2018 AMWA

Medical Writing & Communication Conference

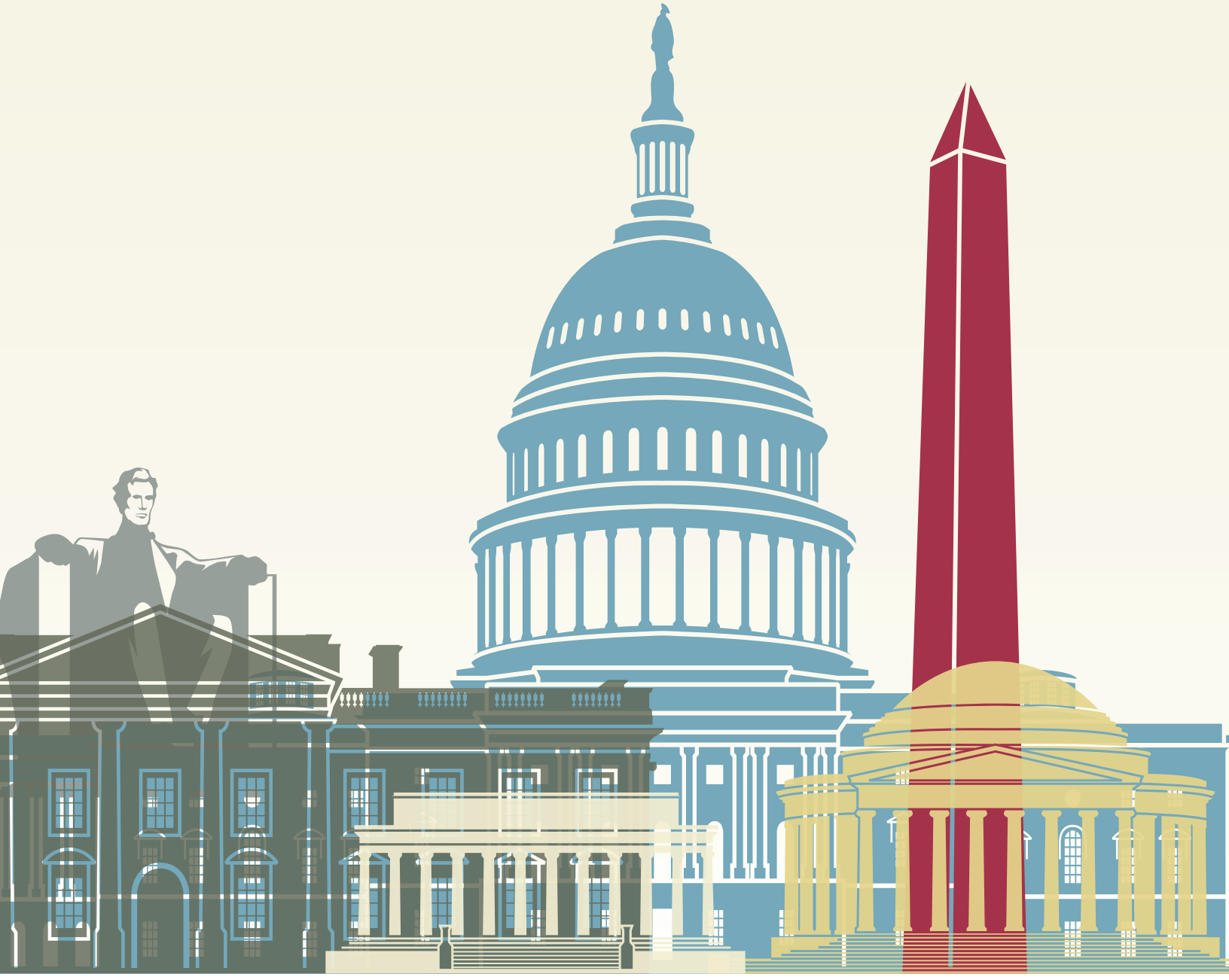
NOVEMBER 1-3, 2018
WASHINGTON, DC

Trends and Opportunities for Medical Communicators

REGISTER BY JUNE 15 FOR BEST RATES!

Pre-Conference Education and Networking Activities on October 31

Link. Learn. Lead.



REGISTRATION BROCHURE

SCHEDULE AT A GLANCE

WEDNESDAY, OCTOBER 31	
9:00 AM–12:00 PM	AMWA Workshops (*additional fee*)
9:00 AM–12:00 PM	BELS Examination (*additional fee and registration*)
10:30 AM–12:00 PM	Pre-conference Sessions
11:00 AM–12:00 PM	New to AMWA and Medical Communication Session
2:00–3:30 PM	Pre-conference Sessions
2:00–5:00 PM	AMWA Workshops (*additional fee*)
3:00–5:00 PM	Exhibitor set-up
4:00–5:00 PM	Pre-conference Sessions
5:00–7:00 PM	AMWA Mix and Mingle Lounge
THURSDAY, NOVEMBER 1	
8:30–9:15 AM	Continental Breakfast in the Exhibit Hall
9:30–10:30 AM	Education Sessions
10:30–11:00 AM	Beverage Break
11:00 AM–12:00 PM	Opening General Session
12:15–1:45 PM	Networking Lunch with the exhibitors
2:00–3:30 PM	Education Sessions
2:00–5:00 PM	AMWA Workshops (*additional fee*)
3:30–4:00 PM	Beverage Break
4:00–5:00 PM	Education Sessions
6:00 PM	Meet in lobby for Chapter and Regional Networking dinners
FRIDAY, NOVEMBER 2	
7:30–8:45 AM	Roundtable Topic Discussions with Breakfast (*additional fee*)
9:00–10:00 AM	Education Sessions
9:00 AM–12:00 PM	AMWA Workshops (*additional fee*)
10:00–10:30 AM	Beverage Break
10:30 AM–12:00 PM	Education Sessions
12:15–1:45 PM	Networking Lunch with the exhibitors
2:00–3:30 PM	Education Sessions
3:30–4:00 PM	Beverage Break
4:00–5:00 PM	General Session with Alvarez Award Address
5:00–6:00 PM	Happy Hour in the Exhibit Hall
6:30 PM	Meet in Lobby to depart for Dine Arounds
6:30–8:00 PM	Exhibitor Teardown
SATURDAY, NOVEMBER 3	
9:00–10:00 AM	Education Sessions
9:00 AM–12:00 PM	AMWA Workshops (*additional fee*)
10:00–10:30 AM	Beverage Break
10:30 AM–12:00 PM	Education Sessions
12:15–1:45 PM	Roundtable Topic Discussions with Lunch (*additional fee*)
2:00–2:30 PM	Annual Business Meeting for AMWA Members
2:00–3:30 PM	Education Sessions
2:00–5:00 PM	AMWA Workshops (*additional fee*)

REGISTRATION INFORMATION

2018 REGISTRATION FEES

	AMWA Member			Nonmember			AMWA Student or Retired Member		
	First Advantage Early Bird Rates	Regular Rates	On-site Rates	First Advantage Early Bird Rates	Regular Rates	On-site Rates	First Advantage Early Bird Rates	Regular Rates	On-site Rates
	May – June 15	June 16 – Sept. 30	October 1- Nov. 3	May – June 15	June 16 – Sept. 30	October 1- Nov. 3	May – June 15	June 16 – Sept. 30	Oct. 1- Nov. 3
Full Conference Registration	$695	$795	$850	$850	$950	$995	$400	$500	$550
Wednesday or Saturday Only	$150	$175	$200	$250	$275	$300	$150	$175	$200
Thursday or Friday Only	$300	$400	$450	$400	$500	$550	$200	$300	$350
AMWA Workshops	$175	$200	$250	$225	$250	$300	$175	$200	$250
Breakfast Roundtable	$30	$30	$30	$40	$40	$40	$30	$30	$30
Lunch Roundtable	$40	$40	$40	$50	$50	$50	$40	$40	$40

HOTEL AND TRAVEL

Located in the heart of Washington, DC, the Renaissance Washington, DC Downtown Hotel is walking distance from restaurants, museums, galleries, and other unique attractions. Known for its history and culture, DC boasts distinctive dining options, Smithsonian Museums, national monuments, and more. Don't miss this opportunity to be at the center of it all. Discover more online. AMWA has secured a discounted room block at the Renaissance Washington DC Hotel. To receive the discounted rate and AMWA benefits, book through the AMWA hotel block. More hotel and travel information is available online.

CANCELLATION POLICY

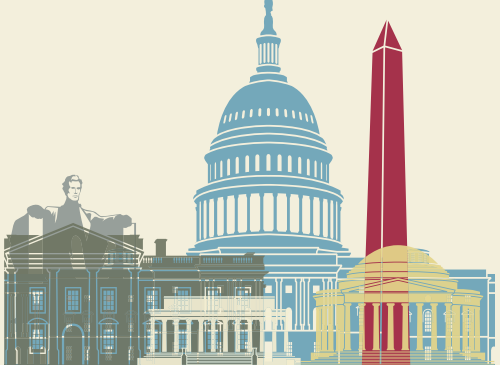
Email AMWA at conference@amwa.org no later than October 10, 2018 to cancel your registration and request a refund. Refunds will be issued through your method of payment, less a non-transferrable $75 cancellation fee. A cancellation fee of $50 will be charged for workshop cancellations/changes made before October 10, 2018. A cancellation fee of $10 will be charged for roundtable cancellations/changes made before October 10, 2018. Conference registration and workshop fees are nonrefundable after October 10, 2018. No refunds or credits will be given for failure to attend, late arrival, unattended events, or early departure.

PARTICIPANTS WITH SPECIAL NEEDS

If you have a special need that may affect your participation in the conference, please contact AMWA at conference@amwa.org before October 1, 2018 to indicate your requirements and/or request accommodations.

CONSENT TO USE OF PHOTOGRAPHIC IMAGES

Registration and attendance at, or participation in, AMWA's Annual Conference and related events constitutes an agreement by the participant to AMWA's use and distribution (both now and in the future) of the participant's image or voice in photographs, videotapes, electronic reproductions, and audiotapes of the conference.



SCHEDULE

WEDNESDAY, OCTOBER 31

9:00 AM–12:00 PM — **AMWA Workshops (*additional fee*)**

WS-10 Regulatory Aspects of the Drug Development Process

Aaron Bernstein, PhD, Aaron Bernstein Consulting, LLC, Millburn, NJ

Breaking into regulatory medical writing—in the US, the EU, or any country using ICH guidelines—is easier when you understand the drug development process and regulatory and reporting requirements.

At the end of the workshop, participants will be able to

- Describe the history, organization, and functions of the US Food and Drug Administration
- Appreciate the various phases of drug development and where Medical Writers are typically involved
- Describe key regulations and health authority guidelines; how and when they shape a drug's development
- Access valuable resources provided by health authorities, professional and trade organizations

WS-11 Writing and Editing NIH Grants

Kristina Wasson-Blader, PhD, ELS, Clearly Communicating Science, LLC, Orchard Park, NY

An integral part of the regulatory and publication writers' job is turning raw data into tables, figures, and text. This workshop provides tips on where to begin and how to provide data in the most impactful way.

At the end of this workshop, the participant will be able to

- Determine what information is important to pull into the body of the CSR.
- Summarize data in the body of the CSR concisely.
- Identify some appropriate and inappropriate language to use in the body of a CSR.

WS-12 Basics of Molecular Biology

Dominic De Bellis, PhD, Senior Associate Director, Medical Writing, Boehringer Ingelheim Pharmaceuticals, Inc.

Learn basic molecular biology concepts about DNA, RNA, and protein structure. Key terms and commonly used techniques will be reviewed, as will useful writers' resources.

At the end of the workshop, participants will be able to

- Describe the structural building blocks of DNA
- Assess how nomenclature and basic lab methods derive from DNA structure
- Assess molecular biologic text for editing and clear writing
- Communicate more clearly about the basic molecular biologic processes presented

9:00 AM–12:00 PM	**BELS Examination (*additional fee and registration*)** (Registration is available through the Board of Editors in the Life Sciences.)
10:30–11:00 AM	**Workshop Beverage Break**
10:30 AM–12:00 PM	**Pre-conference Session: Planning for Retirement**
11:00 AM–12:00 PM	**New to AMWA and Medical Communication Session** If you're new to AMWA or the profession, join us to learn how to get the most out of the conference, with expert advice on must-do sessions and events tailored to your interests and professional goals. Also discover how AMWA programs, products, and services can help enhance your professional skills and how you can further expand your professional reputation by becoming more involved in AMWA.
2:00–3:30 PM	**Pre-conference Sessions** **Identifying Experience and Expertise to Succeed as a Medical Writer** *Damiana Chiavolini, MS, PhD, Instructor, UT Southwestern Medical Center, Dallas, TX* *J. Kelly Byram, MS, MBA, ELS, CEO | Scientific and Medical Communications Lead, Duke City Consulting, LLC, Albuquerque, NM* *Anne Murray, PhD, Scientific Research Writer, UT Southwestern Medical Center, Arlington, TX* This session will be highly interactive and dedicated to career development. The aim is to discuss how to apply and leverage one's expertise and background to enter and/or progress in the medical writing and editing world. It will draw upon expertise in multiple fields and discuss a range of elements including job-seeking practices, interviewing strategies, personal branding, transferable skills, continuing education, and mentorship. The session will be geared toward academia and freelance, but many of the lessons will be broadly applicable. **Targeted Level of Experience: New to the Field (less than 3 years)** **If You Build It, They Will Come: An Unconventional Path from Freelance to Business Owner (Reimagining the Industry of Medical Writing)** *Emily Stephens, CEO, Global Medical Writing and Translation, Kent, WA* This session will covering the following topics: Recognize What You Do Best: The Art of Specializing. Confidence + Good Old Fashioned Hard Work + A Little Fake It Till You Make It. Understanding Contracts (Short-term & Long-term). Develop Relationships with Recruiters. Build on Your Successes. The Long Stretch: How to Move from Freelancer to Business Owner. Small Business to Midsize Business. Pitfalls, Lessons Learned, and Redefining What's Possible. **Targeted Level of Experience: All Levels of Experience**
2:00–5:00 PM	**AMWA Workshops (*additional fee*)** **WS-20 Serving Two Masters — Comparing and Contrasting US and EU Regulatory Processes (*note this workshop ends at 5:30 PM*)** *Art Gertel, MedSciCom, LLC, Lebanon, NJ* Although medical writers work in a global environment, requiring the preparation of dossiers that will often be submitted to more than one regulatory authority, the process is by no means monolithic. There are significant differences in the requirements and processes of US and EU regulators. These will be explored in a compare-and-contrast journey through the twists-and-turns of the submission review processes.

