

DELAWRITER

The quarterly newsletter of AMWA-DVC

Indian Summer, 2021

What's Your Niche: Exploring the Medical Writing Habitat

By Tara Rachinsky

Where do your skills and interests fit within the medical writing ecosystem? Are you looking for a new niche to inhabit? At AMWA-DVC's 24th Annual Princeton Forum, held virtually on May 1, 2021, a panel of experienced medical communicators representing six specialized areas shared their insights over lunch.

Chemistry, Manufacturing, and Controls

If you love science and enjoy the challenge of synthesizing vast amounts of complex information from technical documentation into a compelling story with strategic messaging, writing about Chemistry, Manufacturing, and Controls (CMC) may be for you. Tracy Janus, MS (Sr VP, Regulatory Affairs & CMC at Global Regulatory Writing & Consulting) described that CMC writing includes regulatory documents such as clinical trial and license applications, drug master files, responses to agency information requests and clinical holds, as well as technical documents such as manufacturing batch records, deviation investigations, protocols, reports. Janus appreciates that by using her communication skills to help scientists address the expectations of regulators, she can have a direct impact on human health.

Pharmaceutical Labels

Cathleen O'Connell, RPh, PhD (Associate Professor and Director of Biomedical Writing Programs, University of the Sciences) discussed the regulatory specialty devoted to creating labels for prescription medicines. "Labeling" includes all written, printed, and graphic matter on the drug product itself, as well as accompanying material, including inserts, packaging, and websites. These are governed by an array of ever-changing laws and regulations. While prescribing information is written primarily for healthcare providers, it is also public-facing and is available to other audiences; the dangers of poor labeling include risks to public health and the potential for expensive recalls. According to O'Connell, success in this niche requires visualizing the big picture while paying close attention to detail, collaborating with often challenging cross-functional teams, and appreciating the importance of the work.

Clinical Trial Documents

Darryl L'Heureux, PhD, MSc, MS Pharm QARA (Quality Assurance and Regulatory Affairs) described his journey from a bench scientist who realized that he "never wanted to pipette again" to a medical writer who relies on his strengths in communication and engagement to create documents supporting clinical research. This specialty focuses on documents prepared early in drug development that are necessary to conduct and evaluate a clinical trial (eg, investigator brochures, clinical study protocols, informed consent documents, clinical study reports, and disclosure documents). These materials may be created in different environments, such as pharma/biotech companies (from small startups to large multinationals), clinical research organizations, and academic/research institutions. L'Heureux provided the audience with ample resources for exploring this niche, including example documents and templates.

Sales Force Training

While Deborah Anderson, PhD, MSc, MT (DGA Medical Communications) also supports the regulated pharmaceutical industry, she approaches her work from an educational perspective. Anderson develops medical training and/or promotional materials for sales representatives: these deliverables instruct on a particular topic, unmet need, new drug, or new indication. Clients include agencies of record (whose clients are pharma companies), medical communication companies, and managed care companies. The work is deeply rooted in science and developed using principles of instructional design. One benefit to writers is the broad array of deliverables that may be produced, including slide decks, e-learning, case studies, conference panels, podcasts, video scripts, and augmented/virtual reality. Anderson enjoys the variety of creating in these and many other formats to educate on a wide range of topics.

Continuing Medical Education

The professional niche occupied by Don Harting, MA, MS, ELS, CHCP (Harting Communications, LLC) is also focused on developing educational materials—in his case, for clinicians. Harting described his path from journalist to continuing medical education (CME) writer who crafts stories that report on the progress being made in medical science. One advantage of this specialty is its growth trajectory: as commercial support for CME continues to increase, so do opportunities for writers. Deliverables created for CME include needs assessments, video scripts, slide decks, monographs, and outcome reports (which may be published in peer-reviewed journals). Harting provided the audience with an example of an interactive animated patient case study; developing this type of material may enable CME specialists to become “medical screenwriters.”

Patient Narratives

Not all niches are growing, and some are changing with advancing technology. Dan Benau, PhD (Professor of Biomedical Writing, University of the Sciences) described an already narrow niche that may be further contracting as the use of artificial intelligence (AI) expands. All adverse events (AEs) with pharmaceuticals that are marketed or undergoing clinical research, whether drug-related or not, are reported to regulators. Depending on AE severity or clinical interest, a patient narrative may be created. Data provided in these short summaries include demographic information, medical history, concomitant medications, treatment-emergent adverse events, outcome, and the investigator’s opinion on the causal relationship between the AE and drug. Benau showed the audience how the process of assembling tabulated patient information into a text narrative can be automated; this is likely to enable AI to perform this role in the future.

