



AMWA Carolinas Chapter 2013 Spring Conference

Friday, May 3, 2013

7:45 AM to 5:00 PM

**The Friday Center
Chapel Hill, NC**

2013 SPRING CONFERENCE SCHEDULE

THURSDAY DINNER 6:30–8:30 PM | FRIDAY CONFERENCE 7:45 AM – 5:00 PM

Preconference Dinner (Thursday, May 2, 2013, 6:30-8:30 PM)

Join us for a preconference dinner at Piola’s, 1101 Environ Way in Chapel Hill near the Friday Center. Get to know fellow AMWA members in a relaxed environment before the conference begins.

Conference Registration & Breakfast (Friday, May 3, 7:45-8:30 AM)

Pick up your registration packet, network with colleagues, and enjoy a deluxe continental breakfast.

Morning Session (8:30-11:30 AM)

AMWA WORKSHOP OPTIONS:

Statistics for Medical Writers and Editors (ES/G/SG) [2010]
Tom Lang, MA

Assessing and Communicating the Benefits and Risks of Medicine (RR) [4021]
Lawrence Liberti, RPh, RAC

OPEN SESSION OPTIONS:

8:30 – 10:00 AM* Introduction to Clinical Subject Narrative Writing
Karen L. Campbell, MS

10:15 – 11:45 AM* The Pathology of Breast Cancer
Howard Reisner, PhD

**Please note, there will be a short break between sessions (from 10:00 to 10:15am) so that you can check messages, use the restroom, etc.*

Lunch (11:45-1:00 PM)

A buffet lunch is included with your registration. Some tables will have a topic to discuss to help facilitate conversation and getting to know one another. Other tables will have open discussion. You may select a topic during registration.

Inside the client-vendor relationship Leader: Dayle H. Cohen, PhD, RAC Associate Director, Global Medical Writing, PPD, Inc.	All about RAC certification Leader: Deana Betterton-Lewis, MS, RAC
Personal branding Leader: Robin Whitsell, BA, BPh President, Whitsell Innovations, Inc.	QC issues in the publishing of regulatory documents Leader: Suzanne Lawton, RAC, CCRP Freelance Medical Writer and Quality Reviewer, Lawton Clinical Associates, LLC
Cutting corners without cutting quality Leader: Trisha Houser Medical writer, Houser Clinical Research Writing and Consulting	The life of a freelance medical writer Leader: Eugene Casale, PhD Freelance Medical Writer, Casagen Consulting
Navigating the Investigational Drug development plan Leader: Barbara Orban, MS Medical Writer and Consultant, RIBA Technical Solutions	

Afternoon Session (1:00-4:00 PM)

AMWA WORKSHOP OPTIONS:

Tables and Graphs (ES/G) [2011]

Tom Lang, MA

Writing the Final Report of a Clinical Trial (RR/PH) [4016]

Lawrence Liberti, RPh, RAC

OPEN SESSIONS:


1:00 – 2:30 PM* **Secrets of the Editorial Office**
Jan Higgins, PhD and Elizabeth Blalock

2:45 – 4:15 AM* **From Quincy to Quintessential - The Impact of the Orphan Drug Act over 40 Years**
Drusilla Scott, PhD, RAC

**Please note, there will be a short break between sessions (from 2:30 to 2:45pm) so that you can check messages, use the restroom, etc.*

Social Hour (4:00-5:00 PM)

Take time to socialize with colleagues. Exchange ideas, trade business cards, and make plans to attend the next AMWA event. Take a breather after a full day of learning, and kick off your weekend feeling relaxed!



2013 SPRING CONFERENCE

SUMMARY

REGISTER EARLY!

Registration is available online. Early registration is advised. Registration is limited to the first 30 paid applicants for each workshop. Open sessions are limited to 35 registrants. Registration prices are listed for members (or students, postdocs with ID) and nonmembers.

REGISTRATION DEADLINES

If you want to take participate in workshops, the registration deadline is April 5, 2013. If you only plan to attend open sessions, the registration deadline is April 21, 2013.

HOMEWORK DUE DATE

You will receive information about applicable homework soon after your registration is received. **Workshop homework is due by no later than April 19, 2013.**

REFUND INFORMATION

There will be a \$25 nonrefundable charge for each workshop. No refunds for workshop fees after April 5, 2013; no refunds for the registration fee after April 21, 2013.

