

# DELAWRITER

The quarterly newsletter of AMWA-DVC

Delawriter Editors

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## Complexity of Pharmaceutical Regulations Gives Rise to Expansive Writing Niche

By Dan Linehan

Even as a subgenre of medical writing, regulatory writing is a universe unto itself and contains multitudes of writing opportunities, many of which are fertile ground for freelancers.

Darryl L'Heureux, PhD, MSc, MSPharma QARA, led the attendees of AMWA-DVC's 16th Annual Freelance Workshop through a regulatory writer's view of how a molecule (or a medical device) is transformed into an FDA-approved drug.

The workshop, held March 17 at the DoubleTree Hilton Hotel in King of Prussia, PA, provided educational and networking opportunities to new and veteran medical writers. L'Heureux, a senior scientific writer at Bristol-Myers Squibb, gave the last of three morning presentations, titled "Regulatory Documentation: Following Logic Thread from Concept to Submission."

As they make the long journey from promising molecule to FDA-approved drug, prospective pharmaceuticals generate a need for dozens of documents and hundreds of pages. These documents have many goals, including the following goals:

- Showing compliance with regulations around ethics and procedure
- Tracking and evaluating the ethical and procedural conduct of a trial and the quality of the data it produces

L'Heureux said these documents can be seen as pieces in a puzzle; they are individually distinct but link together to create a larger picture. For example, the Investigational New Drug Application, a requirement to proceed into clinical trials, contains information in three broad areas:

- Animal and toxicology studies, to show whether the product is safe for humans.
- Manufacturing information, which relates to the manufacturer, stability, and controls for making the drug.
- Clinical protocols, which assess whether the initial trials will expose subjects to unnecessary risks.

Answering these questions requires plenty of writing and plenty of deliverable documents for medical writers.

Clinical trials themselves, generally split into three or four phases, require still more documents.

The level of technical and scientific detail in these documents, which tend to be written using templates, varies along with the intended audience. Documents written for patients call for plain language, but documents for study leads can use more technical detail.

### How to enter the field

How can medical writers learn about and potentially find clients in the subgenre of regulatory writing?

Inexperienced regulatory writers may have difficulty finding work directly from a pharmaceutical company, but they may find opportunities in contract research organizations, or CROs. These CROs, which are routinely hired by pharmaceutical companies to complete various regulatory writing documents, can be excellent "training grounds" for less experienced regulatory writers, L'Heureux said.

Often, these organizations are eager to find talent; at one dinner meeting L'Heureux attended, 3 of 15 participants were hired. One common way to get into the field, then, is to make an inquiry with a CRO, several of which operate in the Delaware Valley.

Some documents are contracted to CROs more often than others. These include the following:

- Patient safety narratives: Summaries of specific events experienced by patients during a clinical trial
- Investigator Brochure: Provides detailed background on the product being tested, including its benefits and risks
- Clinical study reports: Answer questions central to the trial, including a report of how effective and safe the drug was

For all their painstaking detail, regulatory documents also offer plenty of ways for a writer to excel. These documents require the use of logic trails to create clear, concise, and consistent rationales, explanations, and conclusions.

Dan Linehan is a freelance medical writer who lives in Delaware City, DE.

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### QUICK NOTES

#### Join the DELAWRITER

The DELAWRITER needs contributing authors for the quarterly publication. *Have an idea for an article? Haven't used that byline recently? If so, please contact the [editorial team](#).*

#### Quarterly Quotes

*"If opportunity doesn't knock, build a door."* Milton Berle

*"Action is the foundational key to all success."* Pablo Picasso

#### AMWA-DVC Dinner Meeting/Presentation

**Save the Date**  
AMWA-DVC's Annual Business Meeting and Dinner Presentation to be held on Thursday June 18, 2018 at Sandy Run Country Club, Oreland PA.

