, SoCRA is offering a workshop for research personnel who are new to the field, or for those coordinators who want to refresh their understanding of GCP in the ever changing world of clinical research. This four-hour interactive workshop will include presentations, group discussion and Q & A. The workshop will provide essential tools for coordinating and managing a research project. The material will range from understanding terminology to tackling a new project. .004

### **Presentation Skills Workshop**

**Richard Sloane, MS**

Public speaking is considered one of our biggest fears. Hear simple techniques useful in overcoming this fear and begin to speak with confidence! Learn to give better introductions, use visual aids, give effective technical presentations, and even practice some extemporaneous speaking! Hands-on exercises will be used extensively. .005

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### **SOP Development and Implementation**

**Donna Headlee, BSN, CCRP, RN**

The purpose of this workshop is to introduce, explain, and discuss fundamental concepts and current issues in the development and successful implementation of Standard Operating Procedures (SOPs) at the investigational site. The purpose of this workshop is to introduce the participant to SOP development and the process of SOP implementation at the clinical research site. The workshop will explain the basic principles and current challenges encountered during the implementation and development of investigational site SOPs. There will be discussion of writing techniques for effective SOPs. During the workshop the participant will develop a relevant investigational site SOP. The learning objectives will be accomplished through lecture, discussion and "hands-on" exercises. Critical information will be presented and discussed including investigational site best business practices, the necessity for SOPs, SOP development, prioritizing SOPs, and implementing the SOPs at the investigational site. Discussion of SOP strategies for approval process, tracking SOPs, and development of the training program and continuous process improvement plan will complete this exceptional training workshop. <sup>006</sup>

### **Legal Issues involving Researchers, including Fraud and Misconduct**

**Jason Kaar, JD, Associate General Counsel/ Assistant Professor, Uniformed Services University of Health**

Traditionally research has been the one area in medicine where other than the regulatory process, there has been little interaction with the legal system. However, in recent years this has changed. Within the U.S. and internationally there has been an increase in civil and criminal actions against researchers. This session will provide an overview of recent problem areas, as well as insight on how to avoid them. <sup>007</sup>

### **Grant Writing and Protocol Development Workshop**

**Lesley Mitchell, Associate Professor of Pediatrics, University of Alberta**

This session provides an overview of the development of grant applications and of protocol development. Getting started, avoiding common pitfalls, and identifying strategies to strengthen grant review scores will be addressed. Strategies for the development of defensible protocols will be presented. The session will be in a seminar format. Participants are free to bring new ideas as well as issues that have arisen in their own successful and/or unsuccessful development efforts for discussion. <sup>008</sup>

### **Statistics in Clinical Research - Understanding Protocols and Statistical References**

**Lynn Babin, MSN, AAS, PhD Candidate, RN, CCRP, Senior CRA, PharmaNet**

Do you skip over the statistical section of protocols? Does the thought of having to explain why certain analyses are going to be performed on your study make you wish you could crawl into a hole? If so, you are not alone. This very practical section is designed to be a low-stress, non-intimidating, entertaining, and fun (yes fun!) way to understand what the statistical terms in a protocol really mean. No equations and no math! This course is designed simply to understand the basic concepts. <sup>009</sup>

### **Device Basics**

**Kathi Durdon, BA, MA, CCRP, Clinical Operations Associate, Welch Allyn, Inc.**

**Eddy Lyons, BSE, CCRP, Manager CRA Group, BIOTRONIK Inc.**

The PreConference workshop is designed for those new to research or for those who would like to have a refresher on the device clinical research regulations and guidances. This workshop will be a comprehensive overview for those interested in device clinical research. <sup>010</sup>