REGISTRATION FEES

Registration is required for all attendees and includes breakfast, lunch and all open sessions.

AMWA Members or Students = \$90

Nonmembers = \$150

PAYMENT INFORMATION & CONFERENCE QUESTIONS

Please register online. Payment can be made online at the time of registration or mailed in as indicated below. For questions about the conference, contact Kate Lothman (see below).

To register and pay online:

Online registration and payment is available at:

<http://tinyurl.com/AMWA2013Registration>

To pay by check:

Register online and mail your check (made payable to AMWA Carolinas Chapter) to:

Kate Lothman

PO Box 12194

200 Park Offices Drive (FedEx)

Research Triangle Park, NC 27709

Email: pres-e@amwacarolinas.org

Please register online. Payment can be made online at the time of registration or mailed in. See details in left column.

Registration Fee (Required for all attendees; rates are for members or students / nonmembers; includes breakfast, lunch, and all open sessions)	\$90/\$150
Morning Session	
<i>When you register online, choose 1 workshop or 2 open sessions.</i>	
Workshops	members/nonmembers
Statistics for Medical Writers and Editors (ES/G/SG) [2010]	\$95/\$195
Assessing and Communicating the Benefits and Risks of Medicine (RR) [4021]	\$95/\$195
Open Sessions	
Introduction to Clinical Subject Narrative Writing	\$0/\$0
The Pathology of Breast Cancer	\$0/\$0
Afternoon Session	
<i>When you register online, choose 1 workshop or 2 open sessions.</i>	
Workshops	members/nonmembers
Tables and Graphs (ES/G) [2011]	\$95/\$195
Writing the Final Report of a Clinical Trial (RR/PH) [4016]	\$95/\$195
Open Sessions	
Secrets of the Editorial Office	\$0/\$0
From Quincy to Quintessential - The Impact of the Orphan Drug Act over 40 Years	\$0/\$0
Social Hour	\$0/\$0
Other Fees (optional)	
AMWA annual membership dues	\$165
New Certificate Enrollment (Business; Essential Skills; Regulatory and Research ; good for 6 years)	\$150/\$275
Core Enrollment Extension (4 years)	\$85/\$210
Advanced Enrollment Extension (4 years)	\$95/\$220

When you register online, please also indicate whether you are planning to attend the preconference dinner.

AMWA Workshop Descriptions

STATISTICS FOR MEDICAL WRITERS AND EDITORS (ES/G/SG) [2010]

This workshop is designed for participants who have little or no background in statistics. The workshop leader will cover elementary statistical concepts needed to understand medical and scientific articles, including types of variables, levels of measurement, summary statistics, estimation and confidence intervals, and t test. Emphasis will be placed on understanding statistical presentations and on reporting statistical information—not on calculations or mathematical explanations.

Instructor: Tom Lang, MA

Approximate Homework Time: 2-5 hours

TABLES AND GRAPHS (ES/G) [2011]

The workshop leader will cover definitions and uses of tables and graphs, as well as guidelines for preparing and editing them. The focus of the workshop, designed for the beginner, is the preparation of tables and graphs that are usable, that communicate, and that are appropriate for the situation. Participation is encouraged as we evaluate problematic tables and graphs.

Instructor: Tom Lang, MA

Approximate Homework Time: 3 hours

WRITING THE FINAL REPORT OF A CLINICAL TRIAL (RR/PH) [4016]

This workshop is intended for novices and moderately experienced medical writers; the leader will offer approaches to generating a clinical study report. The components of the report, issues of quality control, and common problems and situations will be covered. Within this framework, ideal and real-world experiences will be discussed. The impact of guidelines from the International Conference on Harmonisation (ICH) and their effect on the standard report **STRUCTURE** will be discussed in detail.