Nina Drinnan, MSN, CRNP will present *"Understanding the Impact of the Heroin Epidemic"*

#### Princeton Forum Saturday 4--21-2018

**Register today** for a full day of education and networking.

By Shannon Hach

In her presentation at the AMWA-DVC 16th Annual Freelance Workshop, Katherine Molnar-Kimber, PhD, shared 36 tips to help boost productivity. Molnar-Kimber is president of Kimnar Group LLC in Worcester, PA. She is an active AMWA member and is an editor with the Delawriter. To demonstrate ways to engage the productivity mindset, Molnar-Kimber collected tips from several sources and consolidated them into 7 categories. Here are a few highlights:

## Preparation:

- Target marketing to clients who need your expertise, cultivate resources through professional organizations in your specific areas of interest, and obtain guidelines for specific types of writing.
- Create shells of your freelance business documents and make or obtain templates for deliverables, which will greatly reduce repetitive work.
- Reduce distractions by turning off e-mail notifications and batching miscellaneous tasks like checking e-mail and texts. One study showed a 20% increase in productivity by keeping your smartphone in a different room!

## Writing process:

- Molnar-Kimber shared a story about Ivy Lee, who was hired by steel tycoon Charles Schwab to improve productivity. After 3 months of using Lee's 3-step method, Schwab paid him \$25,000 in 1918-worth \$449,861 in 2018! Lee's method is as follows: (1) list all projects, estimate completion dates, and break into parts; (2) determine and set priorities for tomorrow and this week and prioritize the top six items; (3) do priority #1 until done or requiring more resources, then work on priority #2. To maintain focus on priority #1, determine the ideal blocks of time your brain can focus on that type of task (as it differs for all of us). Take 5- to 10-minute breaks to stretch, walk, get water, and complete easier tasks.
- Learn keyboard shortcuts, which are much faster than mouse clicks.
- Use checklists from evaluators during your writing process to ensure that you're addressing all your client's expectations.

## Time-saving software:

- Molnar-Kimber noted one survey that estimated that 40% of medical writers do not use reference management software. These programs allow you to quickly obtain full citations and format them into specific styles. She mentioned several vendors such as EndNote and Mendeley, as well as Zotero, which is free.
- Attendees offered their positive opinions about software that can be used to polish grammar and identify plagiarism. Examples include Grammarly and PerfectIt 3.

## Computer hardware:

- Many in the audience, along with Molnar-Kimber, commented on the great boost in productivity they have experienced by using two or even three monitors.
- The importance of having both local and online backup (if approved by your clients) was emphasized. This can save hundreds of hours and thousands of dollars in the event of damage to your computer-think floods and fires-they happen!

## Supportive office:

- A lively discussion surrounded Molnar-Kimber's suggestion to create a healthy atmosphere with natural light and "NASA-approved" plants that remove volatile compounds from the air.
- Another creative idea was to invest in a crockpot, fill it with water, and run during the dry winter months, creating a warmer and more comfortable office.

## Wellness:

- For your vision, glance out a window often, ie, 10 to 20 seconds every 20 minutes (look 20 feet away); maintain adequate nutrition for vision health.
- Take breaks and move around; keep feet limber using a wobble board.
- When your brain tires of analytical tasks, switch to a more creative task such as designing figures.
- "Work it out overnight." If you get mentally stuck, sleep on it!

## Freelance mindset:

- "It's not the amount of time you spend in the office that counts; it's what you've accomplished that matters."
- Invest in your business and yourself wisely. When considering a class or software program, decide if it will improve your efficiency or product, if it will save time, and whether you expect a quick return on investment.
- Cultivate repeat clients; clearly define goals, audience, and format. Create excellent deliverables and provide value to keep the clients coming back!

To assess attendees' work habits and implement these tips, Molnar-Kimber encouraged the audience to apply Lee's principles. Pick six tips that may help improve your productivity. Prioritize the tips by their potential to benefit you most and your ability to easily maintain them for 1 month. Do the first priority consistently for 1 month. Evaluate, adjust, and enjoy an improved bottom line!

Shannon Hach, MD is a freelance medical editor and fact checker and owner of STAT editing LLC, near Pittsburgh, PA

## VOLUNTEER CORNER

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

## A Warm Attachment to Our AMWA Chapter

By Jacqueline M. Mahon

Here is an AMWA-Delaware Valley Chapter (DVC) member who continues to manage the AMWA-DVC website despite having relocated to Bel Air, MD 6 years ago. "The DVC is a great group," said Janet Manfre, Senior Medical Writer at Medscape, "so I still want to be involved with them." Manfre did not hesitate once the idea to volunteer arose but dove in to contribute her skills and time. Volunteering is an easy way to get to know people. When actively helping, for example at a dinner meeting, concerns about being in a group of unfamiliar faces fall away. "It's good for introverts!" laughed Manfre.

