September 13: Dinner Meeting in Cambridge, Mass.
Medical Writers in Drug and Medical Device Development: Roles and Regulations

The New England Chapter will open the 2006-07 year with a dinner meeting on Wednesday, September 13, at Ristorante Marino in Cambridge, Mass. Linda F. Wood, RN, MPH, will speak on medical writing for the drug and medical device industries.

These heavily regulated industries have defined stages of product development, each with its own set of required documents. Ms. Wood will describe the development phases, the documents associated with each phase, and the education and experience needed to write these documents.

As a writer for the pharmaceutical, biotechnology, and medical device industries for 20 years, Ms. Wood is an expert on this topic. After a career as a registered nurse, working in hospitals and clinics, she earned a master's degree in epidemiology and biostatistics from Yale University and entered the world of drug development. She was the first medical writer hired by Parexel International Corporation, a contract research organization. Recently, she served a stint as director of global regulatory communication strategy for Boston Scientific Corporation. For 16 years, through her company, MedWrite Inc. in Westford, Mass., she has provided consulting services for numerous pharmaceutical, biotechnology, and medical device companies.

She has given many presentations on a variety of regulatory writing topics at meetings of the Drug Information Association, the Massachusetts Biotechnology Council, the Society for Technical Communication, and AMWA.

An AMWA member since 1989, Linda Wood was president of the New England Chapter of AMWA in 2002-03.

ROLES AND REGULATIONS

DATE: Wednesday, September 13
TIME: Social hour (cash bar) from 6:00 to 7:00 p.m. Dinner 7:00 to 8:00. Program 8:00 to 9:00.
PLACE: Ristorante Marino, 2465 Massachusetts Avenue, Cambridge, Massachusetts. DIRECTIONS AND PARKING INFORMATION ON BACK PAGE.

BUFFET MENU: Assorted Rolls ● Garden Salad ● Penne with Plum Tomato Sauce ● Marinated Grilled Chicken ● Grilled Vegetables ● Italian Cookies ● Coffee, Tea, Decaf

REGISTRATION: Please use the enclosed form to register. The registration fee is $23 for members, $27 for guests and prospective members.

DEADLINE: To guarantee dinner reservations, we must receive your payment by mail (checks only, no credit cards) no later than Friday, September 8. (Sorry, no refunds for cancellation after 2:00 p.m. that day.)

Are you interested in writing for the pharmaceutical or medical device industry? Don’t miss this chance to get an overview of these industries’ needs, the requisite skills, and a sense of where you might fit in.

As always, the New England Chapter welcomes guests and prospective members.

—Julie Martin
President-Elect/Program Director

You can earn 5 points toward an AMWA Professional Development Certificate by attending this meeting. For information about the certificate, go to the AMWA Web site (www.amwa.org) and click on Education/Development.
Chapter Calendar

The New England Chapter holds seven regular meetings a year, from September through June. Five meetings are in the Greater Boston area, and two are in Connecticut. Every meeting begins with a social hour, followed by dinner (except for a Sunday brunch in midwinter), then a program with a speaker, a panel presentation, or roundtable discussions. A writing competition culminating in the Will Solimene Awards is held every other year, alternating with the New England Conference, an all-day program of workshops. Often, informal networking meetings or tours are scheduled.

October 18: Networking Dinner in Western Mass.

An informal networking dinner will be held on Wednesday, October 18, in Western Massachusetts (location TBD). Another dinner is tentatively planned for Thursday, December 14.

For information, contact Patricia Boone at 413-533-5711 or pat@btmc.biz.

TBD: Connecticut Fall Meeting

As is customary, the New England Chapter will hold a dinner meeting and program in Connecticut in October. Details and a registration form will be sent to all Connecticut members by regular mail.

Other members, as well as guests and prospective members, are welcome. To receive information, e-mail your postal address to Lynne Dodson at ldodson@snet.net.

October 26-28: Chapter Meet & Greet

AMWA Annual Conference in Albuquerque, N.M.

If you are fortunate enough to be attending the annual conference, AMWA’s premier event, don’t miss the Chapter Meet & Greet, on Thursday, October 26, from 6:45 to 7:45 p.m. The New England Chapter, like other chapters, will have a designated area in which to gather. This is a perfect time to catch up with old friends and make new acquaintances.


The chapter's 7th biennial conference is scheduled for Saturday, May 5, at the Sturbridge Host Hotel & Conference Center. The program will offer six 3-hour workshops, four of them in the AMWA Core Curriculum. Three of the classes will run concurrently in the morning, and three in the afternoon. The Conference Luncheon will include several tables devoted to career-development topics as well as open tables for those who would prefer to network, socialize, or just relax between classes.