Instructor: Lawrence E. Liberti, RPh, RAC

Approximate Homework Time: 4 hours

ASSESSING AND COMMUNICATING THE BENEFITS AND RISKS OF MEDICINE (RR) [4021]

We balance benefits and risks for every activity in daily life. Regulators, drug developers, clinicians, patients, payers and other stakeholders attempt to apply benefit-risk (BR) assessments to medicines. Despite intuitive approaches, the formal evaluation of a medicine's BR is a relatively new, continually emerging science. A common framework for assessing and communicating BR is quickly approaching. This course is designed to introduce participants to the concepts that underlie techniques to assess the BR of medicines and to apply this knowledge to ways writers can approach more effective BR communications with stakeholders.

Instructor: Lawrence E. Liberti, RPh, RAC

Approximate Homework Time: 2 hours

NOTE: Workshop homework is due by no later than April 19, 2013.

Workshop Acronym Key: ES=Essential Skills; G=General (previously offered certificate); PH=Pharmaceutical; RR=Regulatory and Research; SG=General Science (previously offered certificate); SM=Concepts in Science and Medicine

Open Session Descriptions

Open Sessions (OS) do not have homework.

INTRODUCTION TO CLINICAL SUBJECT NARRATIVE WRITING (OS)

This slide lecture will provide information about the “why, what, and how” of clinical subject narratives. It is intended for medical writers who want to learn about another piece of a clinical study report. The content of narratives, types of events for which narratives are written, data used for writing narratives, and a review of the writing process will be covered.

Instructor: Karen L. Campbell, MS

THE PATHOLOGY OF BREAST CANCER (OS)

Pathology is the study of etiologies (causes) and pathogenesis (progress of disease) with a strong historical emphasis on classification. By classifying disease based on how it presents at the tissue, cellular, biochemical and molecular levels, the pathologist can suggest a prognosis and therapeutic approach to the internist and surgeon. In studying the molecular nature of disease, and in particular neoplasia, the experimental pathologist attempts to decipher the molecular lesion, which is causative. This talk will explain the pathology of breast cancer and review the role of the pathologist in both helping the clinician and unraveling the nature of this disease at the molecular level.

Instructor: Howard Reisner, PhD

SECRETS OF THE EDITORIAL OFFICE (OS)

Why do editorial offices insist on things being *that* way and why do different journals ask for things in quite different styles? How can you make your manuscript better? How can you ensure your article will be reviewed? The editorial office is actually there to help authors (though it might not always seem like it!). So come and find out what happens *after* your manuscript is submitted to a research journal.

Instructors: Jan Higgins, PhD and Elizabeth Blalock

FROM QUINCY TO QUINTESSENTIAL - THE IMPACT OF THE ORPHAN DRUG ACT OVER 40 YEARS (OS)

Prior to enactment of the Orphan Drug Act (ODA) in 1983, only 10 products had been approved in the US for the treatment of rare disorders. This dearth of treatments eventually came to broad public attention in the television drama Quincy, which focused on the need for new drugs for these “orphan” conditions. The ODA provided the pharmaceutical industry with incentives to study, and bring to market, products for the small populations affected. Now in its 30th year, the ODA has been an unqualified success. As of January 2013, more than 400 orphan products have been approved and more than 2700 have received orphan designation. Orphan products have become a “quintessential” example of targeted drug development and are represented in the product pipelines of both large and small large pharmaceutical companies. We will review the principles of the ODA and the proposed revisions to the implementing regulations, which FDA intends to clarify its interpretation of the most challenging aspects of the law. We will also discuss trends in orphan designations and approvals.

Instructor: Drusilla Scott, PhD, RAC

Instructor Biographical Sketches

Elizabeth Blalock is managing editor of the *Journal of Investigative Dermatology*. Previously, she managed the journal *Endocrinology*. Elizabeth is a founding member of the International Society for Managing and Technical Editors and a longstanding member of the Council of Science Editors; she has presented at both societies' annual meetings on editorial office operations and publication ethics.

Karen L. Campbell, MS is the President of Campbell Consulting Enterprises, Inc. and has over 20 years' experience in the pharmaceutical industry. Her experience spans from working at a study site, to moving to a CRO and then a pharmaceutical company. She has gained a wide range of cross-functional knowledge in many areas of clinical trials. Understanding how the data are obtained and "moved" through the process has strengthened her ability to write, review data and documents, and train others on the various aspects of clinical trials. Karen has worked on several projects which successfully received regulatory approval. Karen has written and/or reviewed an estimated 5,000+ clinical subject narratives.