Tara Rachinsky, PhD, is a freelance medical writer and the owner of Valence Biomedical Communications LLC in Philadelphia, PA. She specializes in scientific publications and CME.

No Light Under a Bushel Here

Volunteer Corner: Showcasing members who contribute time, energy, and expertise to AMWA’s Delaware Valley Chapter

by Jacqueline M. Mahon

You can always count on Katherine L. Molnar-Kimber, PhD, for an informative and helpful presentation at local AMWA workshops or the national AMWA conference. Despite a packed schedule, our past president of the AMWA-DVC chapter finds the time to teach and share her expertise. Moreover, Kathy is a longstanding AMWA organizational volunteer and leader. This generous nature has extended to a number of other areas as well, including 30 years of community service to her church as a trustee and participation in the Ladies Auxiliary of the Worcester (PA) Volunteer Fire Department, which raises funds and supports the volunteers during long stints working fires. “The thing about volunteering,” says Kathy, “is you get to know people in a different, broader light.”

Professionally, Kathy collected awards and honors over 20+ years as a scientist, including for principal investigator and writer roles, and then started her own freelance medical writing business: KMK Consulting Services, which now operates under her company Kimnar Group, LLC.

Perhaps Kathy’s “can-do” spirit first bloomed during her 12 years as a Girl Scout. Later, when her daughter, Olivia, was unable to join the area troop because it was full, Kathy followed in the footsteps of her own mother and started a new Girl Scout troop for Olivia and friends. Kathy and co-leaders took 9 children camping once a year. They also enjoyed visiting several nature centers and the Elmwood Zoo among a variety of other activities (eg. cooking day, Broadway). Two Girl Scouts earned the Gold Award.

In the same intrepid vein, Kathy took off for parts unknown after college to polish her foreign-language skills (French and German) and see the world via a program that provided orientation and a job in Europe. As she spread her wings beyond her initial landing, cooking, waitressing, and bartending provided necessary funds. Kathy reminisces, “It was in Europe that I decided to definitely study immunology. In need of mental stimulation, I visited the University of Bern [Switzerland] Medical School Library and devoured many articles over a month. And that was it: host-pathogen interactions became my passion.”

A solid background in medical communications is ideal for the entrepreneur in this field, and Kathy’s is extensive. In addition to achieving AMWA’s Medical Writers “Essential Skills” and “Regulatory and Research”

Certificates, Kathy devoted approximately 20 years to molecular and cellular immunology laboratory work and animal studies, often teaching and presenting on related topics. In particular, she delivered an annual lecture on transplantation and immunomodulation at the University of Pennsylvania. Kathy notes, "My laboratory at Wyeth was researching rapamycin, a transplantation drug now approved for prophylaxis of organ rejection in patients with kidney transplants, so it was a topic near and dear to me." Kathy also maintains a number of memberships in professional and scientific societies, such as the American Association for Cancer Research, American Society for Gene and Cell Therapy, AMWA, International Society for Medical Publication Professionals, and the Mid-Atlantic Alliance for CME. She has coauthored more than 53 scientific publications and posters and given 25 presentations on medical writing.

Kathy maintains a very low profile, and many AMWA members may not be familiar with her rich and interesting life path. Here are a few additional highlights:

- Editor of the AMWA *Delawriter* Newsletter (previously assistant editor), 6 years
- Co-chair of the AMWA-DVC Princeton [NJ] Workshop, 1 year
- Ad hoc reviewer for up to 12 scientific journals, 37 years
- 9 patents issued in immunologic research
- Recipient of the AMWA-DVC President's Award for commitment and volunteerism 2018 and 2019

Kathy has often participated in the Drexel University orientation program for international students (eg, Fulbright scholars), which offers a dinner with an American family during their session. Kathy, her husband of 42 years, and daughter have welcomed students from Russia, Paraguay, Afghanistan, Korea, Tajikistan, Indonesia, Brazil, and Chile to their dinner table — often 2 to 3 at a time. These events become quite an international gathering and feast when Olivia invites her friends, too.

Of course, such events were on hold during the height of the coronavirus disease (COVID)-19 pandemic. How did Kathy cope during that difficult time? "I relied on several strategies," she says, "including strolling our property to enjoy the outdoors while complying with stay-at-home orders; reading and writing; taking online classes; remaining open-minded to various perspectives (because, for example, it took about 40 years for physicians to accept that washing their hands between doing autopsies and delivering babies saved lives); staying in touch with friends and family; and being grateful — for our health, our freedoms, and the checks and balances here in the USA." Among post-pandemic developments, Kathy remarks on the expansion of technologic skills around virtual meetings, which allow a broader geographic pool of speakers and participants.

So, there you have it! Another fascinating AMWA member and volunteer to meet and greet at our next event. As always, thank you for reading and being involved.