An AMWA-DVC member since 2005, Manfre reinvented herself after a 14-year career as a registered dietician (RD). During her initial foray away from the RD world, she worked for several medical communications companies as a project manager, doing mostly continuing medical education (CME) programs. However, because of volatility in the medical education field at that time, Manfre eventually arrived at the momentous decision to start her own business as a freelance.

Her volunteering with AMWA-DVC began after she attended the annual Freelance Workshop, which offered practical tips for her business and also inspired closer involvement with chapter event planning. She then joined the Programs Committee. After helping in that capacity for a while, Manfre became Chair of the Programs Committee and coordinated AMWA-DVC events for 2 years. When that position concluded in 2010, she became AMWA-DVC Website Chair, a position she holds today.

Having freelanced for about 3 years, including for Medscape, Manfre received an enticing offer to write grant proposals for CME that brought her to her current full-time position with Medscape. Amid all of these accomplishments, she continues cooking, gardening, reading, and learning to play golf. For whole-body health, she took up running a few years ago and completes several 5K races each year.

"No one ever regrets volunteering for AMWA-DVC," Manfre remarked. Other members are willing to share their experience and knowledge to help you. Pick a position that suits: it can be totally behind the scenes or more interpersonal. Be willing to explore the many opportunities to support AMWA-DVC as a happy, thriving group. Hope to see you soon at an AMWA event.

Jacquie Mahon, MA, is owner of Acorn Freelance in Philadelphia and has been a medical writer and editor of journal publications, medical textbooks, and hospital and pharmaceutical communications for 22 years.

## UPCOMING EVENTS

*Upcoming educational and networking events for our members*

### 2018 Princeton Forum on April 21, 2018

The **22nd Annual Princeton Conference** will be held on Saturday, April 21, 2018, at the **Princeton Marriott at Forrestal**. This year's conference offers novel programming in an all-open-session format that includes sessions in "Medical Writing Essentials" and sessions in "Hot Topics in Medical Writing" in medical communications and scientific writing. These dual tracks allow participants to pick and choose relevant sessions for their individual needs.

## MEDICAL WRITING ESSENTIALS

### **Presenting Numeric Evidence Part 1 (of 2)**

*Jane E. Miller, Professor, Rutgers - The State University of New Jersey*

This two-part workshop will introduce ways to bridge the gap between correct statistical analysis and good expository writing to communicate quantitative research results clearly to patients, medical providers, or other non-scientific audiences. The first half of the workshop will cover how to present numbers as evidence, criteria to include when reporting one number, and principles for how to convey comparisons between two numbers or series of numbers. The second half of the workshop will build on those principles by covering pros and cons of the different types of tools for presenting numbers, how to organize data in tables and charts, and the importance of differentiating between statistical and substantive significance. To tie together all of these principles, we will learn a systematic approach to summarizing a complex numeric pattern. Each part of the workshop will include time for participants to apply the newly learned principles to hands-on exercises, and discussion of answers to those exercises.

### **Presenting Numeric Evidence Part 2 (of 2)**

*Jane E. Miller, Professor, Rutgers - The State University of New Jersey*

These two sessions are intended to be taken in series.

### **Medical Writers are Project Managers**

*Eileen M. Girtten, Principal Medical Writer, PRA Health Sciences*

Medical writing isn't just limited to writing. It involves managing workloads, timelines, and teams—that is, project management. Although project management may be associated with other fields, such as engineering and construction, it has also been used in the pharmaceutical industry. This session will explore how medical writers can apply principles of project management in their work and discuss some best practices.

### **Soft Skills: The Critical Accompaniment to Technical Skills**

*Kelleen Flaherty, Freelance Medical Writer, Adjunct Assistant Professor of Biomedical Writing*

Obviously, medical writers have the technical skills they need to create excellent deliverables. However, to be a successful employee (including remote and freelance work), writers (everyone, actually) also need to have a firm command of soft skills (AKA "transferable skills"). Soft skills encompass abilities not related directly to your writing skill and include things like interpersonal relationships, ethics, time management, teamwork, enthusiasm, problem-solving, negotiation, etiquette, attitude, self-confidence, and other attributes. In this presentation we'll discuss what soft skills actually are, as well as explore several individual soft skills and how they're characterized. Everyone is better at some than others. This presentation will give you something to think about!

