



Advanced Auditing Topics



Norton Training Institute

A Service of Norton Audits, Inc.

\$1,250 Advanced Topics

**Upgrade to 4-Day
Auditing Forum for \$745**

Includes lunch and breaks
Group Discounts Available

Learn Auditing from an Auditing Company

Acquire proven *Norton Methods™* skills and techniques for GCP & ICH auditing of pharmaceutical, medical device and biologics investigators, sponsors, CROs and IRBs from our expert level skills and techniques for industry and academia.

This law-based program will provide a skill-based learning environment with expertise shared in seven areas of auditor and monitor proficiencies.

**October 27-28, 2011
Columbia, SC**



SpringHill Suites by Marriott

511 Lady Street
Columbia, SC 29201
803-978-2333, \$119-
124/night
Room block expires
10/1/2011

**Located in the Vista
of Downtown
Columbia, SC**

with 100's of
restaurants, shopping and
entertainment options

For more Information:
803-233-4809, 866-552-
8832

Advanced Topics Class Modules

- General Session; 4 hours
 - Designing and Measuring Audit Metrics
 - Auditing Sponsors and Contract Research Organizations
- Concentrations; 2 - 4 hours each
 - Advanced Auditing of Sponsors and Contract Research Organizations
 - Investigating and Securing Compliance
 - QA/QC Role in the FDA Inspection Process
 - CAPA Plans including Investigative Action Plans
 - Advanced Scientific Misconduct

Bring Your Laptop

- for more in-depth participation
- not required

Recommended Class Attendees

- Clinical Research Auditors
- Clinical Research Sr. Monitors
- Directors of Compliance & QA
- 3-10+ Years Research Experience

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, medical device and biologics industries. Her more than 22 years' experience in the clinical research industry includes national and international auditing of IRBs, CROs, sponsors and clinical investigators, and consulting and monitoring on clinical trials. Dr. Smith is a frequent ACRP conference instructor and has taught at the FDA. Dr. Smith brings an unparalleled level of energy, creativity and enthusiasm to her subject matter.

More Norton Audits Instructors:

Deidra Poucher

RN, BSN, MSHS, CCRC, ROAP-GCP
Principal Compliance Analyst

Ms. Poucher has 18 years of expert level research experience as an international auditor, consultant and instructor. She has experience as an IRB member, IRB Accreditation surveyor, research nurse, and regulatory affairs professional plus 16 years of critical care nursing experience. She is currently an Assistant Adjunct Professor in the Clinical Research Administration and Regulatory Programs at the George Washington University. She has served as a volunteer for ACRP and SQA.

Margo Holland

RN, BScN
Senior Compliance Analyst

Cathy Metcalfe

RN, BHS, CCRC, CCRA
Senior Compliance Analyst