At the end of the workshop, participants will be able to

- Assess the processes associated with new drug review and approval by the FDA.
- Assess the processes associated with new drug review and approval by the EMA.
- Compare the differences between FDA and EMA new drug review and approval processes.

WS-21 Essentials of Copyediting

Loretta Bohn, BA, Senior Editor/Writer, RTI International, Research Triangle Park, NC

Copyediting is a basic but essential skill that every professional medical communicator should master to ensure clarity, accuracy, and consistency when revising scientific and medical manuscripts for publication.

At the end of the workshop, participants will be able to

- Describe the characteristics of a successful copyeditor.
- Evaluate a document in accordance with a given style guide.
- Determine when and how to query authors for more information to complete the copyedit.

WS-22 Advanced Data Presentation: Tables, Graphs, and Charts

Janet Novak, PhD, ELS, Senior Editor/Grant Writer, Memorial Sloan Kettering Cancer Center, Philadelphia, PA

Good graphics convey specific information more efficiently than text, but choosing the best type table or graph is not always easy. Learn new types of graphs and explore solutions to graphic problems. This workshop is intended for medical writers and editors who have at least a moderate degree of experience working with graphical displays of data.

At the end of the workshop, participants will be able to

- Describe the roles tables, graphs, and charts can play in the reduction, summarization, understanding, communication, and analysis of data
- Decide which is the most appropriate graphical presentation form to use for any given circumstance—and provide a rationale for the decision
- Suggest improvements for poorly designed and executed graphical presentations.

3:00–5:00 PM **Exhibitor Set Up**

3:30–4:00 PM **Beverage Break**

4:00–5:00 PM

Pre-Conference Sessions

Word Masterclass Part I - Best Tips and Techniques

Zoe Wright, Ideagen PLC, Nottinghamshire

Microsoft® Word is one of the most sophisticated software products in the world. It has 10 menus, not including the help function and over 350 commands – in fact, the standard and formatting toolbars alone have around 200 options… Perhaps not surprising when you consider its creator, Bill Gates, has an IQ of 170 (genius is defined as an IQ exceeding 140). And it is a 'genius' product. However, it is said that 90% of people only use 10% of the functionality, but of course the 90% don't all use the same 10%! Many issues with Microsoft Word formatting arise because documents, or sections of documents, have been inherited or converted from earlier versions of Word – in particular the earlier pre-XML versions of Word, such as 97, 2000 or 2003. This class is the first part of our Word Masterclass series and provides lots of information on how you can speed up many routine actions, with tips and techniques on tables, styles and macros.

Targeted Level of Experience: All Levels of Experience

Making a Career Out of Medical Writing

Madison Hedrick, MA, Scientific Writer and Editor, Science Communication Group, University of Arkansas for Medical Sciences, Little Rock, AR

Breaking into medical writing can be daunting. In my communications on Engage, I have received many messages asking for help or "free" projects. In this session I will talk about my experience breaking into medical writing, how to obtain and build a client base, and how to use AMWA to assist you in your effort to become a successful medical writer. I will also show how to use a web platform to create a website/portfolio that will highlight the participants' work and CV. I will use my own website as an example. I will also describe what a good CV and writing sample should include. I will also answer questions.

Targeted Level of Experience: New to the Field (less than 3 years)

5:00–7:00 PM **AMWA's Mix and Mingle Lounge featuring entertainment and cash bar.**
Meet and greet fellow attendees before enjoying an evening on your own in DC.

THURSDAY, NOVEMBER 1

8:30–9:15 AM **Continental Breakfast with Exhibitors**

9:30–10:30 AM **Education Sessions**

Regulatory Medical Writing in the Digital Age

Becky Nuttall, Lead Medical Writer, EMD Serono, Wayne, PA

Health authorities like the FDA and EMA require electronic submissions. How does writing for the screen differ from writing for paper reviews? Should there be a difference? What can research in web design and reading behavior tell us? In an atmosphere where social media encourages short, to-the-point snippets of information, how do we get our points across succinctly yet completely? Does it matter where on the screen information is, or how many links there are? It's time for medical writers to embrace a new paradigm and lead others to develop better strategic documents, ones that help reviewers navigate to the content and draw their attention to the key messages. By understanding how people read on screen and utilizing strategies that write to their needs, we can impact how quickly reviewers acquire the knowledge they seek–potentially influencing review cycles. Beyond theory, there are practical applications we can use, today, that not only write to the Regulatory reviewer's needs, but can help teams organize the process of creating strategic documents. This presentation will open your eyes to a new way of looking at things and will provide a practical approach to developing documents.

Targeted Level of Experience: All Levels of Experience

From Protocol to Package Insert - A Data Journey

M. Alexandra Rohall, Sr. Manager, Medical Writing, PROMETRIKA, LLC, Cambridge, MA

Christine Quagan, Sr. Medical Writer, PROMETRIKA, LLC, Cambridge, MA

The Package Insert (PI; also Product Label(ing), Prescribing Information) is the most easily accessible regulatory document for an approved drug in the US. This document describes and summarizes the characteristics, actions, effects, and risks of a drug or biologic. The content of this document is the result of a negotiation between FDA and the biopharmaceutical company during review of a drug/biologic and after the drug/biologic is approved. Using case histories from recent NDA/BLA submissions, we'll trace the final content backwards from the Package Insert to the protocols that began the clinical research.

Targeted Level of Experience: New to the Field (less than 3 years)

Narrative and Communication Techniques for Medical Writers to Improve Scientific Communications – Why Medical Communications Needs a Story

David B. Clemow, PhD, MWC, Advisor Scientific Communications Information Strategy, Eli Lilly and Company, Indianapolis, IN

Medical communications is changing to meet evolving and modernized customer needs. With information highways that provide stimulus overload, it is increasingly important to gain and retain the audience's attention if a writer wants their message heard. However, sometimes stuck in ivory towers of yesteryear or brow beaten about writing without promotional slant, science writers often do not use proven communication techniques in their writing. They therefore frequently do not convey a narrative that helps their audience understand the key medical messages the writers are attempting to convey. In the end, this hinders companies in helping regulators, healthcare providers, payers, and patients understand their therapeutics. This session will provide scientific communication techniques that are based in story telling that will improve writer's ability to connect with their audience, have their clinical trial data or medical information understood, as well as help their audience remember key points. This session will also provide perspective to help writers and their medical affairs colleagues accept that use of narrative in medical science is appropriate and compliant, since science by default is accurate, honest, and reliable and not fabrication, deception, or exaggeration.

Targeted Level of Experience: All Levels of Experience

Strategies for Building a Successful Freelance Writing and Editing Business

Kristin Harper, PhD, MPH, Owner, Harper Health & Science Communications, LLC, Seattle, WA

Mia DeFino, MS, Owner, Medical and Science Writer, DeFino Consulting, LLC, Chicago, IL

What with attracting new clients, doing stellar work for current clients, and living your life, building a successful freelance writing and editing business can be challenging. However, many of us enjoy the freelance approach to work and life, and we have found that mastering a few strategies makes running our businesses much easier. This session will use real-life examples to cover how to get repeat business and build your business with referrals, as well as how to go beyond the basics to help your clients. We'll help you think through different ways to approach your business and meet your goals.

Targeted Level of Experience: All Levels of Experience

What Should a Medical Writer Know About Gene Therapy and Gene Editing?

Elise Eller, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc., Lafayette, CO

CRISPR and now CARTs keep popping up in the news. What are they, and what should a medical writer know about the wider worlds of gene therapy and gene editing? Session attendees will learn about gene therapy and gene editing, including the scientific fundamentals, the current state of research, and the regulation of gene-based therapeutics. The presentation will also cover ethical concerns of gene editing.

Targeted Level of Experience: All Levels of Experience

Introduction to Health Economics and Outcomes Research (HEOR) for Writers

Catherine Mirvis, Senior Communications Analyst, Pharmerit International, Bethesda, MD

Beth Lesher, PharmD, BCPS, Associate Director, Strategic Market Access, Pharmerit International, Bethesda, MD

This is an introductory session for writing professionals interested in the growing field of health economics and outcomes research (HEOR). We will discuss the basics of HEOR and provide tips for freelance writer/editors and people from both technical and non-technical backgrounds. Topics will include real-world evidence (RWE), patient-reported

outcomes (PRO), sources and end users of HEOR evidence, types of HEOR content (AMCP and global value dossiers, SLRs, economic models, manuscripts, review articles, etc.), and tips for getting started in HEOR writing/editing.

Targeted Level of Experience: All Levels of Experience

10:30–11:00 AM	**Beverage Break**
11:00 AM–12:00 PM	**Opening General Session**
12:15–1:45 PM	**Networking Lunch with the Exhibitors**
2:00–3:30 PM	**Education Sessions**

Grant Editing Basics: Appealing to Reviewers

Meagan Ramsey, Grant Development Specialist, Michigan Institute for Clinical & Health Research, University of Michigan, Ann Arbor, MI

Grant editing is a valuable service medical writers can offer to investigators who are submitting research grants to the National Institutes of Health (NIH). Although grant writing requires content expertise, grant editing is beneficial when the editor is a knowledgeable reader but not a content expert; this critical lens is valuable because grant reviewers are rarely experts in the content of the grants they are critiquing. Moreover, if editors understand the grant review process, they can enact specific strategies to help a grant appeal to reviewers. For example, if a grant lacks logical flow, clarity, or persuasion, it is less likely to score well even if the science is strong. Editors can identify and fix these key issues that authors often overlook or can't see, helping ensure the grant will incite reviewer enthusiasm rather than confusion and annoyance. In this session, we will briefly describe the NIH review process to help editors understand common non-scientific issues that could turn off reviewers, and we will discuss how editors can address these issues and best practices in grant editing. Participants will leave the session with actionable strategies they can use to help create competitive NIH grant submissions that appeal to reviewers.

Targeted Level of Experience: All Levels of Experience

Master the Disaster

Brian Bass, MWC, President, Bass Global, Inc., Fort Myers, FL

R. Michelle Sauer Gehring, PhD, ELS, CRA, Senior Research Scientist, Center Advanced Heart Failure, University of Texas Health Science Center-Houston, Houston, TX

Larry Lynam, MS, SM, RM(AAM), Principal, The Lynam Group, Coral Springs, FL

Lori L. Alexander, MTPW, ELS, MWC, President, Editorial Rx, Inc., North Fort Myers, FL

As the saying goes, *stuff* happens. Sometimes we get fair warning, like when a hurricane is approaching. But sometimes there's no warning at all. An accident, a broken bone, a sudden illness, and worse. We're not talking paper cuts here. As if dealing with the occasional exploding project, ridiculous deadline, or unreasonable client doesn't present enough of a challenge, freelances also get to face the occasional actual disaster. Is your freelance business prepared for it? Are you ready to work through disaster, recover, and if necessary, rebuild your business? Can your business keep going in the face of extreme circumstances that are nearly or completely out of your control? In this open session, 4 very experienced (unfortunately) disaster survivors share their stories about how their freelance businesses withstood expected and unexpected disasters. Learn what they did and didn't do to prepare and how they made it through. Most importantly, find out what they've learned from their mistakes and face-palm moments, and what they'll do differently the next time—because there's always a next time.

Targeted Level of Experience: All Levels of Experience

Can You Teach an Old Reviewer New Tricks?

Robin Whitsell, BA, BPh, President, Whitsell Innovations, Inc., Chapel Hill, NC

Documents and even full submissions are hinged on the ability of the writer to manage a team and provide a deliverable. Yet, often the most challenging part of a medical writer's job is dealing with the review period and reviewers. Much like a real-life reality TV show, once a draft leaves a writer's hands (or computer), the fate of the document and timeline lie with other team members. Metaphorically speaking, the writer is waiting to see if he or she is voted off the island as the control is elsewhere. From fussy to hostile to passive aggressive to complacent, the dynamics of the team and the quality and timeliness of the review have the greatest impact on the outcome. Meanwhile, teams can drive messaging and strategy or they can argue over grammar, regulatory interpretation, and even individual data points. What is a brave medical writer to do? During this session, we will reflect on how we currently manage our review teams. Audience members will share their ideas about what does and does not work. Interactively, we will detail specific challenges associated with review teams and explore potential solutions for how to manage them. We will discuss how to wrangle even the toughest individual reviewers and the most dysfunctional teams. At the end of this session, writers will be able to more fully understand the tools that they routinely use to guide their teams and, hopefully, have some new tools for managing their reviewers.

Targeted Level of Experience: All Levels of Experience

Medical Writing between Dossier Submission and Drug Approval

Douglas Fiebig, Senior Partner, Trilogy Writing & Consulting, Frankfurt, Hesse

While the Common Technical Document harmonizes the structure of regulatory documents submitted to the US FDA and the European EMA for marketing approval, the review processes leading to the decision on whether to approve or not still differ markedly between the two authorities. In both cases, though, the demand for medical writing skills in the broadest sense (linguistic, scientific, organizational, diplomatic) can be high. The objective of this session is to familiarize participants with the post–submission review processes of these two authorities and illustrate the pivotal role medical writers can play in helping to optimize a sponsor's chances for obtaining a successful drug approval. The session will navigate you through the post–submission review processes you can expect to encounter, and through the numerous medical writing activities that can arise during FDA and EMA reviews of a submission dossier (e.g., drafting responses to the authority's questions, preparing safety updates and NDA amendments, writing briefing documents, organizing and preparing presentation materials for FDA Advisory Committee meetings and CHMP Oral Explanations). The session illustrates salient points and potential pitfalls by recalling personal experiences working on a US-European approval team. Participants will be encouraged to share their experiences in this situation, especially in terms of the challenges to be overcome.