Jan Higgins, PhD started out as a research scientist before transitioning to her current position as managing editor for *Genetics in Medicine*. Based in Raleigh, she has been in this role since 2006 but has continued as a freelancer in editing and writing scientific manuscripts. She also teaches graduate students how to write scientific manuscripts at the University of North Carolina at Chapel Hill. She currently serves on the board of the International Society for Managing and Technical Editors.

Tom Lang, MA of Tom Lang Communications and Training, is an international consultant and educator in medical writing and scientific publications. The author of *How to Report Statistics in Medicine: Annotated Guidelines for Authors, Editors, and Reviewers* and *How to Write, Publish, and Present in the Health Sciences: Guidelines for Clinicians and Laboratory Researchers*, he teaches for the University of Chicago's Medical Writing Program and is Adjunct Professor of Biomedical Writing at the University of the Sciences in Philadelphia. He received the 1994 Golden Apple Award for Outstanding Workshop Leader from AMWA, the 2002 Excellence in Continuing Education Award from the American Statistical Association, and the First Excellence in Teaching Award from the Graham School of General Studies, University of Chicago. He is a Past President of the Council of Science Editors, Treasurer of the World Association of Medical Editors, a Fellow of AMWA, and the recipient of that association's 2002 Harold Swanberg Distinguished Service Award for outstanding contributions to medical communications.

Lawrence E. Liberti, RPh, RAC has worked in and with the pharmaceutical industry, in the fields of pharmaceutical and clinical research and development for 34 years. He spent nine years at Wyeth Laboratories in product development, clinical R&D, and medical affairs. He served as editorial director, North America, for ADIS International before starting Pharmaceutical Information Associates, a company specializing in regulatory writing and regulatory consulting. He was a co-founder of Astrolabe Analytica under which he helped develop and commercialize the Astrolabe Message Mapping System. He currently serves as the Executive Director of CIRS - the Centre for Innovation in Regulatory Science, Ltd. He is an active member of the American Medical Writers Association (AMWA), the Regulatory Affairs Professional Society, and the Drug Information Association. He was awarded a fellowship of the AMWA and is a Golden Apple Award recipient. Larry has been actively involved in promulgating best practices in the regulatory aspects of medicines development, especially in the emerging markets. He lectures on regulatory issues concerning expediting patient access to medicines, new paradigms of drug development and ways to improve communications between regulators, HTAs and sponsors.

Howard M. Reisner, PhD, is professor of Pathology and Laboratory Medicine at the University of North Carolina at Chapel Hill. Howard has published in the area of blood coagulation and immunoassay development but is primarily engaged in teaching pathology at the Medical and Dental School. In addition, Howard teaches a course on introductory pathology to undergraduate students. He is the co-editor of a pathology text and is in the process of working on a second text.

Drusilla Scott, PhD, RAC, has worked in regulatory affairs in the pharmaceutical industry for more than 20 years and is Senior Vice-President, Regulatory Affairs, at Cempra Pharmaceuticals. She previously held regulatory positions at EMD, Isis, Parke-Davis, and Pennwalt, and was an adjunct professor at the University of Michigan and Temple University, and a lecturer at Eastern Michigan University. She has been responsible for working with

development teams and within the regulatory department to construct regulatory strategies for the development and registration of drug products in several therapeutic areas, with a focus on anti-infective drugs. Drusilla holds a BS in Chemistry from Western Carolina University and a PhD in Pharmacology from the University of North Carolina at Chapel Hill. She serves on the Regulatory Affairs Editorial Board of the Drug Information Association and as a faculty member in IND/NDA courses.

AMWA Education Programs

The American Medical Writers Association (AMWA) offers one of the most extensive education programs available to professional communicators in the medical and allied scientific fields. Programming is tailored to the profession, and the number of offerings is continually expanded to broaden the selection of options for both novice and experienced medical communicators. AMWA offers several certificate programs: Essential Skills, Business, Composition and Publication, Concepts in Science and Medicine, and Regulatory and Research. **Participants may take the workshops without enrolling in a certificate program but must be enrolled in the applicable certificate program to receive workshop credit toward a certificate.** Persons who successfully complete the workshop have up to 90 days after the conference to enroll in the appropriate certificate program. Credit can not be assigned after this date. Persons who were enrolled in the Core certificate program, the Science Fundamentals certificate program, or the Advanced* certificate program before December 1, 2009, can still work toward those certificates. Multiple designations are included in workshop listings to accommodate persons enrolled in both the old and new certificate programs.