The chapter newsletter will give more information as the program evolves.

April Meeting Report

Epidemiology: Making Sense of Scientific Findings

At the chapter’s April meeting at the Sheraton Lexington Inn, Julie Buring, ScD, epidemiologist, professor of medicine at Harvard Medical School, deputy director of the Division of Preventive Medicine at Brigham and Women’s Hospital, and coauthor of the popular textbook, Epidemiology in Medicine, explained how to understand and interpret the results of scientific studies.

Dr. Buring, who has been involved in several large-scale clinical trials on preventing cardiovascular disease and cancer, began by introducing basic principles of epidemiology. Analyzing epidemiological studies “is very much like being a medical sleuth,” she said. “Trust your instincts when interpreting study results,” she advised.

Although the Women’s Health Initiative study has been well publicized, Dr. Buring pointed out that media coverage was confusing. The recommendation that study participants stop taking their estrogen-progestin led many women in the U.S. to quit their regimen immediately, even though there was no pending crisis. That led to rebound symptoms in many.

Another study investigated whether reducing total fat to 20% of total caloric intake would decrease the risk of breast cancer and colorectal cancer in women over an 8-year period. The results suggested that while a low fat diet may reduce the risk of breast cancer among women who had been consuming a high fat diet, it did little to protect them from colorectal cancer. “There are no magic bullets,” concluded Dr. Buring. “No one study can definitively answer a question.” Rather, we need to examine the totality of evidence and context.

—Adriane Bishko, Secretary
May Meeting Report
Hughes Updates Connecticut Members on CME

Once upon a time, most continuing medical education (CME) was funded and controlled by a pharmaceutical company’s marketing department. The company might organize the program or subcontract the work, but in either case, some, or even all, of the faculty were selected by the manufacturer.


Speaking to about 20 Connecticut members in New Haven on May 30, Dr. Hughes described how the threats of multimillion dollar fines and sanctions have significantly altered the way CME is developed, but have also created some opportunities for medical writers. The three sets of guidelines share a common prescription against the funding manufacturer having any control over the content or faculty. Reacting to the changes, companies have reorganized so that marketing departments neither fund CME nor have a prominent voice in organizing the programs. Medical affairs and regulatory staff play a much larger role in developing CME; decisions about funding are usually handled by committees. In accordance with the new guidelines, many medical communication companies that serve pharmaceutical firms have divided themselves into two businesses, one handling CME and the other marketing and other medical communications projects.

As a result of these and other changes, funding decisions for CME can take as long as 18 months, and getting funding is much less certain. The ACCME requires an extensive needs assessment before a program is designed. Dr. Hughes said preparing the assessment document, which can run 10 academically styled pages, is a project often assigned to freelance writers.

Dr. Hughes and others predict that as CME providers and funders become more comfortable with the various guidelines, the ultraconservative atmosphere may ease. “High-quality CME will always be desirable,” Dr. Hughes concluded.

—J. Lynne Dodson
Vice President for Connecticut

Dr. Hughes produced an audio CD of her presentation, which is available for a modest fee to those who were unable to attend. For information, contact her at chughes@hughesbiopharma.com or visit www.hughesbiopharma.com to hear a sample.

June Meeting Report
Awards banquet was a festive evening

The 12th Awards Banquet at the Westin Hotel in Waltham, Mass., in June brought the chapter’s year to an elegant and festive close. After a spirited cocktail hour and a delicious dinner, Master of Ceremonies Jill Shuman welcomed the more than 70 members and guests in attendance, and deftly guided us through the evening’s ceremonies.

Introduction of New Officers

Outgoing president Andrea Gwosdow thanked those who served her last year and introduced the new officers as she passed the gavel to her successor, Lonnie Christiansen. Also serving in 2006-07 are Julie Martin, president-elect; Adriane Bishko, secretary; Jill Shuman, treasurer; and Lynne Dodson, vice president for Connecticut.

Judy Linn Membership Award

The Judy Linn Membership Awards provide support and encouragement to medical writers who are fairly new to the field. The award is a one-year membership in AMWA, compliments of the chapter, and the recipient may attend three chapter meetings during the year at no charge.

