

Standard Operating Procedures (SOPs) Development and Implementation

DAY ONE

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

8:15- 9:30 **Where Do Written Procedures Fit into the Product Development Process?**
In this session, the speaker will illustrate how standardized written procedures can benefit the clinical site.

9:30-9:45 **Break (with opportunity for discussion)**

9:45-10:30 **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.

10:30-11:15 **Where to Start? Developing a Strategy**
What policies and procedures will enable a site to conduct successful clinical research? Participants will consider written procedures appropriate for clinical trial management.

11:15-11:30 **Break (with opportunity for discussion)**

11:30-12:15 **Introduction - How to Get Started!**
The speaker will discuss policy, procedure, and practice related to workflow and offer basic guidelines for creating written instructions; the SOP on SOPs!

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**
During this session, the speaker will discuss format and content that can optimize written procedures. She will address mechanisms for effective procedure implementation.

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

3:15 - 4:00 **What is Process Mapping and How Can It be Used to Describe a Process?**
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 detailed flow you can identify areas that need enhanced and identify best practices. This section will discuss concepts of developing and implementing process maps.

4:00 - 5:00 **Writing Exercise**
Group activities will allow participants to develop sample operational procedures.

DAY TWO

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

9:00-10:00 **Writing Exercise (continued)**
Group activities will allow participants to develop sample operational procedures.

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

10:15-11:45 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 Adapting Generic, Institution, or Sponsor SOPs for Your Specific Needs**

Institutions and sponsors often have SOPs. However, those SOPs are usually not specific to your clinical site. SOPs may need to be adapted to fit the specific needs and policies of your clinical site. This session will discuss concepts and strategies for adapting generic, institution, and sponsor SOPs for site adherence.

1:45 - 2:00 Break (with opportunity for discussion)**2:00 - 2:30 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.

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.

COURSE FACULTY:

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 Associate Scientific Director for the Fonds de la recherche en santé du Québec in Montréal, Quebec, 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 Physiotherapy from the same institution. She has been involved in clinical research for the last 16 years and has held many positions including Director of Clinical Research Quality Compliance & Training, Director of Clinical Site Network Management, Director of Quality Management Systems, Senior Project Manager, Senior Study Coordinator, and Principal Investigator. Her expertise is primarily in clinical research quality management, training in Good Clinical Practices, study methodology, writing and implementing standard operating procedures as well as in team management. She is certified by the Society of Clinical Research Associates as a Clinical Research Professional and is responsible for the French language translation of the SoCRA certification examination and Preparatory Course. She is a Past President of SoCRA's Board of Directors.