Targeted Level of Experience: Mid-career (3-6 years)

Elevating the Patient Voice: Opportunities and Challenges for Medical Communicators

Moderator Monique Pond, Medical Writer and Consultant, Whitsell Innovations, Inc., Chicago IL

Engaging patients as active partners is widely recognized as a vital component to achieving better care that improves health at lower costs. However, significant communication gaps remain between patients and decision-makers that impede transforming this vision into a reality. Patients and their families may feel overwhelmed by treatment options, passive in the care process, and unappreciated by researchers. As

content creators, medical communicators are uniquely positioned to connect patient's voices with decision-makers at the hospital, industry, and policy levels. For example, patient insights during study planning can increase participant recruitment and improve trial data. This panel will host a discussion about improving patient engagement with panelists from different levels of the healthcare system. In addition to questions from the moderator, attendees will have the opportunity to ask the panelists questions.

2:00–5:00 PM **AMWA Workshops (*additional fee*)**

WS-30 Electronic Common Technical Document

Nancy Katz, PhD, MWC, President, Illyria Consulting Group, Inc., Soda Springs, CA

Common to the United States, Europe, Japan, and other countries, the eCTD is part of the regulatory landscape. Mastering eCTD-based submissions is an essential skill for regulatory writers.

At the end of the workshop, participants will be able to

- Define the Common Technical Document (CTD) and the electronic CTD (eCTD).
- Compare the relationship between the CTD, the eCTD, and the US Investigational New Drug (IND) Application and New Drug Application (NDA).
- Describe the writer's role(s) on a submission team

WS-31 Clinical Study Reports in Oncology

Thomas M. Schindler, PhD, Head Medical Writing Europe, Boehringer Ingelheim Pharma GmbH & Co.KG, Biberach ad Riss, Germany

Kirsten Herbach, PhD, Principal Medical Writer, Boehringer Ingelheim Pharma GmbH & Co.KG, Biberach, Germany

This is a workshop for moderately experienced medical writers who understand the structure of clinical study reports. Based on the ICH E3 report structure, we will explain the special features of oncology CSRs. The focus will be on the development of treatments for solid tumors.

At the end of the workshop, participants will be able to

- Describe the special features of oncology clinical study reports (CSRs) including the endpoints in oncology (tumour response according to RECIST criteria, progression-free survival, overall survival) and the analysis of safety data (CTCAE grading, SMQs, adverse events of special interest)
- Apply the key oncology concepts to the writing of the different sections of an oncology CSR.

WS-32 Fundamentals of Ethics and Practical Applications (*note: this workshop ends at 5:30 PM*)

Art Gertel, MedSciCom, LLC, Lebanon, NJ

Clinical researchers are increasingly confronted with difficult decisions that often pit the interests of society against the interests of the patient. The workshop will explore ethical issues that will provide medical writers with a better understanding of this dynamic tension in the context of human research subject protections.

At the end of the workshop, participants will be able to

- Identify ethical issues in the informed consent process and the challenges that may arise in developing countries.
- Describe the importance of ethics in good clinical practice.
- Compare the infrastructure of ethics committees and data safety monitoring committees.

WS-33 Ethical Standards in Medical Publications

Andrea Gwosdow, PhD, President, Gwosdow Associates Science Consultants, LLC, Arlington, MA

Ann L. Davis, MPH, CMPP, Scientific Director, StemScientific, Lyndhurst, NJ

Nowhere in the medical communication field is ethical scrutiny more focused than in medical publications. Publication writers must know the guidelines, ethical standards, pitfalls, and controversies relevant to their craft.

At the end of the workshop, participants will be able to

- Define ethical challenges related to scientific publications.
- Compare perspectives of different publications stakeholders.
- Describe common pathways for resolution of ethical challenges.

WS-34 Sentence Structure and Patterns

Michael Schneir, PhD, Professor, Herman Ostrow School of Dentistry of the University of Southern California, Los Angeles, CA

Well-structured sentences say what they mean clearly, concisely, and coherently, ensuring that readers receive the message we intended to convey—a necessity for effective medical communication.

At the end of the workshop, participants will be able to

- Identify syntactic structures, functions, and patterns in a sentence.
- Distinguish a clear sentence from another with clarity-impeding syntactic distractions.
- Determine nomenclature for identifying and revising the distractions.

WS-35 Establishing Style: Exploring and Developing In-House Guides

Nicole Van Hoey, PharmD, Medical Writer/Editor, Freelance, Arlington, VA

Learn how to use major style manuals to create a style guide that is best suited to the goals of your writing team, the content, and your target audience.

At the end of the workshop, participants will be able to

- Describe the evolution of textbook style manuals and scopes of other manuals.
- Compare style guide design options for content, presentation, and ease of use.
- Develop and maintain a concise house style guide that best fulfills the needs and goals of a writing team.

3:30–4:00 PM **Beverage Break**

4:00–5:00 PM **Education Sessions**

Miscommunication Epidemic: How Close Are We to Finding a Cure?

Cynthia L. Kryder, MS, CCC-Sp, Medical Communicator, Phoenixville, PA

As medical communicators we're experts at communicating information about health and medicine to our target audiences. But how many times have you thought you communicated clearly with clients, colleagues, employers, or employees only to find that your words were misinterpreted? In a world with ever-growing ways to communicate, there are ever-growing ways to misinterpret the messages we receive. The uncomfortable truth is that despite our best communication efforts, people often don't hear what we say. This session will review the complexities of communication and the challenges inherent in a world where multitasking has become the standard and where digital natives (people who have no memory of life before computers, smartphones, or the internet) and digital immigrants (those who matured before the digital age) work

together in a multigenerational workforce. After discussing some of the latest research into the causes of miscommunication, including technology's role, the session will focus on strategies you can implement immediately to reduce the risk of your messages getting lost in translation.

Targeted Level of Experience: All Levels of Experience

The CSR Simplification Project: Creating a Clear, Compliant, and Concise CSR

Diane R Petrovich, PhD, Head, Infectious Disease & Vaccines Medical Writing / Medical Writing / Global Clinical Trials Operations, Merck, Upper Gwynedd, PA

Mitzi Allred, PhDEE, Head, Clinical Content Standards/ Medical Writing/ Global Clinical Trial Operations, Merck, Upper Gwynedd, PA

on behalf of the CSR Simplification Project Team, Global Clinical Development, Merck

The clinical study report (CSR) process and structure were re-tooled and revised at Merck to ensure that our CSRs not only facilitate the job of the Health Authority Reviewer but also fully leverage the efforts and expertise of Merck authors and reviewers. The CSR Simplification Project is part of an overall approach within Merck to simplify documentation for clinical studies. A cross-therapeutic area team collected key cross-functional input, conducted industry benchmarking, and critically assessed all CSR templates and procedures. The new CSR template and process embrace focused authoring principles, leverage the electronic environment, address disclosure concerns, and build on structured authoring initiatives (including the common protocol template). Revisions and other changes fell into 4 categories: Synopsis; CSR Template; Streamlining Sections 4-9; Focusing Sections 10–12; Clarifying Section 13; Appendixes and Tables, figures, and listings (TFLs); Development of TLF insertion tool; Minimize redaction issues; Review process; Clarifying roles, expectations, and process. The new template is expected to reduce author, reviewer, and quality control times while providing the Agency Reviewer with a compliant, concise, and focused document.

Targeted Level of Experience: All Levels of Experience

Cancer Immunotherapy – Overview of Current Landscape

Petra Volna, PhD, RPh, Senior Regulatory Documentation Scientist, Genentech, Inc., South San Francisco, CA

Emerging cancer immunotherapies constitute a shift in cancer treatment. The role of immune system in cancer remained unappreciated until relatively recently. However, with recognition that the tumor microenvironment appears to actively suppress T-cell responses by activation of negative regulatory pathways, new therapies preventing suppression of T-cell stimulation have been successful in driving durable anticancer responses albeit only in a subset of patients. Approved cancer immunotherapies are now available for patients with a wide range of solid and hematologic cancers, including melanoma, lung cancer and classical Hodgkin lymphoma. Favorable therapeutic approaches include inhibition of immune checkpoint molecules like cytotoxic T-lymphocyte protein 4 (CTLA4) and programmed cell death protein 1 (PD-1) or its ligand (PD-L1), or direct modification of T cells to recognize target tumor cells via chimeric antigen receptor-modified (CAR)-T. Another new approach, currently being tested in clinical trials, helps T cells recognize target tumor cells and prime protective T-cell response by presenting tumor derived neo-epitopes in a form of therapeutic vaccines—achieved by the injection of synthetic peptides or messenger RNA. This session will provide an overview of mechanisms that drive tumor escape from immune surveillance and current cancer immunotherapy landscape.

Targeted Level of Experience: All Levels of Experience

Instructional Design: Where Do You Fit in as a Medical Writer

Deborah Anderson, DGA Medical Communications, Langhorne, PA

With the rush, rush, rush, of today's learning landscape, microlearning is emerging as a new approach for providing pieces of information in a quick and concise manner. This presentation will describe what microlearning is as well as discuss different ways it can be incorporated into medical writing via the written word, informatics/graphics, or video outlets. In addition, special note will be paid to the sound instructional design of these microlearning outlets to ensure they meet the specified goals and objectives of a program.

Targeted Level of Experience: All Levels of Experience

QC Detours: Improving the Quality Control Process

Pamela Fioritto, Quality Reviewer and Medical Editor, Whitsell Innovations, Inc., Cleveland, OH

Mandy Pennington, Quality Reviewer and Medical Editor, Whitsell Innovations, Inc., Downingtown, PA

As a document motors its way through quality control (QC) on the road to submission, reporting, or publication, the QC Specialist often encounters a variety of roadblocks that result in unreasonable expectations and deadline delays. We've all been there: lack of a set style, missing source documents, hand-tabulated tables, formatting errors, and a host of other obstacles. In this interactive session, we will identify common QC challenges and methods of maneuvering around them that maintain the integrity of the final document, adhere to the allotted timelines, and meet budgetary constraints. What are your QC roadblocks? Attendees are encouraged to share situations and map out solutions.

Targeted Level of Experience: All Levels of Experience

6:00 PM **Meet in lobby for Chapter and Regional Networking dinners**

Meet up with your local colleagues before heading out for dinner.

FRIDAY, NOVEMBER 2

7:30–8:45 AM **Roundtable Topic Discussions with Breakfast (*additional fee*)**

Are You Excited About SQUIRE 2.0 Yet?

Donald Harting MA, MS, ELS CHCP, Manager of CE Grant Writing and Outcomes, National Comprehensive Cancer Network, Fort Washington, PA

In recent years, more medical education providers have been choosing to report their learning outcomes as manuscripts submitted for publication in peer-reviewed journals. The trend has become so pronounced that there is now an effort among some medical writers and journal editors to standardize how these manuscripts are written and edited. The first Standards for Quality Improvement Reporting Excellence (SQUIRE) were published in 2008, and SQUIRE 2.0 came out in 2017. At this roundtable we will discuss how SQUIRE 2.0 may affect the scope of work for medical communicators in the CME space going forward.

Been There, Done That, Train Them - Raising the Next Generation of Regulatory Writers

M. Alexandra Rohall, Sr. Manager, Medical Writing, PROMETRIKA, LLC, Cambridge, MA

For regulatory writers active over the past 20 or more years, some things have changed; much has stayed the same. We've adapted to (or even instigated) the changes and refined our skills along the way. How do we effectively, and relevantly, pass on our wisdom? Or is that even necessary in light of the many courses and programs currently available? This Roundtable will elicit and discuss attendees' methods and experiences with training colleagues newer to regulatory writing.

Best Practices for Excellent Quality Control

Julia Tonelli, Manager, Medical Writing Quality Control, Shionogi, Inc, Florham Park, NJ

Aaron B. Bernstein, PhD, Principal, Aaron Bernstein Consulting, LLC, Millburn, NJ

The Quality Control of regulatory documents is performed to verify accuracy, consistency, and completeness of data against source documents and an established Style Guide to enhance the quality of final documents. This is an interdependent and resource-intensive activity that can add significant time to the overall lifecycle of a regulatory document if not planned and executed efficiently. As such, effective use of resources, time management, clear communication and planning between medical writers and QC reviewers are crucial to conduct the QC of complex regulatory documents. In this roundtable, a medical writer and a QC reviewer will provide some tips on best approaches to plan and complete the QC review of documents while working with limited timelines, multiple medical writers, and frequent difficulties. Find below some of the tips that will be discussed: From the Medical Writing perspective: how to build quality into the writing process, prepare the document and sources needed for QC, how to keep track of source documents, list of final checks before sending the document for QC. From the QC Review perspective: how to communicate with multiple medical writers working on documents for the same program to ensure consistency, how to make sure all sources are received, how to complete the QC on time, how to work with multiple QC reviewers, how to send queries for sources.

Career Paths in Medical Writing

Paul Carpenter, Vice President of Business Development, Global Medical Writing and Translation, Madison, WI

This interactive presentation details career paths for Medical Writers. An individual writer's experience may be vastly different depending on the organization that they choose to support. The freelance route can be the most lucrative, but the writer may sacrifice stability and benefits. Working embedded within a sponsor company is an entirely different option, bringing a writer into proximity with the forefront of clinical research. CRO work can be fast paced and exciting, allowing variety and tempo. Apprenticeship arrangements with freelancers offer a foot in the door, and on the job training. There are other options out there including companies offering the flexibility of freelance, with the stability of a sponsor. The Medical Writing landscape is ever evolving, and writers have more and more options for employment in today's dynamic marketplace.

Certification of Editors in the Life Sciences

Norman Grossblatt, ELS(D), Editor, Chevy Chase, MD

The discussion will cover the meaning of certification, the history and purpose of the Board of Editors in the Life Sciences, eligibility for applying for Board examination, and what the Board's examinations are like and how to prepare for them.

