SOCRA

Clinical Research Monitoring and GCP Workshop for Site Coordinators, Monitors and Auditors

Day 1-

7:45-8:00am Registration and Continental Breakfast (Provided)

8:00-9:45am **Good Clinical Practice: Obligations of the Sponsor and Monitor**

- Basic Principles
- International Conference on Harmonisation
- Investigator's Responsibilities
- Sponsor's Responsibilities
- Monitor's Responsibilities
- Record Retention
- Basic Requirements for Conducting Studies in Canada

9:45-10:00am Break

10:00-11:00am **Investigator Recruitment and Selection: What is the Sponsor Looking For?**

- Investigator Recruitment
- Potential Investigative Sites
- Investigator Selection Factors
- Site Selection Visits

11:00-12:00pm **Ethical Considerations**

- Institutional Review Boards
- Financial Disclosure

12:00-1:00pm Lunch (Provided)

1:00-2:00pm **Informed Consent**

2:00-3:00pm **Study Initiation Activities**

- Budget/Contract Negotiation
- Essential Document Definitions and Collection Mechanisms

3:00-3:15pm Break

3:15 – 5:00 **Monitoring Activities and Site Visits**

- Purpose
- Preparation
- On-site Document Review
- Visit Summary with Study Personnel
- Visit Report and Follow-up Correspondence

Day 2-

7:45-8:00am Continental Breakfast (Provided)

8:00-10:00am **Monitoring Activities and Site Visits CONTINUED**

10:00-10:15am Break

Day 2- continued

10:15-11:30am **The Quality Assurance Audit – Audit Preparedness**

- Distinguishing Auditing from Monitoring
- Sponsor Audits
- Getting Ready for an Audit
- FDA Inspections
- FDA Warning Letters

11:30am-12:15pm **Quality Assurance Exercise**

12:15-1:15pm Lunch (Provided)

1:15-2:30pm **Completion and Discussion of Exercise**

2:30-2:45pm Break

2:45-3:45pm **Proactive Study Management**

- Expecting the Unexpected
- Addressing Specific Challenges
- Improving Performance

3:45-5:00pm **Question & Answer;**
Discussion: Investigator Initiated Research

- Pros and Cons of Investigator Initiated Research
- Informed Consent / IRB Oversight
- Protocol Development / Protocol Approval
- Budgeting: Funds, Supplies, Personnel
- Is an IND/IDE Required?
- Sponsor-Investigator Responsibilities
- Data Management / Report Development / Publishing
- Adverse Event Reporting

Course Faculty

George H. D'Addamio, PhD is President of PharmConsult, Inc., a consulting company in Atlanta, GA. During 8 years at SmithKline & French Laboratories (now Glaxo SmithKline), Dr. D'Addamio was responsible for preparing protocols, case report forms, integrated study reports, and regulatory submissions in Clinical R&D and Medical Affairs. As Scientific Manager, Clinical R&D, he was responsible for coordinating clinical research programs in Canada, Latin America, and the Pacific conducted under the US IND. In Medical Affairs, he managed operational groups responsible for medical writing, clinical monitoring, and safety reviews and quality control checks of CRFs. After leaving SK&F, Dr. D'Addamio worked for a CRO for 1.5 years before forming PharmConsult in 1987. Previous consulting experience includes project management, data management, statistical services, and medical writing. Currently, PharmConsult specializes in preparation of clinical development documents in various therapeutic areas for domestic and foreign pharmaceutical companies.

Jacqueline Busheikin, RN, CCRP, is President of JANA Research Corporation, an independent clinical research consulting/monitoring organization established in 2001. She is a registered nurse and had been working in the field of clinical trials since 1989 as a study coordinator, specializing in mental health, mainly schizophrenia, at the University of Calgary/Foothills Medical Centre. She was the first research coordinator at the Foothills Medical Centre and was responsible for establishing all standard operating procedures and for organizing the functioning of the unit. Ms. Busheikin has also presented numerous training and educational programs for site coordinators and clinical research monitors.