



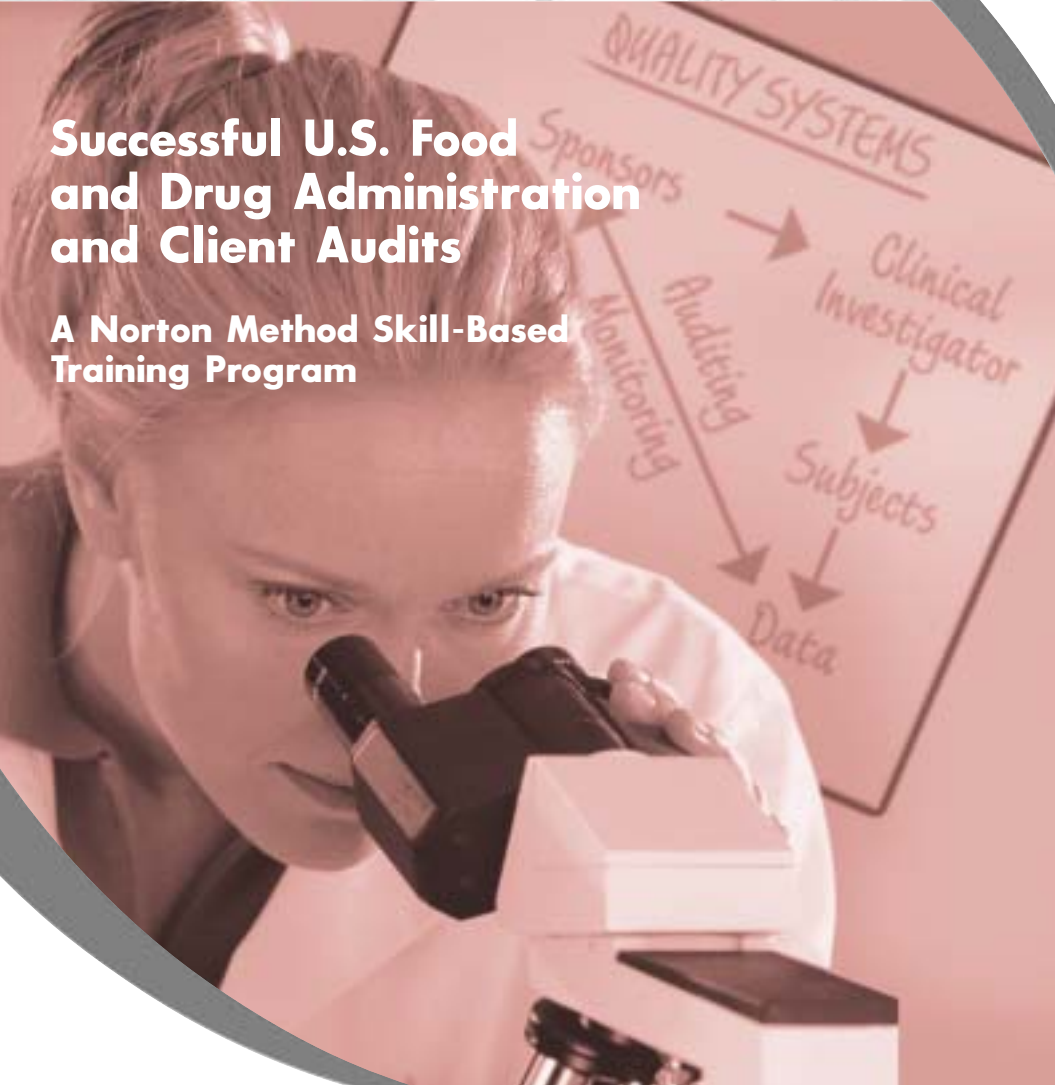
Norton Audits, Inc.

Defining and Driving Clinical Research Excellence



Successful U.S. Food and Drug Administration and Client Audits

**A Norton Method Skill-Based
Training Program**





Since 1999, Norton Audits, Inc. (NAI) has been an expert resource for achieving clinical research excellence through specialized training and compliance services. Our skill-based training philosophy allows us to deliver practical information that is anchored in regulatory law and guidelines and teach skills you'll utilize immediately within your organization.

YOUR CLASS SPECIFICS

Course Name - Successful U.S. Food and Drug Administration and Client Audits: A Norton Method Skill-Based Training Program

Course Number - TC-10

Class Length - One day

Description - This skill-based training program is taught by personnel with more than 15 years of field experience and teaches the skills and techniques utilized during U.S. FDA and client audits. The course has a two-fold focus: on organizing, participating in and conducting external regulatory and client audits; and on the current FDA Bioresearch Monitoring Programs. Attendees will prepare an audit plan and complete an auditing standard operating procedure.

Class Agenda/Modules -

- FDA's Bioresearch Monitoring Programs
- Planning, Organization and Participation
- Corrective and Preventative Actions (CAPA)
- FDA and Client Audits Standard Operating Procedures
- Common Audit Findings and Responding to Observations

Typical Class Attendee -

- Sponsor Auditors
- Contract Research Organization Auditors
- Clinical Investigators
- Clinical Research Associates and Coordinators
- Institutional Review Board Internal Auditors
- Independent Consultants
- Compliance Auditors

Class Level - Intermediate; research position for one year

YOUR GENERAL CLASS INFORMATION

Classes include handouts, manuals, lunch and snacks and are usually limited to 15 students in order to maximize student-instructor interaction.

Class times are generally 8:00 a.m. to 5:00 p.m. Visit www.nortonaudits.com for current class

schedules. Most courses are offered every three months.

Continuing Education Units (CEUs) are provided, and other educational hours may be available. Please call for more information.

YOUR INSTRUCTORS



**Tamera Norton
Smith,**
PhD, MT(ASCP),
President,
Senior Consultant

- Seventeen years' experience in clinical research including auditing, monitoring and consulting
- More than 10 years of teaching experience
- Former award-winning FDA investigator
- Nationally recognized by the U.S. Department of Health and Human Services for her work in biologics and GMP fraud detection
- Currently active as an auditor, author and trainer throughout the pharmaceutical and medical device industries
- Selected to train the U.S. FDA's Center for Devices and Radiological Health Division, 2004



**Elizabeth Ronk
Nelson,**
MPH, National
Compliance Director,
Senior Consultant

- Seventeen years' experience in the medical and clinical research field
- Direct experience with all site-based functions of clinical research
- Extensive experience in investigating and pursuing suspect clinical data cases
- Worked professionally with industry and government legal representatives to pursue legal actions for severe noncompliance cases
- Currently active throughout the pharmaceutical and medical device industries as an auditor, investigator and trainer

Student Comments

- "This training will help us win more studies."
 - Study Coordinator, Clinical Research Site
- "Very knowledgeable on topic she presented. Energetic and kept group engaged well. Great presenter. Very informative and applicable to my every day job."
 - Clinical Research Associates from Aventis
- "Every time I have heard your presentations, you have given me new life."
 - Senior Clinical Research Associate, Novartis

YOUR CLASS LOCATIONS AND SCHEDULES

We can set up on-site training for a dedicated group of employees or as part of your company's regional or annual meetings. We also hold classes at our primary training location in Columbia, South Carolina, at a convenient meeting center or in local hotel conference rooms. In addition, we can schedule training at

our satellite locations in Atlanta, Georgia; Charlotte, North Carolina; and Philadelphia, Pennsylvania, as needed.

Monthly class schedules for our Columbia, South Carolina, location can be found at www.nortonaudits.com.

YOUR CONTACT INFORMATION

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