September 4: Dinner in Waltham, Mass.

*Practical Aspects of Regulatory Writing*

The New England Chapter will launch the 2019-20 program year on Wednesday, September 4, with a dinner meeting in Waltham, Mass., featuring a presentation by Debbie von Rechenberg and Dr. Anu Gaur: “Stories from the Frontlines of Regulatory Submissions for Drugs and Medical Devices.”

Pharmaceutical and biotechnology companies must submit product-specific applications to regulatory agencies in the U.S. and worldwide to demonstrate that their treatment candidates are effective and safe. Companies that produce medical devices, diagnostic tests, and the like must also demonstrate effectiveness; but the regulatory requirements are somewhat different. Our speakers will discuss the regulatory pathway for each type of product.

Debbie von Rechenberg will give examples of one part of the drug application package, the clinical study report (CSR), and outline the basics of study and protocol design. She will show how a CSR is organized and how developing an effective CSR involves more than just presenting the reams of data that come from a clinical study. She will also talk about the role of medical writers on study and submission teams and how they contribute to interactions between pharmaceutical companies and regulatory agencies.

Anu Gaur will present a high-level overview of the regulatory pathway and market release process for medical devices. She will explain the compliance regulations, mainly focusing on FDA requirements.

Debbie has been preparing regulatory clinical documents for pharmaceutical and biotechnology companies since 1999, working at large, medium, and small companies including Eli Lilly and Company and the former ARIAD Pharmaceuticals. Before that, she utilized her BS in biology as a microbiologist at Lilly for several years before applying to an internal job posting for a medical writer. These days, she does mostly short-term assignments on a contract basis. An AMWA member since 2000, Debbie was president of the New England Chapter in 2009-10. She is certified as an Editor in the Life Sciences.

Anu is a global regulatory affairs strategist, consultant, and lecturer in the Regulatory Affairs Program at Northeastern. She holds a PhD in chemistry, an Executive MBA, and a master’s in regulatory affairs, and has worked in academia and in the pharmaceutical/biotech and medical device industries in multiple functions, including leadership roles in both pre-market and post-market regulatory affairs in the U.S. and worldwide. Anu is active in the Regulatory Affairs Professional Society and has earned both U.S. and global Regulatory Affairs Certification.

Come early for the social hour to catch up with friends and make new acquaintances at this first meeting of the New England Chapter’s 2019-20 year.

As always, guests and prospective members are welcome.

—Haifa Kassis

President-Elect/Program Director
CHAPTER CALENDAR
The New England Chapter’s year begins on July 1, when a new slate of officers takes over. The chapter’s Board of Directors may convene in person or by teleconference over the summer, but there are no general activities during July and August.

The chapter usually holds six regular meetings from September through June. Four of these meetings are in the Greater Boston area, and two are in Connecticut. Typically, these meetings start with a social hour, followed by dinner (except for a Sunday brunch, most often in the winter), then a program with a speaker, panel presentation, or roundtables.

In addition to the regular meetings, the chapter occasionally schedules other events, ranging from informal networking lunches or evening meetups to workshop programs.

Every fall, at the national AMWA meeting, attendees from New England get together for an informal dinner at a restaurant near the conference site.

September 12
Dinner Meeting
Wallingford, Conn.

The New England Chapter’s customary fall meeting in Connecticut is taking place a little early this year—on Thursday, September 12, at Ola Restaurant in Wallingford. Everyone is welcome! Come network over drinks and have dinner with friendly medical writers and editors. This event features a practical presentation on “DIY Graphics for Medical Writers” by our AMWA colleague Laurie LaRusso, MS, ELS, principal and owner of Chestnut Medical Communications in Walpole, Mass.

As soon as registration opens, members will be notified via the AMWA New England E-News.

November 7
Chapter Networking Dinner
AMWA Annual Conference
San Diego, Calif.

If you’re attending the 2019 AMWA Medical Writing & Communication Conference in San Diego this fall, plan to join your New England colleagues for a private dinner at a restaurant near the conference hotel on Thursday, November 7.

The traditional chapter dinner at the national conference is a popular event that gives New England AMWA members a chance to spend some time together. No other conference events are scheduled for that evening. Watch the AMWA New England E-News for details.

(For complete information about the conference, please go to https://www.amwa.org/page/Conference.)

A Note to Connecticut Members
If you would like to be involved in selecting topics or speakers for future Connecticut dinner meetings, which are held twice a year, or if you have any suggestions about the meetings, please contact Margaret Burke, Vice President for Connecticut, at mburkepharmd@cox.net.