CERTIFICATE DESCRIPTIONS

- **Essential Skills (ES)**—skills that all medical communicators should possess, regardless of the area in which they work
- **Specialty Certificates** (while registrants may enroll in 1 or more specialty certificate programs, completion of an Essential Skills, Core, or Advanced certificate is required in order to earn a specialty certificate.)
 - **Business (B)**—management and operations skills for freelance businesses and larger organizations
 - **Composition and Publication (CP)**—specialized editorial and publication skills
 - **Concepts in Science and Medicine (SM)**—broad, introductory concepts in science and medicine for nonscientists, or as refreshers
 - **Regulatory and Research (RR)**—specialized regulatory/drug development writing and scientific research skills

To enroll in a certificate program, use the enrollment form included on the registration site—or you may enroll using the enrollment form located on the AMWA Web site (www.amwa.org under Education/Certificates).

CERTIFICATE REQUIREMENTS

- A separate certificate can be earned in each of the 5 certificates listed above.
- Each certificate will require successful completion of 8 workshops (including one ethics-related workshop) in the relevant certificate program within 6 years of enrollment.
- You can enroll in more than 1 certificate program and pursue multiple certificates at the same time. However, an Essential Skills, Core, or Advanced certificate will be required before you can earn a certificate in a specialty.
- As before, you can take any workshop at any time, but earning workshop credit toward a certificate requires being enrolled in the certificate program corresponding to the workshop's designation (ES, CP, RR, B, or SM).

RULES FOR EARNING WORKSHOP CREDIT TOWARD CERTIFICATES—NO EXCEPTIONS

- Enrollment in the certificate program corresponding to the workshop designation (ES or CP or RR or B or SM) is required.
- Workshop homework must be received by the leader by the stated deadline.
- The workshop must be attended in its entirety (3 hours).
- There is a 10-minute grace period, after the stated starting time, for entering a workshop; after that, no one will be admitted and no refund or workshop credit will be given.

Conference Location

The Friday Center is located off NC Hwy 54 in Chapel Hill, North Carolina. See www.fridaycenter.unc.edu for a map and more details about the venue.

Preconference Dinner

Join us for a preconference dinner at Piola's at 1101 Environ Way in Chapel Hill from 6:30 to 8:30 PM. Get to know fellow AMWA members in a relaxed environment before the conference begins. The restaurant offers a variety of entrée options and is conveniently located in East54 off Chapel Hill Road (less than a mile from the Friday Center). For restaurant information or directions, visit www.piola.it/index.php?page=show-local&lang=en&menu_number=3&id=38 or call (919) 537-8488. You can RSVP by indicating that you plan to attend the preconference dinner on the registration form or by sending email to Catherine Champagne (treasurer@amwacarolinas.org). Please **RSVP by Tuesday, April 30, 2012**. Please note that attendees pay for their own food and beverages.

Hotel Information

The Courtyard Marriott of Chapel Hill is on NC Hwy 54, within short walking distance of the Friday Center. The Hilton Garden Inn is located at off of I-40 on Fayetteville Road in Durham, North Carolina and is adjacent to The Streets at Southpoint mall. The Hilton Garden Inn is 10 miles from RDU International Airport and 7 miles from the Friday Center.

Courtyard Marriott of Chapel Hill
100 Marriott Way
Chapel Hill, NC 27517
Phone: (919) 883-0700
www.marriott.com/rduch

Hilton Garden Inn Durham Southpoint
7007 Fayetteville Road
Durham, NC 27713
Phone: (919) 544-6000
www.hiltongardeninn.com

Thank you to our Corporate Sponsors!

AMWA Carolinas would like to acknowledge our corporate sponsors: UCB Biosciences, Inc., and Valesta Clinical Research Solutions (a division of On Assignment, Inc.). We appreciate their support of education for medical communicators in the Carolinas!