Empowering Women Professional in Medical Writing – Exploring the Entrepreneur Within!

Priyanka Ingle, MD, PhD, Aff. MFPM, Translational Clinical Pharmacologist, CRC Pharma LLC, Parsippany, NJ

Challenges for women in STEM are sometimes so subtle. Amidst challenges to hone skills and practice the art effectively, women scientists and writers who may not or may be "introverts" can miss out on some excellent opportunities. The roundtable will focus on discussing what are the challenges women face, how these challenges can be overcome and effectively help each other to move ahead.

7:30–8:45 AM
continued

Freelancer's Guide to Data Security

J. Kelly Byram, MS, MBA, ELS, CEO, Scientific and Medical Communications Lead, Duke City Consulting, LLC, Albuquerque, NM

For freelancers and small business owners, data protection can be something they don't think about until tragedy strikes: a new hard drive fails, viruses and malware attack, or data is taken for ransom. This can be heartbreaking when personal data is lost or destroyed—e.g., emails and photos—but the loss, destruction, or theft of data can be devastating for a business managing ongoing projects and clients' confidential data. In this roundtable session, we will cover the basics of data protection by defining the universe of potential problems, then discuss best practices for securing data without breaking the bank.

From Patents to Protocols: How to Think Like an Entrepreneur

Aneysha Bhat, Clinical Writer, GE Healthcare, Waukesha, WI

My path into the world of medical writing is unconventional. I have a background in engineering and entrepreneurship, and before coming to GE Healthcare as a medical writer, I co-founded a medical device startup company. Despite this unorthodox path, I have found that having an engineering-based and entrepreneurial mindset while writing has allowed me to target nuances in the field and solve problems in a new way that has not yet been explored traditionally in the field of medical writing. I believe that thinking like an engineer and entrepreneur can help medical writers advance both their technological and fundamental skills and be on the forefront of medical innovation, and I would like to share this novel perspective with my fellow peers in the field.

Grow your Own Local Network of Communication Professionals

Joanne M. McAndrews, PhD, Freelance, St. Louis, MO

Online networking (LinkedIn, Twitter, Facebook, etc.) is wonderful, but nothing really beats face-to-face interaction with colleagues. This roundtable will cover the how-tos of starting and maintaining a network of writers, editors, and other communication professionals in your area. We'll discuss recruiting members, finding a place to meet, meeting formats, meeting topics, maintaining a membership list, and the many benefits of connecting in person on a regular basis with professionals in your field.

How do I get Out of Here???

Sandra Buckley, Medical Writer, self employed, Lansdale, PA

For those of us of a certain age —or a certain number of years in the business -- there comes a time when we start thinking of cutting back. How to do that and preserve credibility, sanity, and at least partial income. Let's begin to think about things like: how to cut back on business, how to say no gracefully, preparations we should make ahead of time, what to do if we haven't made those preparations. I don't have the answers, but maybe together we can come up with a sensible strategy.

7:30–8:45 AM
continue

How to Advance a Medical Writer Career in the Corporate Industry? The Importance of Defining Your Personal Objectives

Zineb Roumane, Senior Medical Writer, PAREXEL International, Montréal, Canada

When someone starts a career in regulatory medical writing, it is not always clear where it may take you. One possible path would be to start at a junior level, further moving into more senior positions, including potentially a managerial role. However, this path follows a basic consideration of what a medical writing career could be. The medical writing career is complex and the path might not be the same for all writers; skill levels differ between writers, and how to achieve the next level may not always be clear. Medical writing is a vast field that involves multiple types of documents, all requiring different competencies. In addition, the work environment plays a role in your career (e.g., working for a pharmaceutical company or a contract research organization offers different opportunities). Medical writers should contemplate what they want for their careers based on their aspirations, define their personal objectives, and work towards getting the necessary trainings and expertise to reach their career goals. The key to succeeding is to develop your plan for the future and work towards getting that accomplished. Having a clear vision of the direction of your career in the coming years will help you to tailor the skills you need to acquire to reach your personal objectives.

How to Find a Job

Kelleen Flaherty, MWC, CMPP, Adjunct Assistant Professor, University of the Sciences in Philadelphia Graduate Biomedical Writing Programs, Jamison, PA

There are a variety factors associated with finding a job in medical writing. Experience, obviously, is of paramount importance, but so is education, certification, specialization in a specific area of science, and the ability to promote yourself. New writers particularly struggle with breaking into the field (even with a background in a therapeutic area). There are a variety of ways, however, to both look for and prepare for finding a job. Not everyone is aware of how to look, where to look, the importance of networking, the importance of preparation, and how the process works in general.

I Have the Abstract: How Do I Make it into a Poster?

Michelle E. Stofa, Research Communications Manager, Nemours/Alfred I. duPont Hospital for Children, Wilmington, DE

To effectively promote and communicate results of research presented at a meeting, a poster must be organized in a clear, easy-to-read, and attractive format. This roundtable will discuss how to develop a poster from an abstract and will include tips about text, figures, and overall format to create a well-organized and attractive presentation. It will also include exercises to help attendees recognize how information is best presented, as well as 'short-cuts' to make creating a poster and manipulating its components easier for the presenter.

Importance of Mentoring in a Decentralized Work Environment

Vicki Foster, Principal Medical Writer, PAREXEL International, Raleigh, NC

In the increasingly decentralized work environment of medical writing, the importance of a mentoring partnership for new writers cannot be overstated. A mentoring program for new writers functions primarily to promote learning, share knowledge, and guide the new writer's career development; however, there are other benefits to this relationship, which transcend the obvious. A mentor, functioning as teacher, advisor, advocate, and general point of contact in the largely solitary decentralized work setting, not only

educates the new writer, but also provides a familiar contact in an environment consisting primarily of electronic communication. Thus, the mentor provides a safe and secure atmosphere for the new writer to ask questions, share experiences, and obtain candid feedback. Additionally, mentors and mentees from different regions have the opportunity to gain enhanced cross cultural awareness and understanding. The potential to form long term relationships during a mentoring partnership can facilitate a sense of community and teamwork. The benefits of mentoring extend to writers at all levels, contributing to the career development and enhanced knowledge of both mentor and mentee. This roundtable discussion will focus on how mentoring can facilitate the development of skilled writers, contribute to a positive learning environment, and foster connectedness in a decentralized working environment.

Inalienable Rights: Major Health Organizations' Response to Health Disparities and the Impact on Medical Communicators

Tamara Ball, MD, Freelance, Asheville, NC

Bob Kirsch, MA, Freelance, Ossining, NY

Although medicine has long focused on genetics and behavior, there is a 3rd arm of risk, the social determinants of health care, that includes socioeconomic status, race, health literacy, environment, etc. Leading organizations and leading research funders— including the National Academy of Medicine, American Heart Association, CDC, NIH, and AMA— are pushing to address health disparities and the social determinants of health in ways that change medical practice, public health practice, public policy, and modes of collaboration among medical and nonmedical entities. These changes will affect the day-to-day work of AMWA members, and it behooves us to understand these initiatives and learn best practices for addressing health disparities. This is pertinent to writers working on medical and public education, health policy, training materials, hospital publications, scientific publications, grant applications, journalists, publication writers, and other AMWA members. This roundtable will provide a brief introduction to changes occurring and opportunities for writers due to these changes. In addition, participants will be encouraged to share their experiences with addressing disparities. An annotated handout highlighting premiere and impartial sources will be provided.

Tips for Studying to Take the MWC Exam

Brian Bass, MWC, President, Bass Global, Inc., Fort Myers, FL

You may have seen the announcement that the Medical Writer Certified (MWC) Examination will now be administered in June and December each year via computer-based testing at IQT testing centers near major cities across the globe. The Medical Writing Certification Commission (MWCC) has also released a new Applicant and Candidate Handbook and Study Guide. The table discussion will focus on the best ways for candidates to prepare for the exam.

NIH Grant Mechanisms and Resources for Grant Writers and Editors

Meagan Ramsey, Grant Development Specialist, Michigan Institute for Clinical & Health Research, University of Michigan, Ann Arbor, MI

The National Institutes of Health (NIH) is the primary federal granting agency for biomedical research. Grant writers and editors should have a solid working knowledge of NIH funding mechanisms, funding opportunity announcements, and policies to help increase chances of funding success. We will review different types of NIH grant mechanisms (e.g., research grants, career development awards, program projects and center

grants) and discuss opportunities for grant writing and editing across the mechanism spectrum, specifically discussing how grantsmanship strategies may differ by grant mechanism. We will then discuss how to stay up to date on the constantly evolving NIH policies that could impact grant writers and editors. In addition, we will share helpful NIH resources that writers and editors can use to enhance their NIH knowledge. Discussion topics will be summarized in a resource sheet that participants can refer to when working on NIH grants. This roundtable will provide an opportunity for both seasoned and new grant writers and editors to learn from each other through sharing their NIH knowledge, resources, and tips and tricks they implement to improve the quality of various types of NIH grant applications.

Numbers, Meet Letters: CDISC for Medical Writers

Christine Quagan, CC, Senior Medical Writer, PROMETRIKA, LLC, Cambridge, MA

The ability of medical communicators to provide high-quality information depends on the collection of accurate data. Over the last two decades, data collection and formatting have become more consistent through the adoption of standards. The most prominent data standards organization is the Clinical Data Interchange Standards Consortium – CDISC. Medical writers, especially regulatory writers in biopharma or contract research organizations, may have heard the acronyms "CDISC," "SDTM," and "ADaM" in project team meetings that include clinical data managers, database programmers, and biostatisticians. What are the CDISC standards? Do they affect medical writing at all? This roundtable will introduce medical writers to the work of CDISC and relate its work to the flow of information in clinical research.

The Ups and Downs of Working From Home

Gail Flores, PhD, President and Principal Medical Writer, Encore Biomedical Communications, Encinitas, CA

Discussion may include separating life from work; working at home with children and/or a partner; managing distractions; maintaining a professional facade; handling isolation; knowing when to stop working; healthy and unhealthy habits; and considering renting offsite space.

Writing Clubs: What, Why, How, and More

Barbara Gastel, MD, MPH, Professor, Texas A&M University, College Station, TX

Writing clubs (groups of people who confer periodically about their writing) can increase members' productivity, improve their writing, and decrease their writing-related stress. This roundtable will introduce models of face-to-face, online, and hybrid writing clubs. It also will discuss ways that medical communicators in freelance, academic, and other settings can use writing clubs to foster their own and others' writing. Finally, it will explore factors to consider when establishing and conducting a writing club. Participants will have opportunity to ask questions, exchange experience, and share advice.

9:00–10:00 AM **Education Sessions**

As You Wish. Fall in Love with Word, Again or for the First Time

Kelly Crossett, Quality Reviewer and Publishing Specialist, Whitsell Innovations, Inc., Cary, NC

Fall in love with Word? Inconceivable! Well, perhaps not. Maybe we just need to look beneath the surface to find our true love of Word. This presentation explores the "behind-the-scenes" capabilities of Word. Word tries so hard to help us in ways that are not always helpful. It creates and updates our styles; automatically applies styles; corrects our "mistakes;" numbers our headings, tables, and figures; and critiques our

spelling and grammar (all without asking!). Unfortunately, this can lead to unhelpful and perplexing results. Come and explore ways to enhance Word's helpfulness through better direction for styles, tables, autocorrect, numbering, document properties, search/replace, and more. The session includes suggestions for troubleshooting issues with these same capabilities. Discover options to customize Word to be the writing and editing companion we have all wished for. In the end, we should all be able to respond to Word's helpful suggestions with "As you wish."

Targeted Level of Experience: Mid-career (3-6 years)

Leaping from Desk to Podium: Essential Presentation Skills for Medical Writers

Angela Johnson, MSE, PMP, RAC, Assoc Director Regulatory & Scientific Affairs, CTI, Cincinnati, OH

Medical writers are experts in building consistent, compelling content for medical and clinical documents. The same skills that you have developed for writing can also be translated to help you become a more effective presenter and speaker, skills increasingly in demand for medical writing projects that involve presenting to sponsors, investigators, and regulatory agencies. The ability to translate your written word to effective oral presentations will also serve you well in modern media applications, such as using teleconferences, making videos, and contributing to oral education materials --or even in landing your next job or client. Do you know how to effectively use arrangement, triads, and narrative arcs? Can you choose the perfect words when you write? A few simple strategies will have you on your way to speaking as professionally as you write. This presentation is designed to overview case studies of presentations given by medical-regulatory and medical communications writers and best practices for preparing to speak, enabling you to utilize the real world experiences of your colleagues to translate your writing skills into effective oral presentations. Using these strategies, you will be able to confidently prepare and deliver presentations relevant to medical writing.

Targeted Level of Experience: All Levels of Experience

Large, Complex Freelance Medical Writing Projects: Best Practices

Debby Berlyne, PhD, President, Deborah Berlyne, Inc., Rockville, MD

Tom Drake, MA, CMPP, Director, Global Outcomes Group, Inc., Reston, VA

This session will explore the challenges of large, complex projects involving multiple freelance writers, editors, graphic experts, and project managers and will identify best practices for managing these projects to produce successful written deliverables. Topics covered will include managing client expectations, selection and supervision of multiple freelancers with varied responsibilities, communications, shared authorship, and use of technology to support resource sharing and version control. The session will include case studies with lessons learned and opportunities for participants to share and discuss their own experiences. Participants will learn dos and don'ts for initiating, managing, and completing these types of projects. They will also gain skills in leveraging these opportunities to build and deepen relationships with clients, collaborate with other freelancers, and expand their medical topic knowledge.

Targeted Level of Experience: All Levels of Experience

A Practical Introduction to the Clinical Evaluation Report (CER) and How to Make It Compliant with MEDDEV Rev 4

Thomas Stone, JD, CER Manager, Global Medical Writing and Translation, Kent, WA

James Vinton, PharmD, CER Lead Writer, Global Medical Writing and Translation, Kent, WA

This presentation will briefly introduce the basic components of the CER and focus on the new requirements mandated by MEDDEV Rev4 and how these changes affect the scope and purpose of the document from a practical standpoint. Topics discussed will include a short introduction to CERs, the elements of the State of the Art section, claims matrices, plans for post-market surveillance and clinical follow-up, and writing strategies for successful Rev4 submissions.

