ONE DAY COURSE:

8:00 to 8:30 - Registration and Continental Breakfast

8:30 to 9:15 - Introduction
Certification program
Topics of discussion
Pre-test Foundations of ethical research

9:15 to 10:00 - Basic Concepts of Compliance
Laws, regulations, guidances, standard operating procedures

Drug Development
Overview of drug development
Non-clinical activities
Application to begin clinical trials
Phases of development; characteristics of study design

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

10:15 to 11:00 - Device Development
Define "device"
Classifications
Risk categories
Device development
Safety reporting

11:00 to 12:00 - Good Clinical Practice
Sponsor responsibilities
Monitor responsibilities
Investigator responsibilities

12:00 to 12:15 - Introduction to Case Study

12:15 to 12:45 - Lunch (Provided)

12:45 to 2:00 - Case Study and Discussion

2:00 to 2:45 - Prominent Regulations
Informed consent
Institutional Review Boards
Financial disclosure

2:45 to 3:00 - Break (with opportunity for discussion)

3:00 to 3:30 - Planning and Coordinating Clinical Trials
Basics of study design
Adverse events and expedited safety reporting
Study closure
Record retention

3:30 to 4:00 - Audits, Misconduct and Fraud
Objectives of sponsor audits and regulatory inspections
Inspections of sponsors, investigators, and IRBs

4:00 - Questions and Answers
COURSE FACULTY WILL BE ONE OF THE FOLLOWING INSTRUCTORS:

**GEORGE H. D’ADDAMIO, PHD**

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.

**SUSAN DEVINE, CCRP**

Susan Devine is a Research Consultant with 32 years experience in pediatric hematology/oncology at Montreal Children's Hospital and the Hospital for Sick Children in Toronto. Most recently Susan established a research infrastructure for a regional health center in Ontario. Susan was a founding member of the C17 Research Network in Canada and a Committee H reviewer for the NIH. Susan facilitated clinical trial training workshops for the Ontario Institute for Cancer Research and was developer and facilitator of the OICR Project Management workshop. Susan has held many leadership roles including Chair of the Children's Oncology Group CRA Discipline, and Treasurer and Board member of SOCRA.

Susan teaches the SOCRA Certification Prep and Review Course and co-chairs the SOCRA sponsored Pediatric Clinical Trials Workshop. Susan authored a chapter in Pediatric Clinics of North America entitled Good Clinical Practice and the Conduct of Clinical Studies in Pediatric Oncology and was a contributing author to a series of articles in Journal of Oncology Practice describing attributes of exemplary clinical trial sites.

**KATHI DURDON, BA, MA, CCRP**

As Director of Operations for the Central New York (CNY) Biotech Accelerator in Syracuse, NY, Kathi supports the Accelerator's strategic objectives in assisting biotech and biomedical for-profit start-up companies become successful. This involves development of grant and venture capital opportunities, service and mentor programs, and implementation of expedient operational process. The Director of Operations works closely with community-based innovation networks, instructs and supports regulatory requirements through Standard Operating Procedures. Kathi oversees various Accelerator programs such as the Upstate MIND, a translational research open concept space which fosters incubator and accelerator ideation and product development activities in a collaborative environment.

**CAROLYN E. RUGLOSKI, MS**

Ms. Rugloski, MS, has over 30 years of clinical trial research experience working within pharmaceutical, biopharmaceutical, university, and CRO environments and has provided functional-area managerial leadership to data management, monitoring, training, project management, quality assurance, and business development. She has dedicated her volunteer time over the years to the training of clinical trial professionals through SOCRA and other educational organizations. Recognized internationally as a Good Clinical Practice (GCP) Trainer and subject matter expert, Ms. Rugloski has lectured in North America, Europe, and the Pacific Rim. Ms. Rugloski is a past member of the SOCRA Board of Directors and continues to assist in the development and delivery of SOCRA events.