DELAWRITER

The quarterly newsletter of AMWA-DVC

Spring, 2023

Mid-Winter Networking and Warm-Up, January 25, 2023

by Sarah Staskiewicz

AMWA-DVC members and guests gathered on a cold and rainy January night at the Triumph Brewing Company in New Hope, PA for a Mid-Winter Warm-Up and Networking Dinner. While this was not the first in-person meeting since the COVID-19 pandemic began to wind down, members still expressed enthusiasm for the chance to gather together, share stories, make new friends, and exchange advice. The importance of face-to-face connection and interaction was evident!

The evening included great microbrews and a delicious dinner. President-Elect Debbie Anderson spoke to the group about upcoming chapter events and ways for members to get involved. Other chapter board members shared AMWA-DVC news. In an unusual twist, everyone received a chance to win one of nine items: a Longwood Gardens giftcard, a free pass to attend the 21st annual AMWA-DVC Freelance Workshop (occurred March 11), or a free pass to attend the 26th annual AMWA-DVC Princeton Forum (happening May 20, 2023).

The listing of upcoming events, member involvement, and constant hum of conversation throughout the night were on par for the robust AMWA-DVC chapter, one of the largest AMWA chapters with 350 members.

AMWA-DVC Members arriving for the January Mid-Winter Warm-up event.

Sarah Staskiewicz, RDN, is the Founder of Cultivate: Nutrition Content + Strategy, a boutique agency specializing in nutrition science strategy and content development. Sarah is a writer, editor, and creator of nutrition-focused B2B communications, manuscripts, CME programs, and material for professional audiences.

Volunteer Corner

Showcasing members who contribute time, energy, and expertise to AMWA's Delaware Valley Chapter

by Jacqueline M. Mahon

Regulatory Ninja: Mark Bowlby

"You can do lots of things in the lab that aren't translatable to the

clinic. It's important to ask clinicians, 'Can you envision incorporating this into the management of your patients?' If not, then researchers must keep looking." So began Mark Bowlby's description of his transition from principal research scientist at Wyeth (Princeton, NJ) to director of pharmacology at Merck (West Point, PA). There was the added impetus of Pfizer's 2009 purchase of Wyeth - one never knows how wide and disruptive the ripples from such change may be - and Mark began looking at his options. At the time, Merck was one of the few pharmaceutical companies using biomarkers to check for target engagement. This was exciting work. When there were no biomarkers, Merck scientists were determined to find some parameter that indicated the compound was hitting its target, even if indirectly. While at Merck, Mark often strolled across the street to collaborate face-to-face with his clinical colleagues. He enjoyed the translation from lab to clinic; therefore, it was a natural segue to authoring strategic biomarker plans and interpreting scientific results for clinical audiences at Merck.

It was around this time, 12 to 15 years ago, that Mark became involved with AMWA. "I was thinking about writing more, as *the* job and not just part of the job."

For a moment, though, let us travel back to State University of New York (Stony Brook) when Mark was a young fellow completing a Bachelor's in biology. Was he planning some type of career in medicine? "No," he laughs, "My favorite classes were ornithology and marine organisms." He continued with biological sciences at the University of California, Santa Barbara, where he obtained his PhD. "I began learning about nerve control of various behaviors in marine animals, and that interest led to a neurobiology course that eventually drew me to medicine." Mark has no regrets about the path not taken. Job prospects are poor in oceanography and marine science because there are few locations doing the work and it is funded by grant money.

Plus, he got to examine the modulation and biophysics of glutamate receptor function by neurosteroid hormones as a postdoctoral fellow at Harvard Medical School (Boston, MA). The competition for this appointment was fierce, but Mark was uniquely suited for it: "That particular lab worked on marine animals, mostly lobsters, and some mammalian systems as models."

Continuing toward the present, we see Mark authoring regulatory documents, manuscripts for publication in peer-reviewed journals, and posters/slides for congress presentations as a principal medical writer at Allergan (Bridgewater, NJ) and subsequently at Synchrogenix Information Strategies, Inc (Malvern, PA). Now at Synchrogenix for 8 years, he is also director of global submissions. Mark is a subject-matter expert in neuroscience and frequently mentors junior writers. He notes, "It's incredibly rewarding leading teams for regulatory submissions, particularly investigational new drug or marketing applications. Moving a compound from the lab into clinical phases is a momentous step. Also, we're part of the gargantuan effort to get helpful drugs to people who need them."

I wonder about the public face often required in Mark's current position - does he enjoy public speaking? Many writers tend to shy away from the orator role, preferring to work behind the scenes. "A mix of both is ideal," Mark says. "Oral presentations help your career and keep you engaged with others. But they can be stressful. I think 'relative comfort' is the goal for most people, and I've achieved that. But public speaking will never be my favorite activity."

For the aspiring regulatory writer, facility with teamwork is necessary if you plan to work at a pharmaceutical company. Teams comprise numerous personalities, and as the writer often interacts closely with them all, nimble communications that conform to different styles can smooth processes.

Another challenge is the increasing speed at which regulatory projects advance, and the associated stress. Mark relates that sometimes clients ask, "Can't you just write it with the preliminary data?" Anything can be written, of course, but preliminary data must be identified as such, and reader-stakeholders are vastly more interested in final data. One wonders: Why present incomplete findings of uncertain meaning, when more solid data and conclusions are forthcoming? The regulatory lexicon does not include the word 'patience.'

I ask Mark about some of the fast FDA approvals, given recent yank-backs. He remarks: "There have been many more submissions based on interim data from pivotal studies. I do wish the FDA would allow less of that. Perhaps other factors play a role in these decisions, beyond the science."

