



CLINICAL RESEARCH PROFESSIONAL CERTIFICATION PREPARATION AND REVIEW COURSE

COURSE AGENDA

8:00 to 8:30	Registration
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 1:00	Lunch (provided)
1:00 to 1:45	Case Study
1:45 to 2:00	Discussion of Case Study
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