Chapter Seeks
Local Networking Coordinators

The New England Chapter currently has two Local Networking Coordinators (LNCs—pronounced “links”) who plan and coordinate informal events in the Boston area. If you live or work outside of this area and are interested in becoming a chapter LNC, please get in touch with Andrea Gwosdow (andrea@gwosdow.com) or Haifa Kassis (haifa.kassis@crispwriting.com) to learn more.

Email Blasts Keep
Chapter Members Up To Date

Watch for the occasional email from “President@amwa-ne.org” with “AMWA New England E-News” in the subject line.

These emails let you know about an upcoming event, local job opening, freelance opportunity, or other information of possible interest to you. The notices are usually brief, with just enough information for you to follow up if you wish. Be sure to glance at them so you don’t miss something of possible interest to you.

Email continued on page 3.
Email continued from page 2.

The E-News is sent only to New England Chapter members, but others are welcome to submit items for consideration. Meeting announcements should be short, with a link to details. Job postings must conform to the submission guidelines, which can be downloaded as a 1-page PDF from the chapter website (www.amwa-ne.org).

Please note that we do not send these email blasts to local AMWA members who have not included the New England Chapter in their AMWA Member Profile. Chapter membership doesn’t cost anything—it’s a benefit of membership in AMWA. But you do have to sign up for it. If you live here in New England and are not already in our collegial regional network, you can join by updating your Member Profile on the AMWA website (www.amwa.org). It will only take a minute.

May Meeting Report
How to Influence Gender Bias in STEM

At the chapter’s spring dinner meeting in Connecticut in May, our AMWA colleague Agnella Matic, PhD, CMPP, discussed the role of medical writers in influencing gender bias in STEM. Building on a feature article, “Gender Bias in STEM: How Medical Communicators Can Act,” which she coauthored with Priyanka Jadhav for the winter 2018 issue of the AMWA Journal, Agnella described characteristics of implicit biases and their consequences.

She provided statistics on gender bias in science, technology, engineering, and math fields and shared examples of how gender bias may manifest. Attendees did an editing exercise and discussed how to write or edit to minimize gender bias. Agnella also touched on other ways to minimize bias (such as blinded grant or manuscript reviews) and suggested resources for finding a variety of experts so that a writer or editor may develop a balanced piece.

—Margaret Burke
Vice President for Connecticut

June Meeting Report
Self-Assessment, Goal Setting Aid Career Growth

At our June meeting in Arlington, Mass., attendees learned about goal setting and self-assessment from two accomplished science-communications professionals. Our AMWA colleagues Jenny Thayer, principal consultant and head, medical and scientific communications at BioBridges, and Jill Shuman, head, scientific communications at POXEL, shared challenges and turning points in their careers and offered strategies for keeping a career on track.

For both speakers, self-assessment and goal setting have been critical ingredients of their professional growth and success. Self-assessment is objectively reflecting on strengths (in Jenny’s words, identifying what your “magic” is) and weaknesses, with a fact-finding attitude and without self-criticism. Jill creates a list of what makes her happy, what energizes her and, conversely, the sorts of environments and situations that have the opposite effect. She recommends appraising aspects of life outside of work as well.

The outcome of self-assessment is the basis for setting goals, which Jenny described as consciously determining where you want to go, what you want to do, and how you want to be in the world. In Jill’s words, it’s creating a vision for your future, a life map. Both speakers write down their skills, likes, dislikes, and goals and keep a copy in their desks. It doesn’t languish there; it’s a set of guiding principles that are put into practice daily. Jenny frequently reflects on her actions and thoughts and assesses how they fit into her moral and professional values and goals.

Both speakers pointed out the importance of enlisting a mentor, friend, or colleague who is candid and objective and who will not be personally affected by your career choices and decisions. A mentor does not need to be on the same career path or even in the same industry; Jenny noted that her mentor of 30 years is in another industry entirely. As beneficiaries of mentoring, both women have in turn mentored others.

Jill stressed the importance of embracing change and making change while you can, before it is forced on you (for example, through job loss). Taking courses and keeping up with technology allow a broader range of career options. She also suggested going outside your comfort zone and considering major changes, such as leaving for another industry. She also firmly believes that change and finding employment are possible at any age.

On a personal note, the resolve, thoughtful self-confidence, sense of purpose, and sheer energy of both speakers left a lasting impression on this writer. Their career successes epitomize the satisfaction and focus that can be achieved through disciplined self-appraisal and goal setting.

—Jessica Solodar
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. We are also happy to welcome AMWA members from outside of New England who are planning to move here in the near future or have personal or professional ties here.