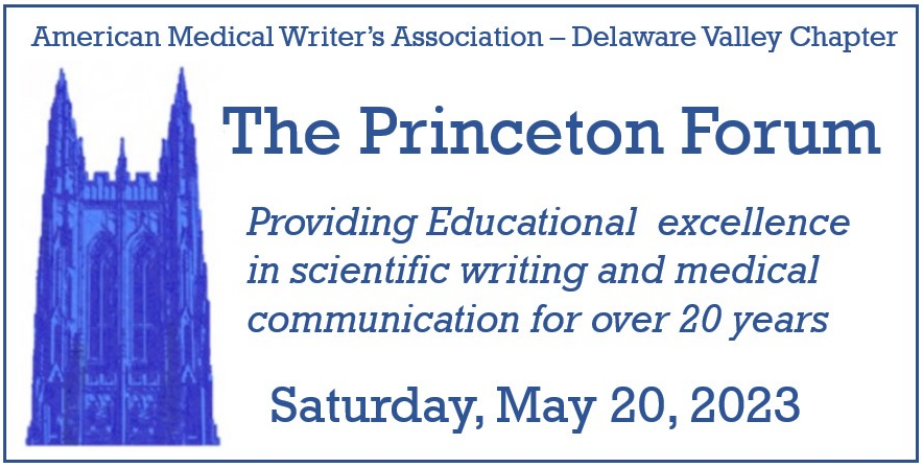
Pharmaceutical regulation is a deeply important and serious industry. But what does Mark do for fun? "My father enjoyed photography, and I learned from him how to navigate a darkroom. I like taking pictures, and especially was involved with this hobby when my kids were in school marching bands. I shared the pictures with the schools and other parents." These days Mark can be found fishing lakeside, practicing catch and release. His two boys are grown: one a sophomore in college, the other working in medical treatment for addiction. Mark's wife is in a completely different field; she has an

MBA and works in finance.

AMWA is fun, too! Mark relates that he went to the national conference first, and then became involved with the DVC chapter. “You meet great people and learn a lot.” He has held numerous volunteer roles over the years, including co-chair of communication, treasurer, and president. We are fortunate that he is our treasurer again this year. Mark is also involved with the Regulatory Affairs Professionals Society (RAPS), the largest global organization for those involved with the regulation of healthcare and related products, including medical devices.

Does Mark have any parting words for Delawriter readers? “Yes! Get involved. It’s counterintuitive, but even when you think you just don’t have the time, participating in AMWA-DVC planning and activities expands your career options, your circle of trusted colleagues, and your enjoyment of life in general.”

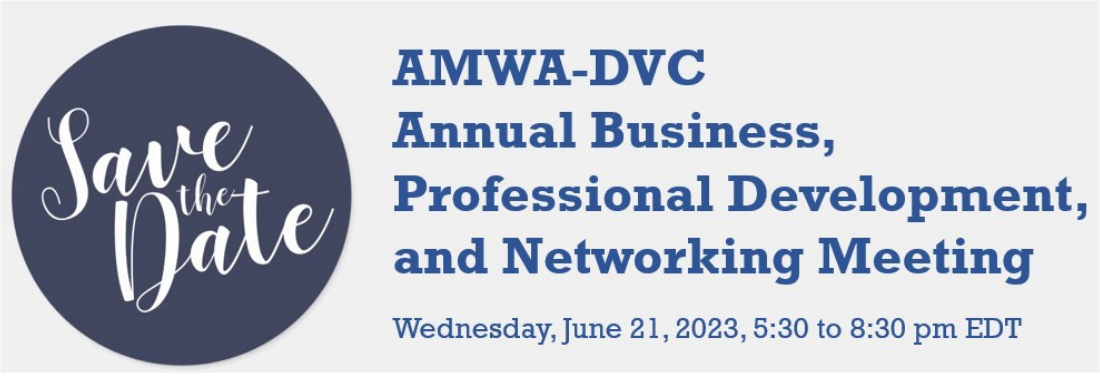
Jacquie Mahon, MA, is owner of Acorn Freelance in Philadelphia and has been a writer of medical-education and pharmaceutical communications for 26 years.



The 26th Annual Princeton Forum will be held on Saturday, May 20, 2023. Educational sessions in this virtual event will include:

- Shining Light on Data Annotations and Data Accuracy Reviews - Jennie G. Jacobson
- Getting to Know CMC and Why We Have More Fun - Tracy Janus
- Five Quick Ways to Create an Aggregate Report: Development Safety Update Report - Xaymara (Mara) Román Vélez
- An Overview of EU Clinical Trial Regulation No 536/2014 - Whitney Graves
- Current Trends in Artificial Intelligence (AI) And Machine Learning (ML) Technology in Medical Writing and Expectations for the Future - Jamie Hijmans

Registration will open soon.



Delawriter Editorial Team

The *Delawriter* is published quarterly by the American Medical Writers Association-Delaware Valley Chapter
Executive Editor: Helen Fosam, PhD
Managing Editor: Jacqueline M. Mahon, MA

Designer: Darryl Z. L'Heureux, PhD, MSc, MS Pharm QARA
Editorial Consultants: Elisha Gillette and Robert Hand, MSc

Please direct change of address/information to AMWA Headquarters Staff:
American Medical Writers Association
30 West Gude Drive, Suite 525
Rockville, MD 20850-1161
(240) 238-0940 (telephone)
(301) 294-9006 (fax)
email: amwa@amwa.org

Visit our AMWA-DVC website