This year the award went to Susan Hollander. Susan received a medical degree from the University of Connecticut and after a residency at Eastern Virginia Medical School, practiced pediatrics in Nashes, N.H. She recently completed studies at Tufts University for a master’s in nutrition communication. While she was an intern in the Tufts Health Sciences Public Relations office, where she was a lead author of Friedman Nutrition Notes, the high quality of her work caught the attention of Siobhan Gallagher, who nominated her for the award.

[Ed. Note: In August, Susan joined The Center for Medical Knowledge in Chester, Conn., as a staff writer.]

Honors Address

Nancy Knoblock Hunton, honors award director, introduced the 2006 Honors Speaker, renowned researcher and bestselling author, Miriam E. Nelson, PhD. Dr. Nelson directs the John Hancock Center for Physical Activity and Nutrition and teaches at the Friedman School of Nutrition Science and Policy at Tufts University. In her talk, titled “From Researcher to Author and Advocate,” she summarized her background and research.

People over 50 used to be considered old, she said, but the paradigm of aging has changed. In her first studies, with a group of 50- to 70-year-old women, she discovered that participants who engaged in strength training, not only increased their bone density and balance, but looked as much as 15 years younger.

Her monthly e-newsletter and weekend training sessions have become legendary. In 2003, she initiated the “strong women program,” which is currently active in 34 states.

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With her eighth book coming out, she noted that years of research have taught her just how resilient the body is. The aging process, she said, is related more to the lack of exercise and poor nutrition than to chronological age. Exercise and strength training not only enhance mood and self-esteem, but the latest data also suggest that there is a reduction of the incidence of Alzheimer’s disease among people who are physically active.

There have been hurdles along the way, she said. For example, when her study on the role of calcium and Vitamin D came out, some news sources stated that calcium supplementation had little effect. However, participants who were 80% compliant had 30% fewer fractures.

At the end of Dr. Nelson’s talk and a lively Q&A session, Nancy Hunton presented her with a plaque honoring her “for her groundbreaking research on the vital role of exercise in healthy aging, for her passionate commitment to communicating the importance of fitness and nutrition to women everywhere, and for her books, Web site, and lectures, which have inspired millions to become stronger.

Will Solimene Awards for Excellence in Medical Communication

With wit and warmth, Tod Forman and Siobhan Gallagher, both judges in this year’s writing competition, presented the 2006 Will Solimene Awards. Plaques went to 20 entries—books, articles, reports, videos, and a CD, some written for lay audiences, some for professionals. Enclosed with this newsletter is a copy of the Awards Banquet Program, listing the works that were recognized.

Neil Duane Award for Distinction

The winner of the Neil Duane Award, given in addition to the Will Solimene Award, remained a secret until the last minute. This special recognition for a publication that stood out above all went to Francesca Coltrera and Carolyn Kaelin for Living Through Breast Cancer (McGraw-Hill, 2005). In presenting the award—elegant Lucite desk clocks, each with an inscribed plate—Awards Director Jill Shuman cited some of the judges’ comments, among them: “an extremely thorough, well-written discussion of one of the most serious and frightening threats to women today” and “a perfect book in every way.”

Writing Competition Judges

On behalf of the chapter, Jill Shuman, thanked the judges: Ellen Barlow, Robert Dunbar, Tod Forman, Siobhan Gallagher, Nancy Knoblock Hunton, Laurie LaRusso, and Bonnie Prescott. With varying backgrounds, experience, and perspectives, these judges worked diligently to select the entries that met the highest standards of excellence.

Chapter members will contribute to 2006 AMWA conference

Several of our New England AMWA colleagues will be sharing their knowledge and experience at AMWA’s 66th Annual Conference in Albuquerque, N.M., October 26-28.

Donna K. Curtis, PharmD, of Curtis Consulting & Communications, Mashpee, Mass., is slated to lead a breakfast roundtable, “Expanding Your Freelance Business.”

Catherine Duffek, MLS, MS, of the Glaucoma Foundation’s New England Chapter, Boston, will lead a breakfast roundtable, “Information Overload: Controlling Current, New, and Contradictory Information.”

Kevin Flynn, MA, is teaching a Core workshop, “Educating Sales Representatives About Science and Medicine,” and will be a panelist in an open session on “What Employers Look For in a Freelance.” Kevin is senior vice president, medical affairs and scientific services, Fusion Medical Education, Wakefield, Mass.,

Thomas P. Gegens, MS, ELS, is co-teaching a Core workshop, “Effectively Searching Online Databases,” and teaching another Core workshop, “The Internet: How and Where to Find the Information You Seek.” He is also slated to lead a table discussion, “Techies Unite! Keeping Up With New Communication Technologies,” at the coffee and dessert klatch. Tom recently left his position as executive director and senior editor of The Center for AIDS Information & Advocacy in Houston, Tex., to move to Connecticut, where he has joined Envision Pharma, a medical and scientific communications company in Southport.