Diane Boucher, PhD
Vertex Pharmaceuticals
Boston, Massachusetts

Meredith Carpenter, BS, MA
Orono, Maine

Blessing Dube, MPH
Corrona
Waltham, Massachusetts

Altha Edgren, BS
Boston, Massachusetts

Maxine Fidler, ND, MSAOM
Middlebury, Vermont

Ashwini Ghatpande
Biohaven Pharmaceuticals
New Haven, Connecticut

Jennifer Hellwig, MS, RDN, ELS
Reading, Massachusetts
Association of Women’s Health, Obstetric and Neonatal Nurses

Sara Kowalczyk, MA, MPH
Sequirus
Cambridge, Massachusetts

Emily Lightle, BS
CVS Caremark
Windsor, Connecticut

Concetta Marfella, PhD
Vertex Pharmaceuticals
Boston, Massachusetts

Jenn Mariano
West Hartford, Connecticut

Thomas Mitchell, MS
Tech Write Plus
Merrimac, Massachusetts

Elizabeth Olesin, PhD
Millbury, Massachusetts

Emily Pugach, PhD
Boston, Massachusetts

Cheryl Redmond, BA
Guilford, Vermont

Kate Roche, MS
Waitsfield, VT

Aviva Schwartz, MA
North American Thrombosis Forum
Brookline, Massachusetts

Kristin Stephan, PhD
Vertex Pharmaceuticals
Boston, Massachusetts

Rebecca Vautour, PhD
Vertex Pharmaceuticals
Boston, Massachusetts

Nagendra Yadava, PhD
Longmeadow, Massachusetts
University of Massachusetts Amherst

Karen Zott, MS/FNP-BC
Hartford Healthcare
Glastonbury, Connecticut

Linn Awards Offer Free AMWA Membership
If you are a fairly new medical writer, with no more than three years of full-time experience, you may be qualified for a Linn Membership Award.

This competitive award may be granted to as many as three new medical writers at a time. For each recipient, the New England Chapter covers the cost of one year’s professional membership in AMWA and waives registration fees for all regular chapter meetings during the award year.

There is no application fee, and an application may be submitted at any time.

To learn more about this award and how to apply for it, go to www.amwa-ne.org/awards.html.

Personal Notes
Kristen Murfin, PhD, is now a medical writer at Invicro, New Haven, Conn. She was previously a postdoctoral associate at Yale.

Diane Shannon, MD, MPH, an award-winning freelance healthcare writer in Chestnut Hill, Mass., has been certified as a life coach. In line with her long-time interest in clinical burnout, Diane is now offering one-on-one coaching for healthcare professionals and others, and “creating a cohort coaching program that will help equip clinicians to understand, address, and advocate for changes to create healthier workplaces.”

At the AMWA conference in San Diego in November, Shawn Watson, PharmD, PhD, BCPS, will join the association’s Board of Directors as an at-large director for the 2019-20 term. Shawn is associate director, clinical sciences at Vertex Pharmaceuticals, Boston. He was president of the New England Chapter in 2017-18.
How to Register for September 4 Meeting

You can register for this event either online or by mail, depending on how you wish to pay.

- **To pay by credit card**, use the electronic registration form on the chapter website (www.amwa-ne.org). Fill it out and continue to the PayPal form, where you can enter your credit card information. (You don’t need a PayPal account, and you will not be charged a fee for the transaction.)
- **To pay by check**, download the printable registration form from the chapter website (www.amwa-ne.org), print a copy, fill it out, and mail it with your check to the address on the form.

Directions to September 4 Meeting

Copper House Tavern/Best Western Plus

380 Winter Street
Waltham, Massachusetts
781-890-8989

The Copper House Tavern/Best Western Plus complex is east of Route 128/I-95, a short drive from the highway. Heading south on Route 128/I-95, take exit 27A. Heading north, take exit 27A-B.

There is ample free parking.

Need a ride to the meeting?

This location is not accessible by public transportation. If you don’t have a car, ask Judy Linn (judyhlinn@aol.com) whether there is someone from your area who might be able to give you a lift.

You can also use the chapter’s LinkedIn page to ask for a ride (or offer one).

New England Chapter LinkedIn Subgroup

Do you know that you can directly connect with other New England medical writers and editors on LinkedIn? It’s easy to do. Just sign up for the regional chapter subgroup at www.linkedin.com, and once you’re there you can ask questions, share tips, register complaints, or exchange pleasantries...anything with a local focus. Everyone is welcome—prospective members as well as members.