Jacque Mahon, MA, is owner of Acorn Freelance in Philadelphia and has been a writer of medical education and pharmaceutical communications for 26 years.

AMWA-DVC Annual Business and Summer Social Meeting on June 28, 2021

By Katherine Molnar-Kimber

The Annual AMWA-DVC business and Summer Social meeting held virtually June 28, 2021, highlighted our triumphs amid the continued social distancing restrictions and provided networking opportunities in the three roundtables on gardening, writing, and travel. The AMWA-DVC President profusely thanked the 2020-2021 volunteers who help run the chapter and its many events.

Position	Volunteer
President-elect	Danny Benau, PhD
Past President	Mark Bowlby, PhD
Secretary	Deborah Anderson, PhD
Treasurer	Robert Hand, MS
AMWA National Chapter Advisory Council Delegate	Mark Bowlby, PhD
Freelance Workshop Co-Chairs	Helen Fosam, PhD & Jen Minarcik, MS
Princeton Forum Co-chairs	Darryl L'Heureux, PhD & Dan Benau, PhD
Program Chair	Don Harting, MS, ELS, CMCP
Communications Chair	Darryl L'Heureux, PhD
Website Chair	Monica Nicosia, PhD
Membership Chair	Nicole Walz, BA
LinkedIn Group Moderator	Jen Minarcik, MS

As editor, Molnar-Kimber also thanked the consultant editors and the volunteer writers for enriching the *Delawriter*.

Position	Volunteer
Newsletter Consultant Editors	Danielle Ippolito Elisha Gillette Robert Hand Viola Brown Priya Chandrashekhar
Volunteer Corner Writer	Jacque Mahon
Contributing Writers	Viola Brown Stephen Drehobl Anne Erlich Linda Felcone Emily Kovach Victoria Ramirez

Recap of AMWA-DVC programs of 2020-2021

Despite the various stages of social distancing restriction due to COVID-19, AMWA-DVC thrived by using Zoom and GoToMeeting for three evening networking meetings, the Freelance Workshop and the Princeton Forum. These virtual formats allowed medical writers from other AMWA chapters and nonmembers to easily participate in the meetings. We had participants from Australia and Africa. Special thanks to Don Harting and Dan Benau for sharing their expertise on the Zoom and GoToMeeting platforms, respectively.

The **AMWA-DVC August 18th** meeting provided updates on the annual meetings of the International Society of Medical Publication Professionals (ISMPP), Drug Information Association (DIA), and the Alliance for Continuing Education of Healthcare Professionals (ACEHP). Discussions about writing publications, regulatory documents, and continuing medical education (CME) continued in the breakout rooms.

AMWA-DVC Freelance Workshop on March 13 provided 64 freelancers with a Keynote session on 5 Habits of Freelancers and access to their choices of 5 roundtables. The **Princeton Forum** on Saturday May 1 provided 70 medical writers with in-depth information on 4 topics and 6 medical writing niches.

President's Award: Molnar-Kimber presented the AMWA-DVC President's Award to Helen Fosam for her numerous contributions to the AMWA-DVC in this challenging year. Fosam, an AMWA-DVC member, went way above and beyond her volunteer title. Very organized and always ready to help, she did most of the heavy lifting during the organization and preparation for the 2020 Freelance Workshop. We discussed the accelerating rate of infection of COVID-19. Two days before the scheduled meeting, Gov. Wolf canceled all meetings and conferences in PA. Fosam took everything in stride and immediately sent notices to all registrants. During the summer of 2020, she also learned about co-hosting Zoom meetings from our program chair and helped with several of the social networking meetings. In 2021, she not only co-chaired a virtual 2021 Freelance Workshop but also hosted the Freelance Workshop on the Zoom Platform.

AMWA-DVC Elections: AMWA-DVC overwhelmingly elected Helen Fosam as President-Elect and Mark Bowlby as Treasurer. AMWA-DVC inducted Dan Benau as the incoming President of AMWA-DVC, Helen Fosam as the President-Elect, and Mark Bowlby as the Treasurer. Their terms began on July 1, 2021.

Medical writers and editors help save lives.

Throughout this year, I have had the privilege of virtually meeting many medical writers and editors. I am giving a huge thank you to all medical writers and editors on behalf of patients here at home and abroad. For example, a family member learned from a routine checkup that his symptoms were not old age but rather leukemia in a blast stage with a 2- to 6-week prognosis. Because of scientists, clinicians, biotech firms, pharmaceutical companies, and medical writers and editors like you, he learned of and received multiple targeted therapies that significantly reduced the disease. His team of physicians with the targeted therapies helped him to beat the odds, and he was sailing in the British Virgin Islands at 8 months. Thus, our work really does make a huge difference in people's lives.

