



Clinical Research Professional Certification Preparation and GCP Review Course

COURSE AGENDA

- 8:00–8:30 Registration and Continental Breakfast**
- 8:30–9:15 Introduction**
- Certification program
 - Topics of discussion
 - Pre-test
 - Foundations of ethical research
- 9:15–10:00 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
- 10:00–10:15 Break (with opportunity for discussion)**
- 10:15–11:00 Device Development**
- Define “device”
 - Classifications
 - Risk categories
 - Device development
 - Safety reporting
- 11:00–12:00 Good Clinical Practice**
- Sponsor responsibilities
 - Monitor responsibilities
 - Investigator responsibilities

- 12:00–12:15 Introduction to Case Study**
- 12:15–12:45 Lunch (provided)**
- 12:45–2:00 Case Study and Discussion**
- 2:00–2:45 Prominent Regulations**
- Informed consent
 - Institutional Review Boards
 - Financial disclosure
- 2:45–3:00 Break (with opportunity for discussion)**
- 3:00–3:30 Planning and Coordinating Clinical Trials**
- Basics of study design
 - Adverse events and expedited safety reporting
 - Study closure
 - Record retention
- 3:30–4:00 Audits, Misconduct and Fraud**
- Objectives of sponsor audits and regulatory inspections
 - Inspections of sponsors, investigators, and IRBs
- 4:00 Questions and Answers**

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, is the Research Manager at the Royal Victoria Regional Health Centre in Barrie, Ontario. Previously Susan spent more than 30 years managing pediatric cancer clinical trials at McGill University Montreal Children's Hospital and subsequently at Hospital for Sick Children. Susan was a founding member of the C17 Research Network, facilitator of Clinical Trial and Project Management in Oncology Trials for OICR and held leadership roles in the Children's Oncology Group. Susan teaches the Certification Prep and Review Course and co-chairs the pediatric workshop for SOCRA. She is first author of 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, MA, CCRP, is the Clinical Operations Associate with device manufacturer, Welch Allyn, Inc., based in Skaneateles Falls, NY. As Clinical Operations Associate she oversees much of the GCP Training at her facility and works with several business units in developing clinical investigation protocols as well as monitoring and managing of studies. Previously, Ms. Durdon directed the Clinical Trials Office at State University of New York (SUNY) Upstate Medical University in Syracuse, NY where she was employed for 15 years. She presents frequently at SOCRA courses, is a past member of SOCRA's Board of Directors, and is the New York State Chapter Chair. Ms. Durdon holds Bachelor of Arts degrees in both English and Anthropology from the State University of New York (SUNY) Potsdam College as well as a Master of Arts degree in Business Policy from the State University of New York (SUNY) Empire State College. Kathi is also adjunct faculty at SUNY Empire State College in a newly developed Clinical Research 4-year degree program.

Carolyn E. Rugloski, MSc, CCRP, is a Senior Project Manager at Clinipace Worldwide. Ms. Rugloski has more than twenty-five years of clinical trial research experience providing managerial leadership in data management, monitoring, training, project management, quality assurance, and business development. She has dedicated herself 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 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.