Day One

8:00-8:15 Registration and Continental Breakfast (Provided)

8:15-9:45 Where Do Written Procedures Fit into the Product Development Process?
In this session, the speaker will illustrate how standardized written procedures for sponsors, IRBs and clinical sites can benefit the conduct of quality research.

9:45-10:00 Break (with an opportunity for discussion)

10:00-10:45 Regulatory Inspection of Site SOPs - A Canadian Initiative
Canadian regulations state that systems and procedures that assure the quality of every aspect of clinical trials are to be implemented. As a result, Health Canada is looking for SOPs and quality processes to be in place at the investigative site with respect to SOPs and quality systems as well as suggestions for sites to assure compliance with this requirement.

10:45-11:30 Where to Start? Developing a Strategy
This session will discuss strategies to initiate an SOP program. Discussions will including strategies for forming a committee, effective meeting management and assess what procedures a clinical site, a sponsor and an IRB should consider for clinical trial management.

11:30-12:15 What is Process Mapping?
Process mapping is a visual depiction of your organization’s work flow/processes. A process map can assist you to define the steps in a process. By analyzing the steps you can identify areas that need enhanced and identify best practices.

12:15-1:00 Lunch (Provided)

1:00-2:00 Effective Writing Strategies
The speaker will discuss the use of effective writing strategies. The session will include an exercise intended to allow the participant to experience an actual development process.

2:00-3:00 Formats for Written Procedures
This session will discuss format and content that can optimize written procedures. Mechanisms for effective procedure implementation will also be reviewed.

3:00-3:15 Break (with opportunity for discussion)

3:15-3:45 SOP on SOP Process
This section will discuss concepts of developing and implementing the SOP on the SOP process. The participants will develop an SOP process.

3:45-5:00 Writing Exercise
Group activities will allow participants to develop a sample operational procedure.
DAY TWO

8:45-9:00  Continental Breakfast (Provided)

9:00-10:15  Writing Exercise (Cont.)
Group activities will allow participants to develop a sample operational procedure.

10:15-10:30  Break (with opportunity for discussion)

10:30-11:45  Discussion of Writing Exercise
Each group will present and offer discussion on the effectiveness of their written procedures.

11:45-12:15  Approval Process
The implementation of written procedures must have support from staff and management. In order to be effective, the review and approval process must be clearly defined and managed. This session will consider examples of successful implementations.

12:15-1:00  Lunch (Provided)

1:00-1:45  Education and Training
Training of research personnel at the study site is paramount to ensuring GCP compliance and adherence to policies and procedures. The speaker will discuss key components of training and education programs that are vital to administering successful clinical research. Discussion will consider the importance of training to ensure each staff member understands their responsibilities and obligations.

1:45-2:15  Adapting Generic, Institution, or Sponsor SOPs for Your Specific Needs
Often institutions and sponsors have SOPs, however, they are not specific to your clinical site. SOPs may need to be adapted to fit the specific needs and policies of the clinical site. This session will discuss concepts and strategies for adapting generic, institution, and sponsor SOPs for site adherence.

2:15-2:30  Break (with opportunity for discussion)

2:30-3:00  Discussion of Real Life Experiences
Using real life examples, the speaker will discuss how SOPs can be helpful at the research site, and some errors to avoid.

3:00-3:30  SOP Feud
This interactive and enjoyable session is designed to provide a review of the concepts and current issues in the development and implementation of SOPs for the investigational site.

3:30-4:00  Pitfalls / Discussion / Questions
During this session, the participants and faculty will discuss the difficulties that can occur in the development and implementation process and offer solutions that will address such concerns.

Donna Headlee, RN, BSN, CCRP, has a Bachelors of Science in Nursing and a Master’s Certificate in Regulatory Compliance. She has been with the FDA in the Center of Devices and Radiological Health since July 2004. She was with the Office of Compliance, Bioresearch Monitoring, Special Investigations Branch for approximately 5 ½ years. One of her responsibilities was coordinating and maintaining SOPs for the Division of Bioresearch Monitoring. Recently she transferred to the Office of Device Evaluation in the Program Support Office on the PreMarket Approval Staff. Prior to joining the FDA, she was a research nurse with National Cancer Institute. She was with the NCI for approximately 14 years and was responsible for coordinating Phase I oncology clinical trials. While with the NCI she initiated and coordinated the development of Standard Operating Procedures for the Division of Cancer Research. She had the honor of serving as president of SOCRA and currently serves as certification committee chair for SOCRA.

Joanne Goldberg, MSc, pht, CCRP, is the Assistant Director of the Canadian Institutes of Health Research’s Institute of Aging in Montreal, Canada. She holds a Master of Science degree in Biomedical Sciences from the University of Montréal as well as a Bachelor of Sciences degree in Physical Therapy from the same institution. She has been involved in clinical research for the past 18 years and has held many positions including Associate Director of Scientific Affairs, Director of Training, Director for Clinical Site Network Management, Director of Quality Management Systems, Senior Project Manager, Senior Study Coordinator, as well as Investigator. Her expertise is primarily in the development and implementation of international partnerships for health research as well as quality management systems, training in Good Clinical Practices, study methodology, and writing and implementing standard operating procedures. She is responsible for the French language translation and administration of the Society of Clinical Research Associates’ (SOCRA) certification examination and Preparatory Course. Joanne is a member of the SOCRA Certification Committee and is a Past President of the Society.