Targeted Level of Experience: New to the Field (less than 3 years)

Precision Medicine: The Impact on the Regulatory Landscape

Teresa McNally, Medical Writer and Consultant, Whitsell Innovations, Inc., Chapel Hill, NC

Christine Flees, MD, Medical Writer and Consultant, Whitsell Innovations, Inc., Chapel Hill, NC

The field of precision medicine is growing exponentially and is impacting drug discovery, development, and clinical treatment paradigms. The transition from a one-size fits all approach to patient care to one that takes into account a patient's environment, lifestyle, and particularly their genotype, has been a priority for the FDA since the 1990s. The 21st Century Cures Act of 2016 encouraged the FDA to develop new regulatory approaches for the oversight of genomic technologies as part of a Precision Medicine Initiative. This initiative seeks to identify genetically-based drivers of disease in order to develop new more effective treatments. As a result, many drugs now have actionable guidance in their labeling that specifically defines the respective indications, contraindications, and direct dosing to specific populations, which are based on genomic and other data. This presentation will highlight the past, present, and future impact of precision medicine on regulatory authorities and on public health, both nationally and internationally.

Targeted Level of Experience: All Levels of Experience

9:00 AM–12:00 PM AMWA Workshops (***additional fee***)

WS-40 Assessing and Communicating the Benefits and Risks of Medicines

Lawrence Liberti, PhD, RPh, RAC, Executive Director, CIRS-Centre for Innovation in Regulatory Science, Holland, PA

Benefit-risk assessment of medicines is invaluable to patients, physicians and drug developers and therefore to medical writers, too. Clearly described BR reporting involves a balanced analysis and the lucid communication of this multi-factorial concept.

At the end of the workshop, participants will be able to

- Describe the concepts that underlie techniques to assess the BR of medicines.
- Compare benefit-risk approaches used by various stakeholders.
- Understand the concepts that underlie the construction of a benefit-risk assessment

WS-41 Summarizing Clinical Safety Data for a New Drug Application

Marijke H. Adams, PharmD, PhD, President, MH Adams & Associates, Inc., Davie, FL

Jennifer Bridgers, MS, MWC, Managing Medical Writer, Merck and Co., Inc. Raleigh, NC

As a regulatory writer, it is critical to be clear on the difference between the high-level

integrated safety analysis versus the detailed summary of clinical safety, two very distinct modules of the new drug application (NDA).

At the end of the workshop, participants will be able to

- Identify the applicable Code of Federal Regulations (CFR) sections, FDA Guidances, and ICH Guidelines associated with the Summary of Clinical Safety (SCS) and Integrated Summary of Safety (ISS).
- Describe the similarities and differences between the SCS (a CTD summary) and the ISS (specific to the US).
- List the basic source documents needed to write these 2 regulatory documents.
- Formulate a strategy to plan and write these documents within a submission team

WS-42 Preparing CME Materials: Concepts, Strategies, and Ethical Issues

Eve Wilson, PhD, ELS, CHCP, Medical Writer/Editor & CME Consultant, MORPHOS Medical Education, Bowie, MD

Marcello Morgan, MD, MPH, Scientific Director, Medscape Education, New York, NY

Continuing medical education is integral to helping health care professionals achieve excellence in patient care, and an outstanding opportunity for medical writers who understand the ins and outs of this field.

At the end of the workshop, participants will be able to

- Demonstrate the need and importance of CME for improving clinician practice and patient care
- Identify stakeholders and their roles and responsibilities in CME program development and oversight
- Describe the process of content development and outcomes measurement for CME activities

WS-43 Usage: Choosing the Right Word for the Job

Stephen N. Palmer, PhD, ELS, Manager and Senior Scientific Medical Writer, Texas Heart Institute, Houston, TX

Minimize miscommunication with clear, concise writing. Selecting the precise word to convey vital and complex information is key, and this workshop provides what medical communicators need to do it right.

At the end of the workshop, participants will be able to

- Formulate clear, unambiguous word choices in his or her medical writing.
- Identify and correct jargon and inefficient wording.

WS-44 Effective Paragraphing

Helen Hodgson, PhD, Emeritus Professor of Communication, Westminster College, Salt Lake City, UT

Effective paragraphing is fundamental to successful writing. Master this skill following a systematic approach to improve your writing by clearly analyzing text and pinpointing key findings.

At the end of the workshop, participants will be able to

- Identify the elements that make a paragraph clear, readable, and effective in emphasizing important points
- Write paragraphs--or edit them--to achieve these elements
- Employ specific techniques to correct paragraph flaws

WS-45 Health Economics for Medical Writers and Editors

Bart Harvey, MD, PhD, Associate Professor, Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada

Learn about the principles of health economics, including trial design, cost determination, sensitivity analysis, discounting, and analytic perspective – all in a simple, nonmathematical manner.

At the end of the workshop, participants will be able to

- Explain the following terms in plain language: Efficiency, Opportunity cost, Outcomes/consequences, Time horizon, Costs, Sensitivity analysis, Discounting, Inflation, Cost-benefit analysis, Cost-effectiveness analysis, Cost-utility analysis, Cost-of-illness
- Describe key health economic principles and analytic approaches in a non-mathematical manner
- Describe issues relevant to the preparation and review of health economic analyses and publications
- Describe important issues relevant to the presentation of health economic reports and abstracts for professional and lay audiences.

10:00–10:30 AM **Beverage Break**

10:30 AM–12:00 PM **Education Sessions**

The Power of Story in Science Communications

Cynthia Lollar, MFA, MAA, Digital Content Manager, Web & Social Media Branch, Office of Communications & Public Liaison, National Cancer Institute, Rockville, MD

James Mathews, MA, Associate Director, Office of Cancer Content, Office of Communications & Public Liaison, National Cancer Institute, Rockville, MD

You know the science you want to communicate, but do you know the story? Can you connect your audience with what is heartfelt and human about the facts? In this session, you'll learn what makes story content different from information content, and why story is so important in today's digital communications ecosystem. You'll also learn some basic narrative nonfiction techniques and when they can be used most effectively.

Targeted Level of Experience: All Levels of Experience

Basics of Pharmacovigilance Writing

Mari Welke, Director US Operations, Trilogy Writing & Consulting, Durham, NC

This session will include an overview of various types of documents generated for pharmacovigilance (PV) purposes, examples of similarities and differences from writing for CSRs, CTDs, and other clinical development documents, and examples of how to approach a PV document from a writer's perspective. Explore what could be the role of a medical writer in a PV capacity, offering exploration of career choices in writing that may not yet be as well known. There will be a presentation and time for Q&A where participants can discuss their experiences and share ideas.

Targeted Level of Experience: All Levels of Experience

The Opioid Crisis

TBD

Networking for Introverted Freelancers: How to Get Better Results with Less Stress

Lori De Milto, MJ, Lori De Milto Writer for Rent LLC, Sicklerville, NJ

Genevieve J. Long, PhD, Genevieve J. Long, PhD, PC, Hood River, OR

As a freelance, networking can help you get new clients, build relationships with clients,

prospects, and colleagues, and better manage your business. But if you're an introvert like many freelances, leaving the safe cocoon of your office to go to a networking event is stressful—or even scary. This session will highlight the networking attitude that makes networking much easier and much more effective. We'll also cover how to build a strategic network that will maximize networking benefits while reducing effort, and provide practical tips on how to network effectively. We'll give you a chance to practice what you learn with some hands-on networking.

Targeted Level of Experience: All Levels of Experience

Tools to Thrive in a Digital World

Monica Nicosia, PhD, Independent Medical Writer, Nicosia Medical Writer LLC, Bryn Mawr, PA

Kathy Boltz, PhD, Owner and Principal Medical Writer, On Point Scientific, LLC, Phoenix, AZ

This session will help new and veteran self-employed medical communicators identify technology (ie, hardware, software, smartphone apps, online/cloud-based services) to help them run their small business. We will talk about the hardware and software we use at our offices and when traveling. Topics that we will discuss include: data storage and access, from the concept of the "cloud" to solutions for sharing files and backing up data; screen sharing solutions for remote work; travel apps, laptop considerations, and network access on the road to help ease travel frustrations; digital solutions for accounting, invoicing, time tracking, audio recording, transcription, and reference management; and how to make a best effort to protect your identity and data through practices that include encryption and passwords. Also, we will describe considerations for choosing email and website providers. Throughout the session, we will illustrate lessons we learned when we faced problems resolved by or caused by tech. The session dynamics and use of an online polling tool will encourage audience participation. Come prepared to ask questions and share your experiences.

Targeted Level of Experience: All Levels of Experience

Jam Session for Mid-Career Managers

TBD

12:15–1:45 PM **Networking Lunch with the Exhibitors**

2:00–3:30 PM **Education Sessions**

You Can't Possibly Understand How I Feel (Because I Won't Tell You): The Riddle of Feedback

Robin Whitsell, BA, BPh, President, Whitsell Innovations, Inc., Chapel Hill, NC

When enjoying a meal with friends, you expect them to tell you when you have broccoli in your teeth, a splash of salsa on your shirt, or something stuck to the bottom of your shoe. So why in a work environment is the metaphorical 'little green tree' lodged in your canine tooth until you go to the bathroom? Researchers have found that people who court feedback do better personally and professionally, yet feedback conversations often feel fraught to the receiver and the giver. And, as a wise medical writer once told me, we all like to assume that we are doing well because someone would say something if we weren't … except they don't. How can we shift the feedback conversation? How do we create a feedback-rich environment and culture? How do we turn feedback into something as drama-free as, "Hey, you've got something in your teeth, there"? This interactive session will explore how we can all benefit from inviting and providing feedback. Audience members will participate by providing horror stories, success stories, and solutions. Together, we will identify specific strategies for giving feedback and discuss what is

holding us back. Attendees will leave with a list of people to whom they will deliver and from whom they will invite to a feedback conversation.

Targeted Level of Experience: All Levels of Experience

Responses to Regulatory Authorities: Measure Twice–Cut Once

Julia Forjanic Klapproth, President and Senior Partner, Trilogy Writing & Consulting, Durham, NC

Art Gertel, Principal, MedSciCom, LLC, Lebanon, NJ

Medical writing support on a submission dossier does not end when the dossier goes out the door to the authorities. Prior to submission, and during the dossier review process, the regulatory agencies may, and generally do, have questions to be answered by the sponsor. What role can a medical writer play in this process? How can we, as writers, help teams plan for, and efficiently prepare, answers to these questions? What is the difference in the process between the EMA centralized procedure and an FDA submission? This session will provide answers to these questions and will highlight tools and tips for coordinating the activities involved. Participants should be familiar with writing clinical dossiers. After a presentation by the 2 speakers, there will be a Q&A session where the participants can discuss their experience and share ideas on optimizing the process.

Targeted Level of Experience: Advanced (6 or more years)

Using a Focused Authoring Strategy to Create a Message Driven Deliverable

Kimberly Jochman, PhD, Principal Medical Writer, Merck & Co., Apex, NC

Elizabeth Brown, MS, PMP, Managing Medical Writer, Merck & Co., North Wales, PA

When writing a deliverable, be it a protocol, clinical study report, new drug application, investigator's brochure, poster, or peer-reviewed manuscript, developing a document that focuses on the key messages is imperative. It is especially important to ensure that documents are easy to read and interpret in today's Medical Writing environment, with increasing study complexity, overwhelming amounts of data, and electronic approaches to document authoring, submission, and review. In this interactive, hands-on session, learn how to get out of the way of the data and implement various techniques for focusing on the story in your writing in a non biased way. Discussion and activities will focus on the following: setting up your story succinctly and efficiently to meet the needs of your target audience, developing messages to focus on the data that support the story, recognizing and avoiding bias when telling the story, and integrating effective organizational elements to ensure your reader stays focused and engaged.

Targeted Level of Experience: All Levels of Experience

Panel Discussion on Predatory Journals

Panelists TBD

Medical Writing Professionalism: Competency Modeling, Application, and Examination

David B. Clemow, PhD, MWC, Advisor Scientific Communications Information Strategy, Eli Lilly and Company, Indianapolis, IN

Medical writers and scientific communication teams often lack a professional guide providing details of the professions needed competency; if they have a technical ladder there is not always guidance on how to apply it successfully. This session will describe the content of the 2017 Drug Information Association Medical Writing Competency Model, how medical writers and their supervisors can apply the content of the model to their professional development, and how the knowledge, skill, and abilities making up the model's functional domains can be used for testing medical writers competency. Additionally, the AMWA Medical Writing Certification (MWC®) will be discussed.

Targeted Level of Experience: All Levels of Experience

Jam Session for Early Career Freelances

Andrea R. Gwosdow, PhD, President, Gwosdow Associates Science Consultants, LLC, Arlington, MA

Theresa E. Singleton, PhD, Owner and Principal Scientific Writer, Singleton Science, LLC, Beverly, MA

If you're an early career freelance with less than 10 years of experience, you won't want to miss this interactive session. The early years of freelancing are often the most challenging with business decisions such as what type of business structure to set up, how to find and keep clients, contracts, collecting payments, estimating projects accurately, whether to bring on subcontractors and the like. We'll cover these and any other questions that arise in this open discussion of freelance business topics. Come discuss your successes and toughest problems with other early career freelances and make new connections to continue the conversations once you're back home.

Targeted Level of Experience: Mid-career (3-6 years)

Jam Session for Seasoned Freelances

Brian Bass, MWC, President, Bass Global, Inc., Fort Myers, FL

When accomplished musicians jam, their combined talent, energy, and experience make a special kind of synergy. A similar kind of magic happens when seasoned freelances get together to discuss their thoughts, ideas, concerns, and challenges with peers of equal or greater experience. These rare gems of collegial conversation and commiseration happen spontaneously and usually unpredictably. (Often they involve a glass of wine.) This no-holds-barred session will provide a supportive space for freelances who have a minimum of 10 years of continuous and current freelance experience to wrestle their demons and share their experiences. Whether you emerged bloodied and bruised, valiant, or victorious, we all have stories to tell, and we can all learn from and teach each other. Now in its third year, this session is lightly structured to permit a free flow of discussion without getting stuck for too long on a single topic.