## HOT TOPICS IN MEDICAL WRITING

### **Good Publication Practice and Authorship**

*Jennie G. Jacobson, PhD, Lead Medical Writer at Fishawack Communications*

Confusion and disputes about authorship may be as old as writing itself. Mistakes, uncertainty, and just plain unethical behavior inspired the International Committee of Medical Journal Editors to develop recommendations concerning authorship and other aspects of medical publications. The International Society for Medical Publication Professionals has issued its own guidance on good publication practice, including authorship. This session will focus on why these guidelines are needed, how they address common authorship issues, and what grey areas still exist. The session also includes tips and tricks for helping authors comply with authorship recommendations, for avoiding authorship disputes, and for defusing them when they occur.

### **Medical Cannabis: An Emerging Topic for CME & Science Writers, Things to Know**

*Cathleen O'Connell, RPh, PhD, Assistant Professor of Biomedical Writing, University of Sciences*

*Gail Groves Scott, MPH Director, University of the Sciences*

This session will describe the inconsistent and changing regulatory and legal status of medical cannabis across the US, and will review trends in research and clinical application of this emerging, yet historic, therapy. Understanding this unique background will illuminate opportunities for medical writers in this evolving segment of healthcare. While we will touch upon medical writing opportunities, the focus will be on educating attendees to the regulatory and therapeutic situation. That way they will appreciate how to make their own medical writing

opportunities.

### Issues with Patient Engagement

*Darshan Kulkarni, Vice President, Regulatory Strategy and Policy at Synchrogenix*

This talk will discuss the basics of why patient engagement has grown in importance and scope recently and further briefly discuss some of the laws that impact patient engagement. The presentation will identify common recent errors and recent Department of Justice investigations.

### Medical Writing: The Job, The Career, The Profession

*Dan Benau, PhD, Director, Biomedical Writing Programs, University of the Sciences*

The subject of research into best practices in developing medical writing materials came up in a recent teleconference that included members of AMWA, EMWA, and other organizations involved in medical writing. This in turn brought up the subject of what indeed differentiates a job, career, and profession. This talk will concentrate on the perspective of an educator and practitioner in the field and will cover aspects of education, training, certification, and other pillars of a profession. Some of these topics will also form the basis of a panel discussion at the end of the conference.

## Workshop Schedule

Time	Medical Writing Essentials	Hot Topics in Medical Writing
8:00 AM - 9:00 AM	Registration/Breakfast/Networking	
9:00 AM - 10:30 AM	<b>Presenting Numeric Evidence Part 1</b> <i>Jane Miller</i>	<b>Good Publication Practice and Authorship</b> <i>Jennie Jacobson</i>
10:30 AM-10:45 AM	Morning Break	
10:45 AM - 12:15 PM	<b>Presenting Numeric Evidence Part 2</b> <i>Jane Miller</i>	<b>Issues with Patient Engagement</b> <i>Darshan Kulkarni</i>
12:15 PM - 1:45 PM	Lunch and Networking	
1:45 PM - 3:15 PM	<b>Medical Writers are Project Managers</b> <i>Eileen Girten</i>	<b>Continuing Medical Education: Cannabis - It's Time!</b> <i>Gail Scott &amp; Cathleen O'Connell</i>
3:15 PM - 3:30 PM	Afternoon Break	
3:30 PM - 5:00 PM	<b>Soft Skills: The Critical Accompaniment to Technical Skills</b> <i>Kelleen Flaherty</i>	<b>Professionalism in Medical Writing</b> <i>Dan Benau</i>

**CME Palooza** hosts two days of free online webinars exploring important issues and techniques in CME on Wednesday, April 25 and Thursday, April 26. Webinars can be loaded at URL: <https://cmepalooza.com/spring-2018/>

**Intellus Worldwide Summit 2018** will provide thought-provoking keynotes who are leaders in rare disease and patient advocacy and will be held on May 6 to 8, 2018 at the Marriott Philadelphia.

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