



Auditing Clinical Investigators



Norton Training Institute
A Service of Norton Audits, Inc.

**\$1,500 Auditing
Investigators**
**Upgrade to 4-Day
Auditing Forum for \$600**

Group Discounts Available

Learn Auditing From an Auditing Company

Learn our proven Norton Methods for GCP & ICH auditing of pharmaceutical and medical device clinical investigators from our expert skills and techniques. This law-based program will provide observational, interviewing, auditing and writing skills, legal expertise, and communication and data techniques for use within FDA-regulated research.

**October 19-20, 2010
Orlando, FL**



Hilton Walt Disney World Resort

1751 Hotel Plaza Boulevard
Lake Buena Vista, FL 32830
407-827-4000, \$129/night

Located at Downtown Disney

with direct access to all Disney
World parks and activities

For more Information:
803-233-4809, 866-552-8832
excellence@nortonaudits.com
www.nortonaudits.com

Auditing Clinical Investigators Class Modules

- Legal Expertise, Foundations of GCP/ICH
- Risk Assessment & Management
- Auditing Through Quality Systems
- Technical Writing Skills and Techniques
- Agendas, Confirmation Letters and Reports
- Audit Plans
- Case History Requirements
- Case Studies and Hands-On Workshops
- Observation & Interviewing Skills
- Organization & Communication Skills
- Data Techniques
- Sensitivity to Fraud & Misconduct
- Risk-Based Auditing of Protocols

6-hours of On-Line Training Included

- Legal Training for Investigator Qualifications
- Introduction to SOPs
- Noncompliance Causalities & Securing Compliance at the Clinical Investigator
- Technical Writing Skills and Audit Reports

Recommended Class Attendees

- Clinical Research Auditors
- Clinical Research Monitors
- Clinical Research Coordinators
- 2-10+ Years Research Experience

Bring Your Laptop (not required) for more in-depth participation in Workshops

Class Handouts (paper and electronic) included

About the Lead Instructor:

Tamera Norton Smith
PhD, MT(ASCP)

President
Norton Audits, Inc.



Dr. Smith is a former award-winning FDA Investigator and current international auditor, consultant, author and instructor throughout the pharmaceutical and medical device industries. Her more than 20 years' experience in the clinical research industry includes national and international auditing of IRBs, CROs, sponsors and Investigators, and consulting and monitoring on clinical trials. Dr. Smith is a frequent ACRP conference instructor and has even taught at the FDA. With more than 10 years of teaching experience, Dr. Smith brings an unparalleled level of energy, creativity and enthusiasm to her subject matter.

Other Instructors May Include:

Melissa Pong, BS, MS, CCRA
Director of Compliance

With seventeen years of research experience as a pharmacologist, senior monitor, project manager, senior auditor and instructor, Ms. Pong brings a broad experience including working for and with sponsors, CROs and hundreds of clinical investigators. Ms. Pong's therapeutic experience includes oncology, ophthalmology, respiratory, infectious disease, urology, women's health, cardiovascular, osteoarthritis and pain management among others.

Deidra Poucher, RN, BSN, MSHS, CCRC

Director of Regulatory Affairs and Ethics
Ms. Poucher has sixteen years of research experience as an international auditor, consultant, instructor, IRB member, study coordinator and research nurse, and 16 years of nursing experience. Ms. Poucher experience includes IRB Surveyor, Adjunct Professor, ACRP Chair and Regulatory Affairs. Ms. Poucher's therapeutic experience includes cardiovascular, ophthalmology, oncology, hematology, CNS, immunology, urinary, OBGYN, respiratory, organ transplant and critical care among others.