Targeted Level of Experience: Advanced (6 or more years)

3:30–4:00 PM	**Beverage Break**
4:00–5:00 PM	**General Session with Alvarez Award Address** This session features the presentation of the Alvarez Award and address by Robert Califf, MD, MACC, Professor of Cardiology at the Duke University School of Medicine and former Commissioner of the US Food and Drug Administration.
5:00–6:00 PM	**Happy Hour in the Exhibit Hall** Join other attendees for a happy hour with light snacks, cash bar, and prize drawings before enjoying an evening out on the town or just relaxing.
6:30–7:30 PM	**Exhibitor Teardown**
6:30 PM	**Meet in Lobby to depart for Dine Arounds** These popular dining out events are a great opportunity to spend some quality time with friends and colleagues outside the conference and sample the tastes of DC. Attendees will be able sign up onsite for a dine-around group and explore the area.

SATURDAY, NOVEMBER 3

7:30–8:30 AM **Yoga at Your Desk: Stretch, Breathe, and Relax**

Mary Kemper, BS, Medical writer/yoga instructor, Mayfield Clinic/Glia Media, Cincinnati, OH

During this 1-hour class for all levels, participants will be guided through basic yoga stretches to release neck and shoulder tension, and wrist and fingers strain. Session will include classic yogic eye exercises, natural wave-like flows to free the spine, and movement to free hips to toes. Participants will experience rhythmic breathing practices for calm and creativity, dynamic concentration, and relaxation with a guided meditation. Enjoy this TriYoga practice combining poses, rhythmic breathing and mindfulness. Class is interspersed with yogic philosophy and health trends for yoga's increasing popularity in the workplace. Question-and-answer period concludes this relaxing session.

Targeted Level of Experience: All Levels of Experience

9:00–10:00 AM **Education Sessions**

Fit for Freelance: Home Wellness Health Secrets

Reggie Wilson, MS, Principal, Wilson Medical Writing LLC, Naples, FL

Get the tools to stay fresh on long work days, save your posture, and prevent and reverse sneaky weight gain during your work-from-home career. Learn the tricks of a Certified Worksite Wellness Program Manager and freelance medical education company owner.

Targeted Level of Experience: All Levels of Experience

If You Can Write a Grant, You Can Write a Pitch Deck

Angela N. Johnson, Assoc Director Regulatory & Scientific Affairs, CTI, Cincinnati, OH

Biomedical venture firms and large corporations often seek to acquire promising new pharmaceuticals and devices. On the other side of the coin, small biotech firms often need funding for their research and development efforts, and must frame its significance for investors. These organizations communicate the science, regulations, and technology in a concise package called the 'pitch', which is typically summarized in a 'pitch deck' comprised of both science and business strategy information for a biomedical product under development. The pitch deck presents a compelling narrative about product development to diverse audiences of scientific and lay reviewers. Like an effective grant application, an effective pitch deck can mean that a company is able to invest in research and development, and ultimately accomplish their organizational goals. Preparing venture pitch documents quite frequently makes the medical writer the center of a collaborative multidisciplinary team. Many of the same strategies used in grant applications can be employed to build corporate venture pitches, but the audience for these documents is very different. This session is designed to compare and contrast grant versus corporate pitch writing, overview essential elements of the pitch deck document, and prepare medical writers to take on lucrative pitch document projects.

Targeted Level of Experience: Mid-career (3-6 years)

27 Tips for Efficiently Writing Scientific Publications

Katherine Molnar-Kimber, President, KMK Consulting Services, Kimnar Group LLC, Worcester, PA

Efficiently writing a scientific or clinical manuscript helps you provide the "on time, on target, and on budget" deliverable to your clients and reduces your stress. A writer of effective scientific publications clarifies any potential inconsistencies and loose ends that peer reviewers search for during their review. Numerous reporting guidelines exist for complex methods and types of clinical studies. I will also present strategies for annotating references, and improving the flow of ideas in manuscripts. Ever wonder which data or methods belong in supplementary files? Should the results section include a rationale for sets of experiments? Should the results section change when the manuscript is being submitted to a journal with methods after the discussion? How to address contradictory published data or articles? Where to cite a recently published article that shows similar or opposite results? How do your suggestions compare to contributions of an author versus acknowledged writer (ICMJE guidelines) versus peer reviewer? Examples of common mistakes that scientists and clinicians make in sentence structure will be paired with several approaches for fixing them. This interactive session will provide a checklist and various examples to illustrate these tips.

Targeted Level of Experience: All Levels of Experience

Accelerating Drug Development through Protocol Harmonization: TransCelerate's Common Protocol Template and the Technology Enabled Addition

Mitzi Allred, Director, Merck & Co, North Wales, PA

Increasing complexity in protocols makes implementation and reporting difficult and the lack of consistency compounds the issue. A significant opportunity exists for an improvement in quality and simplification through protocol harmonization, as all protocols rely on the same health care and regulatory infrastructure for design, review and implementation. This session will explore the collaboration between TransCelerate, FDA, and NIH to achieve alignment on a common protocol structure. It will also describe how TransCelerate's CPT enables use of clinical data standards, as well as next steps towards automation and data traceability from protocol through to downstream processes.

Targeted Level of Experience: All Levels of Experience

Challenges for Biologic and Biosimilar Development: a Chemistry, Manufacturing, and Controls (CMC) perspective

Teresa Chu, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc., Chapel Hill, NC

Mary Ellis Bogden, BA, Senior Writer & Manager, Whitsell Innovations, Inc., Chapel Hill, NC

Medical writers may not have extensive experience authoring Chemistry, Manufacturing, and Controls (CMC)-related sections of Investigator's Brochures or Modules 2 and 3 of an Investigational New Drug Application (IND)/Biologics License Application (BLA), however, these sections are frequently encountered when working on submission-related documents. CMC includes processes that chaperone an investigational biologic to the first-in-human study and processes that remain ongoing during all phases of clinical development. Manufacturing and characterization processes of biologics are more complex than those of small molecule drugs. In biologics, "the product is the manufacturing process itself" and considerable resources are spent early in development on the control of this process. Given the inherent variability of the manufacturing process for biologics, developing biosimilar products that must show similarity to the innovator (or reference) biologic comes with unique challenges. More emphasis is placed on CMC-related

activities than on clinical studies as the development of biosimilars involves extensive characterization with ancillary analytical tools. In this session, we will embark a journey into the CMC world and discuss the challenges for biologic and biosimilar development. We will also present CMC issues that can halt a clinical study or delay the BLA.

Targeted Level of Experience: Mid-career (3-6 years)

9:00 AM–12:00 PM **AMWA Workshops (*additional fee*)**

WS-50 Writing a Protocol in Compliance with the ICH Guidelines

Jennifer Bridgers, MS, MWC, Managing Medical Writer, Merck and Co., Inc. Raleigh, NC

Every clinical investigation kick-starts with the study protocol. Crafting a high quality, immaculate protocol substantially increases your chance of gaining marketing approval, making it an indispensable skill for medical communicators.

At the end of the workshop, participants will be able to

- Identify the purpose and audience for the protocol
- Understand the content and outline of a protocol
- Analyze the differences between objections and endpoints
- Use resources to write an effective protocol
- Evaluate different ways to manage the review process

WS-51 Summarizing Clinical Efficacy Data for a New Drug Application

Marijke H. Adams, PharmD, PhD, President, MH Adams & Associates, Inc., Davie, FL

Thomas M. Schindler, PhD, Head Medical Writing Europe, Boehringer Ingelheim Pharma GmbH & Co.KG, Biberach ad Riss, Germany

As a regulatory writer, it's critical to be clear on the difference between the high-level integrated efficacy analysis versus the detailed summary of clinical efficacy, two very distinct modules of the new drug application (NDA).

At the end of the workshop, participants will be able to

- Identify the applicable Code of Federal Regulations (CFR) sections, FDA Guidances, and ICH Guidelines associated with the Summary of Clinical Efficacy Safety (SCS) and Integrated Summary of Safety (ISE).
- Describe the similarities and differences between the SCE (a CTD summary) and the ISE (specific to the US).
- List the basic source documents needed to write these 2 regulatory documents.

WS-52 Writing and Designing Materials for Patient Education

Genevieve Long, PhD, Freelance Medical Writer - Patient Education, Health Literacy, and Marketing Specialist, Portland, OR

In the Google era of health misinformation, writing for patients has never been more challenging. This workshop will teach you how to reach lay audiences with accurate and understandable information.

At the end of the workshop, participants will be able to

- Identify the different types of patient education materials
- Explain the importance of writing and designing materials specifically for patients and other members of the public
- Understand the principles behind writing and designing materials for patient education.
- Begin developing patient education materials that audiences can understand and use, and have some basic resources to find help

WS-53 Statistics for Medical Writers and Editors

Bart Harvey, MD, PhD, Associate Professor, Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada

Medical writers and editors with a good understanding of statistics are comfortable, confident, competent, and skilled in interpreting and reporting statistical methods and results—the "story" behind the data.

At the end of the workshop, participants will be able to

- Identify the type of data used to measure a variable.
- Summarize categorical and continuous data with appropriate descriptive statistics, and interpret these descriptive statistics.
- Analyze 95% confidence intervals and get a feeling for how they are calculated.

WS-54 Introduction to Cancer Pharmacology

Sunil Patel, MS, Oakland, CA

Gail Flores, PhD, Principal Writer, Encore Biomedical Communications, Encinitas, CA

Whether you already write in oncology or want to get started, this workshop covers the basics of how cancer works and how cancer drugs work to fight it.

At the end of the workshop, participants will be able to

- Compare differences between normal cells and cancerous cells that allow for targeted therapies.
- Describe the mechanisms of several common cancer drugs.

10:00–10:30 AM **Beverage Break**

10:30 AM–12:00 PM **Education Sessions**

Regulatory Compliance Fundamentals for Promotional and Educational Writing In Life Sciences

Ilyssa Levins, President and founder, Center for Communication Compliance (CCC), New York, NY

The U.S. regulatory environment affects the development of materials prepared and submitted by medical communicators. New FDA guidances and fundamental requirements must be understood to ensure compliance. The sessoin will begin with a mini quiz to engage participants in the rules and regulations. An overview of the new FDA philosophy and guidances will be presented along with warning letters to illustrate the do's and don'ts for medical writing. Following the teaching, participants will be asked to take a quick fun quiz to confirm that they understood the material. Participants will also be given a free resource (mobile app) that provides easy access to government and industry sites

Targeted Level of Experience: All Levels of Experience

Your Freelance Brand: How to Stand Out in a Sea of Freelances

Lori De Milto, Lori De Milto Writer for Rent LLC, Sicklerville, NJ

Kathleen Labonge, MBA, Write Point Editing Solutions, Greensboro, NC

Eva Stabenow, MA, Wordplay Translations, LLC, Nashville, TN

Having a brand lets you stand out in the sea of freelances that clients can choose from and makes marketing your freelance business much easier. Yet, most freelances don't have a brand. This session will provide an overview of branding and highlight the key ingredients in a freelance's brand. Using case studies of compelling freelance brands, we'll provide practical tips on how to develop your brand and examples of how we developed our brands. We'll also cover how to use your brand to attract more clients.

Targeted Level of Experience: All Levels of Experience

The Writes and Wrongs of Publication Ethics

Chantelle Rein-Smith, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc., Hillsborough, NC

Recently, there has been a push towards increased transparency when reporting the results of clinical trials in manuscripts or preparing medical publications. Although updated guidelines on transparency, appropriate disclosures, and publication ethics have been introduced to our industry in recent years, many sponsors and writers may not be familiar with the details of these guidances or know how or when to apply them. In this presentation, we will discuss existing guidelines aimed at ensuring proper publication ethics when preparing medical and/or clinical trial publications (eg, International Committee of Medical Journal Editors [ICMJE] guidelines, Good Publication Practice [GPP]-3 guidelines) and will learn to identify potential violations in ethical conduct. We will also discuss the role of the medical writer in raising awareness of publication ethics among all participants in the preparation of publications. Anyone seeking to understand ethical publication guidelines and how they relate to different functional roles when preparing medical publications are encouraged to attend.

Targeted Level of Experience: All Levels of Experience

Think and Communicate Visually

Lori L. Alexander, MTPW, ELS, MWC, President, Editorial Rx, Inc. North Ft. Myers, FL

Cynthia L. Kryder, MS, Medical Communications Consultant, Phoenixville, PA

Jia You, Interactive Graphics Editor, Science Magazine, *Washington, DC*

The use of images to convey information continues to grow exponentially, and with good reason. Visual communication offers important advantages over text: delivery of a clear, unified message, ability to relay a message quickly, and better audience retention of content. Medical communicators tend to think of their expertise as writers, but to stay current and effective, they must learn to think—and communicate—more visually. Attendees will learn about the latest trends in visual communication, including visual abstracts, infographics, and interactive graphics. Speakers will describe the process for thinking visually, discuss tools for creating infographics, and describe best practices for choosing visualizations that are appropriate to the data. Attendees will have the opportunity to put their new knowledge to work with exercises for small-group discussion on how to present information as an infographic and to determine the most appropriate type of data visualization.

10:30–11:15 AM **Dissecting the Critical 'Specific Aims' Page**

Madison Hedrick, MA, Scientific Writer and Editor, Science Communication Group, University of Arkansas for Medical Sciences, Little Rock, AR

For many NIH reviewers, one page can make or break the entire grant application—the Specific Aims page. In this session, we will overview the elements of the Specific Aims section, and show before and after examples. These examples will show how incorporation of the tools presented in the workshop can significantly change the impact of the Aims page. I will then provide information and statistics on the Specific Aims page and its importance in terms of the grant application. This session will also include a group assignment using hands-on techniques to address how to incorporate the new information from the workshop and "Specific Aims worksheet" into a highly effective Specific Aims page.