Jill M. Shuman, MS, ELS, freelance writer in Woburn, Mass., and lecturer at Tufts University School of Medicine, Boston, will teach a Core workshop, “Writing About Health and Medicine for Consumer Publications.” She is also leading a table discussion at the klatch, “Crumbs in the Keyboard: Choosing Snack Foods to Keep by the Computer,” as well as a breakfast roundtable on “Literature & Medicine: My Sister’s Keeper by Jody Picoult.”

Jane D. Stephenson, PhD, MBA, a senior scientific writer at Bristol-Myers Squibb Company, Wallingford, Conn., is leading a workshop on “Writing an Investigator Brochure.” She will also be a panelist in the open session on “Scope of Medical Communications.”

Donna D. Walczak, PhD, president of Cayuga Consulting in Providence, R.I., is giving a poster presentation, “Leveraging Outsourcing Efficiency: Virtual Workplace, Web Meeting Systems, Work Practice Guidelines and a Geographically Dispersed Workforce Engaged in Development of Regulatory Submissions.”

Mary Zoll, PhD, freelance scientific and medical editor, Carlisle, Mass., is co-teaching a Core workshop, “Organizing the Biomedical Paper.”

Adriane Bishko contributed to this report. —JL
Personal Notes

David Shenkenberg has accepted a position as an associate news editor at Laurin Publishing, a Pittsfield, Mass., company specializing in worldwide coverage of optics, lasers, imaging, and related fields. He will be primarily working on Biophotonics International, which covers the role of these technologies in biology.

[Ed. Note: David says, “I greatly appreciate all of the advice that everyone in AMWA gave him during his transition into industry.”]

Julie K. Silver, MD, is a coauthor of Life After Stroke: The Guide to Recovering Your Health and Preventing Another Stroke and the author of After Cancer Treatment: Heal Faster, Better, Stronger, both published by Johns Hopkins University Press in recent months. She is medical director of Spaulding Rehabilitation Hospital’s Framingham, Mass., outpatient center. Julie received a Will Solomita Award for an earlier book, Post-Polio Syndrome, published by Yale University Press. This year, she received a Lane Adams Quality of Life Award from the American Cancer Society.

New Members

The New England Chapter cordially welcomes those from our six-state region who have recently joined AMWA, reestablished their affiliation with the association, or moved here from another chapter area:

Ruth Bauman
Cambridge, Massachusetts
Children’s Hospital

Nazleen Bhamal
Boston, Massachusetts

Madge E. Buus-Frank, RNC, MS
Dynamic Neonatal Solutions
Lebanon, New Hampshire

Darryl Choo, MD
West Hartford, Connecticut

Rosann G. Cote, BS
Pfizer Inc.
Grotton, Connecticut

Amy S. Cox, MS
Newtown, Connecticut
Boehringer-Ingelheim

Laura A. Dever-Fornier, MS
Stoughton, Massachusetts

Jeannie M. Fiber, PhD
Mossyfiber Consulting LLC
Jamaica Plain, Massachusetts
[from Northern California Chapter]

Thomas P. Gegeny, MS, ELS
Black Rock, Connecticut
Envision Pharma
[from Southwest Chapter]

Mary E. Gordon
Niantic, Connecticut

Christine M. Greene, PhD
Glastonbury, Connecticut

Cheryl H. Harris, BSN, RN
Auburndale, Massachusetts
Health Imaging & IT Magazine

Marylyn Howe, CAGS, MPA
Marshfield Hills, Massachusetts

Mary C. Howk, BS
Auburn, Massachusetts
Charles River Laboratories

Jesse T. Johnson
Averyon Inc.
Framingham, Massachusetts

John J. Kelly, MD
Winchester, Massachusetts

Lakshmi S. Kesavan, PhD
The Center for Medical Knowledge
Chester, Connecticut

Cynthia Lewis, RN
Kittery Point, Maine

Helen M. Manson, MB, ChB
Sudbury, Massachusetts

Joy L. Mattson, MTS, MLS
Pfizer Inc.

