QUALITY IMPROVEMENT THROUGH STANDARD OPERATING PROCEDURES WORKSHOP AGENDA

SOCRA®
FOR CLINICAL RESEARCH EXCELLENCE

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)

10:00-10:30 - 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.

10:30-11:00 - 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.

11:00-11:30 - Effective Meeting Management
There are good meetings and there are bad meetings. Bad meetings drone on forever, you never seem to get to the point, and you leave wondering why you were even present. Effective ones leave you energized and feeling that you've really accomplished something. This session focuses on strategies for planning, developing and conducting effective productive meetings.

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 of operational procedures.

DAY TWO:

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

8:15-9:30 - Writing Exercise (Continued)
Group activities will allow participants to develop sample standard operating procedure.

9:30-10:00 - Discussion of Writing Exercise
Each group will present and offer discussion on the effectiveness of their written procedures.

10:00-10:15 - Break (with opportunity for discussion)

10:15-10:45 - Discussion of Writing Exercise
Each group will present and offer discussion on the effectiveness of their written procedures.

10:45-11:15 - 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.

11:15-12:00 - Education and Training
Training of research personnel for the conduct of clinical trials 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 member of the study team understands their responsibilities and obligations.

12:00-12:45 - Lunch (Provided)

12:45-1:30 - Adapting Generic, Institutions or Sponsors SOPs For Your Needs
Often institutions and sponsor have SOPs however, they are not specific for your institution. SOPs need to be adapted for the specific needs and policies of the clinical site. This session will discuss concepts and strategies for adaptation of generic, institution, and sponsors SOPs.

1:30-2:00 - Discussion of Real Life Experiences
Using real life examples, the speaker will discuss how SOPs can be helpful for a research site, the sponsor, and the IRB. Discussions will include common errors and strategies to avoid them.

2:00- 2:15 - Break (with opportunity for discussion)

2:15-3:15 - 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, the sponsor and the IRB.

3:15-4:00 - 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.