Targeted Level of Experience: All Levels of Experience

11:15 AM–12:00 PM **NIH Biosketch - Make It Work for You**

DeAnn Hubberd, MA, PTW, Associate Director, University of Arkansas for Medical Sciences, Little Rock, AR

Attendees will learn best practices for constructing and editing biosketches. This will include the correct format for the biosketch, a description of each section and the information that belongs there, the purpose for and importance of the Personal Statement and Contributions to Science sections, along with tips for writing these sections and key points to highlight in these sections. During the presentation, we will analyze some examples of ways to approach writing the Personal Statements and Contributions to Science sections, and we will discuss how to customize these sections for each grant application and how to approach the Contributions to Science sections for different stages of investigators. The presentation will also include a brief description of SciENcv (Science Experts Network Curriculum Vitae), a web-based system that walks researchers through assembling their biosketches for federal grant applications, and a discussion of how this system can be used to streamline standard biosketch information and reduce administrative burden associated with grant submission and reporting requirement.

Targeted Level of Experience: New to the Field (less than 3 years)

12:15–1:45 PM **Roundtable Topic Discussions with Lunch (*additional fee*)**

Benefits and Challenges of Specialization

Jessica Yen, MS, Grant Writer & Academic Editor, JHY Communications, Portland, OR

Specializing in one or more niche markets can offer many career benefits. It's easier to develop expertise, increase efficiency, and pick up on nuances that generalists might miss. It can also increase your earning potential through higher rates and referrals, as you become known as the "go to person" for specific topics. Although some medical writers prefer to remain generalists, others may not have identified possible niches or may not know how to pursue these opportunities. In this round table discussion we will discuss the benefits and challenges of specializing, including in markets commonly overlooked by medical writers or that may not seem profitable. We will also discuss ways to mine prior employment history, professional interests, and network for opportunities to cultivate niches. This session is recommended for those who are already specialized in one or more niches and those who wish to move in that direction.

Can We Standardize the CME Outcomes Report?

Donald Harting MA, MS, ELS CHCP, Manager of CE Grant Writing and Outcomes, National Comprehensive Cancer Network, Fort Washington, PA

CME outcome reports have received a lot of emphasis in recent years, as commercial supporters press providers to show evidence of learning gains. However, there is wide variation in how these reports are written, edited, and formatted. For example, some providers have begun presenting the executive summary as an infographic done in PowerPoint, and in some cases the entire report is produced in PowerPoint as opposed to Word. What's more, the data included in these reports vary widely but often seem to have key variables in common such as number of participants, medical specialty, % learning gains according to each objective, and remaining educational gaps. (You undoubtedly know of others!) Come join us as we discuss the pros and cons of trying to standardize how these reports are written, edited, and presented.

Challenges and Opportunities for a Post Doc Transitioning into Scientific and Medical Writing

Manju Bhaskar, PhD, NINDS, Bethesda, MD

Science communication is an attractive career option for science-trained individuals. All professionals in scientific and quantitative fields write regularly, and more than often write collaboratively. Indeed, effective scientific writing is a critical component of recommended postdoctoral training. Science writing is an incredible opportunity for scientists who have a way with words and eye for details. Science writers and editors can communicate a broad array of scientific findings. In recent times, several people with scientific training are entering the field of science reporting and writing. If you enjoy research, are skilled in technical writing and can understand complex jargon, becoming a medical writer or editor could be the perfect way to expand your portfolio—and your paycheck. Medical communication field is very broad as well as very deep. Medical writing is a lucrative career option for post doc willing to explore non-bench career options. Being a medical writer, one can work in academia, industry (medical devices, pharmaceuticals, etc.), news organizations, government, or freelance. One can write manuscripts, reports on clinical trials, news articles, regulatory submissions, meeting abstracts, patient education materials, and even slide decks. The group can discuss: How to embark on a career in science and medical writing? How to prepare and market oneself for a career in science and medical writing? What are the opportunities to tap honing the writing skills? Available resources to advance the medical communications skills including various certifications, meeting, etc? The real-life challenge-first break in industry or academia or go independent? Self-experience working in NIH as post doc and various opportunities to enhance self-growth.

Epidemiology 101 for Medical Writers

Molly Aldridge, Lead Medical Writer, IQVIA, Durham, NC

Have you noticed an increase in the incidence of job postings for writers with experience in epidemiology and real-world evidence? Are you confounded by the idea of big data? Would you like help with the causation of this distress? Come learn the basic terms and concepts of epidemiology in words we can all understand. We will discuss the main types of epidemiological studies and the data they can produce. Knowledge about this field transcends every therapeutic area, and a wide variety of documents require epidemiological input, including manuscripts, regulatory documents, medical education materials, grant proposals, marketing materials, and more. A basic knowledge of epidemiology is a useful arrow in the medical writer's quiver. Plus, it's just fun to talk about at dinner parties!

Get It In Writing: Contracts for Freelances

Eleanor Mayfield, ELS, Principal, ELM Communications, Pittsburgh, PA

As the saying goes, an oral contract isn't worth the paper it's written on. Written agreements (contracts) help both freelance medical writers and their clients have clear expectations about projects. At this roundtable we will discuss the basics of contracts for freelances: what to include, what to try to avoid, how to protect yourself. Bring your questions, concerns, and real-life experiences to share.

12:15–1:45 PM
continued

Giving and Receiving Feedback Effectively

Erica Goodoff, ELS, Scientific Editor, Department of Scientific Publications, The University of Texas MD Anderson Cancer Center, Houston, TX

Feedback is a daily part of life as a writer or editor. It can be hard to hear criticism of our work, but we need this feedback to become better writers or editors. As we gain experience, we may also be providing that same feedback to others to improve their skills. In this roundtable discussion, we will talk about how to use professional feedback productively, both when we're receiving the feedback and when we're providing it to others.

Hot Topics in Pediatrics

Stan Sack, MD, President, Stanley Sack, M.D., P.A., Key West, FL

Something new is always happening in the field of pediatrics. Those of us who write for the public need to know what parents are asking and pediatricians are saying. While this roundtable session is open to anyone who wants to discuss timely pediatric topics, it is aimed at attendees who communicate regularly with lay audiences. Although I plan on leaving the session somewhat open ended, I have performed an informal needs assessment through AMWA Engage and will come prepared to discuss a variety of popular topics such as immunization controversies, practices in the hospital's newborn nursery, and reducing procedure trauma in children. I will also share what I have learned as a clinician and a writer about communicating with parents. As an example, I find that much lay literature, while often providing sound medical advice, fails to address the questions I hear from parents! Finally, I will provide advice on searching for information on pediatric topics in a cost-effective manner.

HTAs & AMCP Dossiers: Find Out What They Are In 5 Easy Steps!

Linda Rice, PhD, CMPP, ELS, Medical Writing Senior Manager, Amgen Inc., Thousand Oaks, CA

Have you heard the terms "HTA" and "AMCP dossier" but weren't quite sure what they meant? Find out by attending a roundtable session entitled "HTAs & AMCP Dossiers: Find Out What They Are In 5 Easy Steps!" During this roundtable, an overview will be provided on what these terms mean, what agencies use HTAs and AMCP dossiers, what kind of information they contain, and how the development of a payer document (such as an AMCP dossier) compares with writing a scientific publication. Having a basic understanding of HTAs and AMCP dossiers will be useful to AMWA members interested in working on payer-related documents and in learning about how decisions are made regarding drug access/reimbursement in the managed-healthcare setting. Come join us to learn about the brave new world of writing payer-related documents! During the roundtable, handouts will be provided that summarize the information presented.

Just Slap a Label on It? How Pharmacy Manuals Really Work in Clinical Trials

Ashley Khan, PharmD, Medical Writer and Consultant, Whitsell Innovations, Inc., Chapel Hill, NC

Pharmacy manuals are critical for accurate preparation, dispensing, and inventory management of investigational products. However, the details are often overlooked during their development, which can lead to countless questions and potential errors. In this session, the speaker will share her experiences as both a regulatory writer and a pharmacist. Attendees will learn about the components of pharmacy manuals, their variations by drug type and study design, and the role of the pharmacy in clinical operations. Attendees will also gain insight on the implications of poorly written pharmacy manuals.

12:15–1:45 PM
continued

Medical Congress Coverage for a Major Pharma or Biotech Company

Albert Rhee, PhD, Publications Manager, Amgen Inc., Thousand Oaks, CA

Attending and summarizing a major medical congress can be daunting in scale and scope. Writing daily summaries and the final comprehensive executive summary for a pharmaceutical company may seem relatively straight-forward but requires extensive planning and strategy to capture and disseminate the pertinent information. This roundtable will be a practical guide on how to effectively cover a conference for a pharmaceutical/biotechnology company. We will discuss the process of capturing relevant information in a timely fashion and some of the tips and tricks learned from prior coverage. Key discussion points: Pre-conference preparation, logistics, information gathering and the daily debriefs, writing daily summaries, and overall meeting summaries.

Medical Journalism Do's and Don'ts: Tips for Successful Reporting and Writing

Barbara Gastel, MD, MPH, Professor, Texas A&M University, College Station, TX

This roundtable will focus mainly on do's and don'ts in five key realms of medical writing for the public: finding information, evaluating information, structuring the piece, wording the text, and coping with ethical issues. Tips in each realm will be provided, and participants will have opportunity to share their own tips and ask questions. A resource list will be provided.

Tips for Studying to Take the MWC Exam

Brian Bass, MWC, President, Bass Global, Inc., Fort Myers, FL

You may have seen the announcement that the Medical Writer Certified (MWC) Examination will now be administered in June and December each year via computer-based testing at IQT testing centers near major cities across the globe. The Medical Writing Certification Commission (MWCC) has also released a new Applicant and Candidate Handbook and Study Guide. The table discussion will focus on the best ways for candidates to prepare for the exam.

Pharmaceutical Sponsor and External Medical Writer Interactions: Methods for Effective Communication

Barbara Orban, MS, Senior Writer and Manager, Whitsell Innovations, Inc., Chapel Hill, NC

Ongoing interactions between pharmaceutical clients and external medical writers may result in occasional challenges. To achieve successful engagement, it is important to have a basic understanding of the pharmaceutical client's perspective to enhance the medical writer's own perception of engagement, thus further enabling successful client/writer interactions. Assessing techniques to develop effective communication between these two parties will be the primary focus of this roundtable. Topics presented will include both client and writer viewpoints as follows: developing strong rapport between the client primary contact and the writer, assessing the client culture and dynamics of the assigned team, defining a decision-making process for resolving significant team disagreements, and negotiating strategies for successful document preparation and delivery (agreeing timelines and number of draft reviews, etc.). Other suggestions for effective communication will be discussed if time allows.

12:15–1:45 PM
continued

Policy Changes, Industry Trends, and Emerging Opportunities for Freelance Medical Writers

Yanni Wang, PhD, Principal Medical Writer, International Biomedical Communications, Frederick, MD

Freelance medical writers need to be able to identify new opportunities to sustain and grow their businesses. This workshop reviews recent policy changes and industry trends that affect medical writing, and provides tips and resources to help freelance medical writers identify emerging opportunities.

So, You're Going to Take the BELS Exam...

Leslie Neistadt, ELS, Managing Editor, Saint Louis University, St Louis, MO

This roundtable session is designed for those who are thinking about taking the BELS exam. We'll begin with a brief introduction to BELS and talk about how to decide when, in the course of one's career, to take the exam. We'll then focus on the format of the exam, how to prepare for it, and tips for exam day. Attendees will have sufficient time to ask questions about any aspect of the process.

The Art of Writing an Effective Response Letter to Editor and Reviewers

Katherine Molnar-Kimber, President, Scientific consultant and medical writer, KMK Consulting Services, Kimnar Group LLC, Worcester, PA

Writing an effective response letter to the journal editor and reviewers can move your client's submitted revised manuscript to the acceptance folder. While responding to the editor and peer reviewers requires detailed scientific responses and modifications in the manuscript, writing the response letter is an art. Many comments are relatively easy to address, but others are not so straight-forward. In addition to a guide, we'll discuss when and how to disagree with the reviewers and still get published in the journal. This presentation will provide numerous examples of reviewers' issues, such as request for alternate analysis, unexpected findings from diverse patient populations (real world evidence), and successful ways to address them. Participants are encouraged to bring (non-confidential) examples of challenging reviewers' issues for group discussion. Some journals request that authors tell journals if they've been previously rejected; the pros and cons. Five issues such as journal prestige, document type, and the actual response letter can impact the flexibility of the editor and reviewers.

The Role of Microsatellites in Forensic Science and Medicine

Katie M. Bates, Medical Writer and Consultant, Whitsell Innovations, Inc., Myrtle Creek, OR

Microsatellite DNA plays a pivotal role in forensic DNA analysis and oncology. This roundtable discussion will focus on each of these applications and the overlapping role of microsatellite DNA. Attendees will be given a brief background in forensic DNA analysis and the technologies employed. Discussion will follow on the topic. While the field of forensic science is of interest to many, the role of microsatellite DNA in the oncology arena has the potential to be of immediate use to the medical writer. Microsatellite DNA plays a part in many colorectal cancers and others. The attendee will be introduced to the role of microsatellites in the oncology field, following discussion including the recently marketed drugs to treat microsatellite instability-positive cancers. The science behind the forensic casework use of microsatellites as well as the microsatellite instability in colorectal cancer will be discussed.