In conclusion, I was grateful for the opportunity to lead AMWA-DVC chapter and for the great team. As the outgoing President of AMWA-DVC, I thank all the volunteers who have contributed to make our chapter meetings a success this year despite of the COVID-19 restrictions. Our AMWA-DVC provides a platform to broaden our skill sets, share our collective knowledge, absorb insights from colleagues, and become more efficient so we can maintain a work-life balance. Volunteering can help open doors in your medical writing business, and writers of articles for the *Delawriter* also get a byline. Consider sharing your expertise with your AMWA-DVC community this year. To inquire about volunteer opportunities, send an email to volunteer@AMWA-DVC.org.

Katherine Molnar-Kimber, PhD, is the owner of KMK Consulting Services of Kimnar Group LLC in Worcester, PA and writes predominantly scientific publications, Continuing Medical Education Needs Assessments and programs, and white papers.



The virtual AMWA Medical Writing & Communication Conference provides numerous sessions and roundtables for updating and sharpening your skills while meeting other medical writers. Registration is [open](#).

AMWA-DVC members who are presenting at 2021 Conference include:

Education Session Presenters	Title	Date and time
Monica Nicosia	How to Master Scientific Publications: A Medical Writer's Bag of Tricks	October 28, 10:00 AM – 11:00 AM
Lori De Milto with Mia DeFino and Kristin Harper	Launching and Building a Freelance Business: A Proven 10-Step Process	October 28, 3:15 PM – 4:15 PM
Julie A. Munden with Gail Flores and Lauren Mays Weddle	Sales Training and Beyond: Developing Educational Content Across the Pharma/Biotech Landscape	October 29, 10:00 AM – 11:00 AM
Workshop Leaders		
Art Gertel	Serving Two Masters: Comparing and Contrasting US and EU Regulatory Processes	October 25, 1:00 PM – 4:00 PM
Roundtable Facilitators		
Steve Sibley	What Do Great Medical Writers Do, and How Do You Become One?	October 27, 1:00 PM – 2:30 PM October 29, 2:30 PM – 4:00 PM
Mandy Pennington	Work-Life Balance Flexibility When Working Remotely	October 27, 4:00 PM – 5:30 PM October 28, 4:00 PM – 5:30 PM
Mark Bowlby	Lean Authoring with a Technology-Enabled Twist – Can One Enable the Other to Free the Medical Writer to Craft the Story?	October 27, 1:00 PM – 2:30 PM Oct 29, 2:30 PM – 4:00 PM
Katherine L. Molnar-Kimber	Tips for Efficiently Writing Introduction and Discussion of Scientific Manuscripts	October 28, 11:15 AM – 12:45 PM
	Insights on How Medical Communication Companies Choose Their Freelance or Contract Medical Writers and Editors	October 29, 11:15 AM – 12:45 PM
Art Gertel	Having Your Cake and Eating it Too: Speed AND Quality in Scientific and Medical Publications	October 28, 1:30 – 3:00 PM October 29, 11:15 AM – 12:45 PM

Volunteering with AMWA-DVC helps increase your networking circle and provides an opportunity to hone your organizational and leadership skills. Many AMWA-DVC members credit their volunteering with increased opportunities in their medical writing niches. AMWA-DVC is recruiting volunteers to help run the annual Freelance workshop on Mar 12th, writers for articles in the Delawriter (with a byline), and other opportunities. We welcome all volunteers: please send us an [email](#) with your interests.

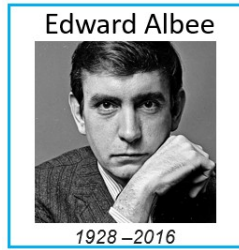
CME Palooza on Oct 13, 2021



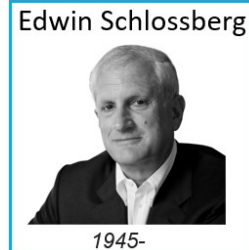
CME Palooza is a 1-day event that features live virtual sessions on a spectrum of CME topics, and participants can often ask questions.

More information is available on their website at <https://cmepalooza.com/fall-2021/>

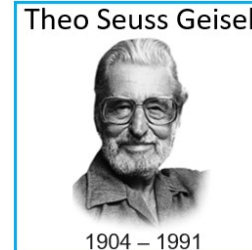
Quotable quotes from notable folks



"The act of writing is an act of optimism. You would not take the trouble to do it if you felt it didn't matter." —Edward Albee



"The skill of writing is to create a context in which other people can think." — Edwin Schlossberg



"So the writer who breeds more words than he needs, is making a chore for the reader who reads." —Dr. Seuss

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