

Quality Systems Auditing Fundamentals and Auditing Clinical Investigators



Norton Training Institute
A Service of Norton Audits, Inc.

**\$1,400 Quality Systems
Auditing Fundamentals**

**Upgrade to 4-Day
Auditing Forum for \$595**

Includes lunch and breaks
Group Discounts Available

**October 25-26, 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
excellence@nortonaudits.com
www.nortonaudits.com

Learn Auditing from an Auditing Company

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

Fundamentals Class Modules

- State of the Industry
 - Updates and trends: FDA and Global Regulatory Efforts
 - Latest regulatory frameworks and metrics
- Legal Expertise, Foundations of GCP/ICH
 - Learn how to properly apply regulations
 - Learn standards auditing methodology
- Risk-Based Auditing of Protocols
 - Auditing to protocols
 - Programs for industry and government protocols
- Quality Systems Auditing Model
 - Methods for auditing investigators, sponsors/CROs, IRBs and other vendors
- Audit Process
 - Tools provided for the complete audit process
 - Risk-Based Methodology
- Seven Auditor Proficiencies
 - Legal expertise, data techniques
 - Organizational skills, writing skills
 - Observational skills, communication skills
 - Interviewing techniques
- Scientific Misconduct
 - Recent cases and trends
 - Techniques and approaches
- Primarily Demonstrated Through Clinical Investigator Audit Case Studies and Examples

Bring Your Laptop

- for more in-depth participation
- not required

About the Forum Leader

**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

Recommended Class Attendees

- Clinical Research Auditors
- Monitors and Coordinators