12:15–1:45 PM
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The Transition From "Bench to Desk": Successfully Navigating a Career Transition From Drug Discovery Research into Medical Writing

Dwyn DeSilver, BS, Medical Writer and Consultant, Whitsell Innovations, Inc., Bethany, CT

The topic of this roundtable is the transition from working as a bench research scientist in the pharmaceutical industry to medical writing. In many ways medical writing is the perfect career segue, and through a discussion of best practices, expectations, strategies (and frustrations!), I hope to convey a path forward to facilitate this career transition. Discussion topics will highlight the commonalities between bench research and medical writing, emphasizing transferable skills such as project management and the ability to convey complex scientific information, as well as some of the areas where the paths differ, such as direct client interactions and the concept of billable time. One of the most interesting aspects of my career transition has been the appreciation for the variety of paths that can lead to medical writing, and I hope the participants in this roundtable will come away with a renewed sense of purpose. As a new medical writer myself with decades of experience in the pharmaceutical industry, I would like to share the excitement and challenge of this new application of my skills, and to help answer questions and provide insight into the transition process.

Targeted Level of Experience: All Levels of Experience

Transitioning Into Regulatory Writing: Starting Where You Are

Christine Flees, Medical Writer and Consultant, Whitsell Innovations, Inc., Chapel Hill, NC

Jody Manning, Medical Writer, Clovis Oncology, Boulder, CO

Navigating from other scientific fields into regulatory writing can be difficult. This roundtable will provide a structured but casual discussion to help participants make this transition. We will provide useful tips from our own experience and help answer questions. Practical information such as important resources, initial steps, and networking will be shared during this interactive roundtable discussion.

Targeted Level of Experience: All Levels of Experience

Writing a Natural History Study Protocol

Benjamin Snow, MS, ELS, Medical Writer, Leidos Biomedical Research, Inc, Rockville, MD

Natural history studies complement investigational drug/device trials by discovering new information about the progression of a medical condition or disease. Researchers use natural history studies to track the course of a disease over time, classify variables associated with disease outcome, and identify biomarkers that can be translated into drug targets. These studies are particularly valuable for improving our understanding of rare diseases for which there are few treatments, if any standard of care even exists. In this roundtable discussion, we will review the critical elements for writing a protocol for a natural history study, which consider the differences between natural history and other clinical trials. We will also discuss how to resolve common difficulties in writing natural history protocols, such as settling on a study schedule that allows for ad hoc visits on the basis of the participant's clinical status and ensuring appropriate safety oversight. Perhaps most importantly, we will craft tools to help determine where routine clinical care ends and research begins.

Targeted Level of Experience: All Levels of Experience

Writing for Peer-Reviewed Journals: How to Make the Production Process Work for You

Kirby Snell, Copyediting Client Manager, J&J Editorial, Cary, NC

Jennifer Fricker, Copyediting Services Coordinator, J&J Editorial, Cary, NC

When submitting work for publication in a medical or scientific journal, making it through peer review can be the most daunting stage; but as an author, your obligations don't end at acceptance. This session will provide an overview of the production process—the stages your paper might go through as it is prepared for publication, and what may be asked of you along the way. For first-time submitters and seasoned authors alike, we will offer valuable tips and strategies for how to optimize the production process, reduce time and stress, and have the journal's production staff singing your praises.

2:00–2:30 PM **Annual Business Meeting for AMWA Members**

All AMWA members are encouraged to attend, to get an update on AMWA from 2017-2018 President, Kathy Spiegel, PhD, MWC, and Treasurer, Julie Phelan, MD, MBA, to witness the passing of the gavel to Cynthia L. Kryder, MS, CCC-Sp, the 2018-2019 President, and to meet the 2018-2019 Board of Directors.

2:00–3:30 PM **Education Sessions**

What's New in the *AMA Manual of Style*

Stacy Christiansen, MA, Managing Editor, JAMA, *and co-chair,* AMA Manual of Style, *JAMA Network, Chicago, IL*

Annette Flanagin, RN, MA, Executive Managing Editor, JAMA *Network, and* AMA Manual of Style *Committee, Chicago, IL*

Cheryl Iverson, MA, Co-chair, AMA Manual of Style, JAMA *Network, Chicago, IL*

Between editions of the style manuals we rely on, new questions arise. And because style, like language, is flexible, there are inevitably some changes in policy. This session will address some of those questions and policy changes: updated terms in many areas of scientific nomenclature; more examples of how to cite social media and other electronic resources, including podcasts, preprints, databases, and data repositories; new standards for authorship and guidelines for group authors; information on open access, data availability, release of information, and managing legal risks; new entries in the popular Correct and Preferred Terminology section; expanded advice and description of statistical terms and reporting of research; recommendations on supplementary online material; and enhanced guidelines on presentation of figures and tables. There will be time at the end of the session to ask questions.

Fake News in Medicine

Kelleen Flaherty, MWC, CMPP, Adjunct Assistant Professor, University of the Sciences in Philadelphia Graduate Biomedical Writing Programs, Jamison, PA

Fake health news and fake medical news are at a critical epidemic. The *Atlantic* candidly refers to this as the "worst kind of fake news." There is all manner of "fake news" associated with medicine and health, which functions in pandering to the mob, inciting the ignorant, preying upon the innocently uninformed, and practicing irresponsible journalism. What is the role medical writers play in the recognition of, deconstruction of, and communication about fake medical news? Lay audiences are the common target for this often dangerous misinformation--how can we help?

Up Your Efficiency Game: How Computer Peripherals Let You Work Faster

Katherine McKiernan, MA, Freelance Medical Editor, San Diego, CA

Computer mice and keyboards are essential everyday tools of medical writers and editors, which makes them perfect tools to optimize for efficiency. There is a diverse array of computer peripherals optimized for rapid, accurate computer input, but because they tend to be marketed to video game players, few other people are familiar with them. This demonstration will teach you how to set up a programmable gaming mouse and keyboard to put your commonly used software functions and macros at your fingertips, with faster results than Word's Quick Access Toolbar, ribbons, or even standard keyboard shortcuts. The demonstration will illustrate how to program peripherals to execute commonly used Word functions (eg, applying styles, formatting tables, inserting symbols, handling tracked changes and comments, and inserting references), but what you learn will apply to whatever functions you use most, even hand-crafted macros or controlling programs other than Word. The session will also include an overview of other useful computer peripherals that can make your life smoother

2:00–5:00 PM **AMWA Workshops (*additional fee*)**

WS-60 Plain Language

Amy D. Stephenson, M.A., principal of Wordacious LLC in Beacon, NY

Translating complex health information into text that is easy to read, understand, and use by consumers with limited literacy skills is a valuable ability for every medical writer.

At the end of the workshop, participants will be able to

- Explain the scope of the health literacy problem and the ethical and practical need for plain language
- Define the main principles of plain language
- Begin practicing and honing the plain language skills learned in the workshop

WS-61 Outlining for Writers and Editors

Hope Lafferty, AM, ELS, Hope Lafferty Communications, Marfa, TX

At the end of the workshop, participants will be able to

- Use outlining at various stages throughout the process of developing a scientific document
- Create outlines using linear, nonlinear, kinesthetic, and electronic methods
- Project plan, facilitate communication, and increase productivity using outlining
- Identify the type of outlining that best suits his or her natural way of thinking

WS-62 Understanding Sample Size and Study Power

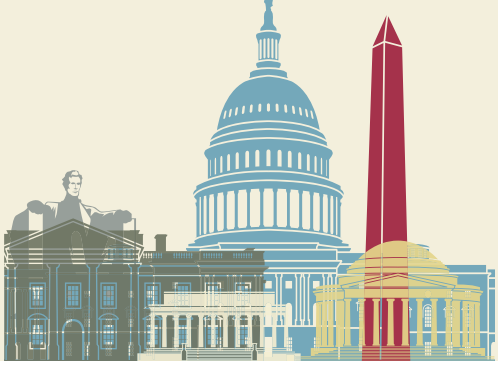
Bart Harvey, MD, PhD, Associate Professor, Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada

With great power comes great responsibility, and medical writers need advanced understanding of how to accurately interpret and responsibly report sample size and study power.

At the end of the workshop, participants will be able to

- Define statistical terms including statistical significance, P-value, clinical significance, number needed to treat, sample size, alpha and beta, confidence interval, study power, type I & II errors, study validity, and precision.
- Classify the factors to be considered, and their inter-relationship, when a study's sample size or power is determined.
- Describe the importance of sample size and study power in the presentation of research reports, abstracts, or material for lay audiences.

3:30–4:00 PM **Workshop Beverage Break**



POSTERS ON DISPLAY

♦ **Expedited Approval Pathways and Safety Label Changes**
Dr. Priyanka Ingle, Translational Clinical Pharmacologist, CRC Pharma LLC Parsippany, NJ

♦ **Best Practices for Writing CME Needs Assessments: 2017 Survey Results**
Donald Harting MA, MS, ELS CHCP, Manager of CE Grant Writing and Outcomes, National Comprehensive Cancer Network, Fort Washington, PA
Andrew Bowser, President, iconCME, Narberth, PA

♦ **Get to Know Your AMWA Member Benefits!**
Gail Flores, PhD, President and Principal Writer, Encore Biomedical Communications Encinitas, CA
On Behalf of the AMWA Membership Committee

♦ **Science Communication: Strategies for Communicating Clearly and Effectively with Laypeople**
Beth Knight, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc., Chapel Hill, NC

♦ **Creating and Evaluating an On-Demand Writing Workshop for a Large Research Institute**
Loretta Bohn, BA, Senior Editor/Writer II, RTI International Research Triangle Park, NC
Julie Shogren, BA, Senior Editor/Writer III, RTI International, Research Triangle Park, NC
William Ferris, MEd, Research Training Specialist, RTI International, Research Triangle Park, NC

♦ **The Growth and Decline of Therapeutic Areas in Medical Writing: A 10-year Bibliometric Perspective**
Angela Johnson, MSE, PMP, RAC, Assoc Director Regulatory & Scientific Affairs, CTI Clincial Trial & Consulting Cincinnati, OH

♦ **Training and Mentoring Model to Support the Transition to a Role in Regulatory Medical Writing (Medical Writer and Clinical Technical Editor for Safety Narratives)**
Carolina Salazar Lara, Senior Medical Writer, MSD, Bogotá, Colombia
Cindy Marlene Fernández López, Senior Medical Writer, MSD, Bogotá, Colombia
Yudy Brigith Artunduaga Dussan, Associate Clinical Technical Editor Medical Writing, MSD, Bogotá, Colombia
Catalina González Rueda, Associate Director Medical Writing, MSD, Bogotá, Colombia
Mary E. McKenna, Director Business Operations Medical Writing, Merck, Rahway, US
Susan Sfarra, Director Clinical Technical Editing Medical Writing, Merck, Rahway, US

♦ **Summarizing Safety Data in Regulatory Submission Documents**
Barbara Orban, MS, Senior Writer and Manager, Whitsell Innovations, Inc., Chapel Hill, NC

♦ **Developing an Editorial Team: Tools for Sustained Success**
Amy Martin, Senior Director, Medical Writing, Editing, and Design Services, RTI Health Solutions Research Triangle Park, NC
Alyssa Dallas, Associate Director, Medical Writing, Editing, and Design Services, RTI Health Solutions, Research Triangle Park, NC
Margaret Mathes, Manager, Medical Writing, Editing, and Design Services, RTI Health Solutions, Manchester, UK

♦ **Enhancing the Authorship Experience, One Survey at a Time**
Amy Kuang, PhD, Sr Manager, Medical Writing, Allergan plc, Irvine, CA
Brittany Jordan, PharmD, Manager, External Scientific Communications, Allergan plc, Irvine, CA
Jeri Freeman, BA, Associate, External Scientific Communications, Allergan plc, Irvine, CA
William Glass, PhD, Associate VP, External Scientific Communications, Allergan plc, Irvine, CA

♦ **The CSR Simplification Project: Creating a Clear, Compliant, and Concise CSR**
Diane R Petrovich, PhD, Head, Infectious Disease & Vaccines Medical Writing / Medical Writing / Global Clinical Trials Operations, Merck Upper Gwynedd, PA
Mitzi Allred, PhDEE, Head, Clinical Content Standards/ Medical Writing/ Global Clinical Trial Operations, Merck, Upper Gwynedd, PA
on behalf of the CSR Simplification Project Team, Global Clinical Development, Merck

♦ **Supporting Drug Development Programs: Where do Medical Writers Fit In?**
Teresa McNally, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc., Chapel Hill, NC
Monique Pond, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc., Chapel Hill, NC

♦ **Best Practices for Creating a Home Office, and Time Management Tips for Working from Home**
Dwyn DeSilver, BS, Medical Writer and Consultant, Whitsell Innovations, Inc., Bethany, CT
Maureen Piotrowski, MBA, Medical Writer and Consultant, Whitsell Innovations, Inc., Needham, MA

♦ **Development of a Disease and Compound Specific Content Library**
Susan Cupo, MS, Managing Medical Writer, Merck & Co Rahway, NJ
Mitzi Allred, PhDEE, Director, Merck & Co, Upper Gwynedd, PA

♦ **Protocols and Protocol Amendments: Effective Quality Review Steps**
Sharad Wankhade, PhD, Principal Medical Writer, Merck & Company Rahway, NJ

♦ **Evaluation of UC San Diego Medical Writing Certificate Program Specialization, Student Characteristics, and Workforce Data**
Tim Mackey, MAS, PhD, Associate Professor/Director, UC San Diego San Diego, CA
Leslie Bruce, JD, Director, UC San Diego - Extension, San Diego, CA
Lori Alexander, MTPW, ELS, MWC, President/Immediate Past President, Editorial Rx/AMWA, North Fort Myers, FL

♦ **Inalienable Rights: Major Health Organizations' Response to Health Disparities and the Impact on Medical Communicators**
Tamara Ball, MD, Freelance, Asheville, NC
Bob Kirsch, MA, Freelance, Ossining, NY

♦ **Publication Planning and Writing in the Age of Clinical Trial Transparency: Trends, Challenges, and Good Practices**
Yanni Wang, International Biomedical Communications, Frederick, MD

♦ **Navigation by the Numbers: A look at the benefits of protocol navigation management at the National Institute of Mental Health (NIMH)**

Charles Servis, Protocol Navigation Manager, Leidos Biomedical Inc., Bethesda, MD
Anne Evans, Medical Writer III, Leidos Biomedical Inc., Bethesda, MD

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