New London, Connecticut

Ellen Ciosek Miller
Madison, Connecticut

Carolyn C. Mitchell, MS, RPh
Pownal, Vermont

Colleen Moffitt, MS
Wakefield, Rhode Island

Linda S. Monko, MA
Faulkner Hospital
Boston, Massachusetts

Saad Nasir, MD
Genzyme Corporation
Cambridge, Massachusetts

Elizabeth Peterson, MFA
Boston, Massachusetts
Custom Learning Designs Inc.

Stephen J. Provost
Prestige Scientific
Milford, Massachusetts

Debra Ruder
Dana-Farber Cancer Institute
Boston, Massachusetts

Katherine M. Schlatter, BA
Cambridge, Massachusetts
[from Hong Kong]

Cecilia R. Schott
Brookline, Massachusetts
Boston Scientific

Marcia L. Shanbaum
Brookline, Massachusetts

Elizabeth P. Shea, PhD
Northeastern University
Boston, Massachusetts

Carolyn Skowronski, PharmD
Quincy, Massachusetts

Kelley P. Smith, PhD
Lancaster, Massachusetts

Kirby N. Smith, MPH
Woburn, Massachusetts
Wyeth
[from Carolinas Chapter]

Timothy E. Somero
New Ipswich, New Hampshire

Jessica Spadola
Northampton, Massachusetts

Shirley J. Tirrell, BS, MPH
Killingworth, Connecticut
Yale University School of Medicine

Beverly Wolfram, MEd
Easthampton, Massachusetts

Alan R. Hagler, MS, MSc, is now a technical writer at Amgen in West Greenwich, R.I. He was formerly a scientist and reporter at Pfizer.

Diane Bell, ScD, is now a senior medical writer at Vertex Pharmaceuticals, Cambridge, Mass. She was previously a medical writer at Critical Therapeutics. Diane served as president of the New England Chapter in 2004-05.

Rita Segal Gelman, MS, is now documentation manager at Microbia, Cambridge, Mass. She was previously document control supervisor at Acambis.

AMWA has selected Peter Morello, a graduate student in the Department of Bio-Med (Bio) at Brown University, Providence, R.I., to receive one of two 2006 Annual Conference Student Scholarships, sponsored this year by Amgen Inc.

CHAPTER CHANGE: Kristy West-Norman, PhD, has moved to Cary, N.C., and is now a member of the Carolinas Chapter.
Directions to September 13 Meeting

Ristorante Marino
2465 Massachusetts Avenue
Cambridge, Mass.
(617) 868-5454

By Car

From Points South
Take Route 128/I-95 North to Exit 29 (Route 2 East to Cambridge/Arlington). Continue on Route 2 and head East on Route 16 (towards Medford) for 1/2 mile until the next traffic light. Turn right at light onto Massachusetts Avenue and proceed about 300 yards. Marino’s is on the left.

From Points North
Take Route I-93 South to Route 60 (Medford) and proceed through Medford Square, bearing left. Take next right onto Route 16 West (Mystic Valley Parkway). Proceed 3 miles and take a left onto Massachusetts Avenue and proceed about 300 yards. Marino’s is on the left.

From Points West
Take the Mass Pike to Route 128/I-95 North. Then following directions from Points South.

Free Parking
- On-street parking is free after 6:00 p.m.
- There is a small parking lot behind the restaurant.
- There is parking underneath Marino’s Center for Health (2500 Massachusetts Ave.), across the street from the restaurant.
- After 6:00 p.m., there is parking at the Valvoline Oil Change station next door to the restaurant.

By Public Transportation

Red Line to Davis Square T-Station
Take street-level exit on left to paved footpath. Follow path through small park, across street, back onto path. Go through gates, across street, through sitting area to Massachusetts Avenue, and turn right. Proceed two blocks on Massachusetts Avenue to Marino’s.

Bus Line
Take the #77 bus from Harvard Square, Porter Square, or Arlington Center. From Harvard and Porter, the bus stops in front of the Restaurant.

Need a ride to the meeting?
If you don’t have a car, contact Judy Linn (508-358-7071 or judyhlinn@aol.com) to find out if anyone from your area is driving to the meeting. Or call Joann Merriman (781-891-0028) to see if she can pick you up at a T station or another, mutually convenient location.

Chapter E-News

The chapter’s e-mail list service allows us to remind you of an upcoming meeting or to let you know when we hear of a job opening, freelance assignment, local event, or anything else that may be of interest to New England AMWA members.

Messages are brief, giving only as much information as is necessary for you to follow up if you want to.

Only the president can post information. If you have something to share, send it to Lonnie Christiansen at editor@kellermedical.com for consideration. (But please do not submit queries. This is not a bulletin board.)