AGENDA

Day 1

8:00 a.m. – 8:30 a.m. Registration and Continental Breakfast

8:30 a.m. – 10:00 a.m. **Starting on the Same Page: Good Clinical Practice Regulatory Requirements and Expectations**

- Review of FDA and GCP requirements for conducting a clinical study
- What role does ICH have in good clinical practices?
- Responsibilities associated with institutional review boards and ethic committees (IRB/EC)
- Principal investigator roles and responsibilities
- Essential elements of informed consent agreement
- What is the sponsor's role in the clinical study?
- Understanding the study protocol
- The investigator's brochure — why is it important?

10:00 a.m. – 10:15 a.m. Refreshment Break

10:15 a.m. – 12:00 p.m. **GCP Audits: What Audits Are Needed to Maintain a Compliant GCP Program**

- What are the fundamentals of a GCP audit?
- Establishing an audit program
- The components of an audit program
- Qualifying a clinical research organization (CRO)
- Central laboratory audits and why they need to be a component of a GCP program
- Auditing clinical sites — who gets the audit and why?
- Why is it important to address the audit observations and follow-up?

12:00 p.m. – 1:00 p.m. Lunch Break

1:00 p.m. – 3:00 p.m. **Working with a CRO: Conducting Compliant GCP Studies**

- When utilizing the services of a CRO, it is still important to meet and maintain the sponsor's requirements
- When working with a clinical site: Are GCPs being followed and most importantly, are they being documented?
- The "relationships": QA, clinical and the CRO — a tenuous relationship at best

- The audit: aspects and specifics — what is the value of an audit?
- Audit follow-up — always important to conduct the audit, but are the recommendations and corrections implemented?
- Post-CRO assessment — was the relationship with the sponsor and the CRO successful? — A checklist to evaluate the performance

3:00 p.m. – 3:15 p.m. Refreshment Break

3:15 p.m. – 5:00 p.m. **Most Commonly Cited GCP Violations at a Clinical Site**

- Principles of GCPs at a clinical site
- The areas FDA investigators focus on
- PI responsibilities for the study — why the sponsor and the PI sometimes differ in this area
- Reviewing FDA inspections and the top five GCP violations

5:00 p.m. Session Wrap-Up, End of Day

Day 2

8:00 a.m. – 8:30 a.m. Continental Breakfast

8:30 a.m. – 10:30 a.m. **Writing GCP Audit SOPs: Elements of the SOPs**

- ☑ **INTERACTIVE EXERCISE!** Writing a clinical site audit SOP; why do you need this SOP; what are the important elements of this SOP?
- ☑ **INTERACTIVE EXERCISE!** Writing a central laboratory audit SOP; why do you need this SOP; what are the important elements of this SOP?

10:30 a.m. – 10:45 a.m. Refreshment Break

10:45 a.m. – 12:00 p.m. **Preparing and Setting Up CQA Audits**

- Selecting sites to be audited — creating a master audit plan and how to make sure it is met
- Auditing contract research organizations — why it is important to audit a phase 1 unit
- Audits of a central laboratory — why lab data and testing are a critical component of the clinical study
- Managing the audits (logistics, time, etc.) — why managing the logistics of an audit are critical to the audit itself
- Conducting the audits — what makes a “good” auditor?
- The site visit audit report — when and how the report is a valuable tool
- Evaluating the audit findings and implementing corrective actions — whose responsibility is it?

12:00 p.m. – 1:00 p.m. Lunch Break

1:00 p.m. – 5:00 p.m. **5 Tools for CQA Auditors**

- Preparing for the audit: A checklist does not make you a good auditor, but it is a useful tool
- The auditor's performance: how to be nice but still maintain professional efficiency
- Interviewing skills
- ☑ **INTERACTIVE EXERCISE!** Interviewing a peer
- Writing skills: report formats most auditors find useful
- ☑ **INTERACTIVE EXERCISE!** Creating a report format
- Postassessment of the study: was it successful and did the "relationships" (clinical, quality and the CRO) work?

5:00 p.m. Workshop Adjournment