Trends and Opportunities for Medical Communicators

AMWA 2020 Medical Writing & Communication Conference
October 20-22, 2020
CONFERENCE PROGRAM
The AMWA 2020 Medical Writing & Communication Conference will take place online October 20-22. Registered attendees will gain access to the virtual conference platform approximately 1 week prior to the event dates to set up networking profiles, watch welcome videos, and explore the educational offerings. The daily schedule includes Education Sessions, Plenary Sessions, live Roundtable Discussions, Posters, and an online Exhibit Hall. There are a variety of ways to engage with others.

### 2020 CONFERENCE SCHEDULE AT A GLANCE*

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*All times listed are Eastern Time.*
EDUCATION SESSIONS

Education Sessions are pre-recorded and most feature a live question-and-answer period through the chat function. Attendees can listen to Education Sessions whenever they want after their debut at the starting time.

Collaborative Writing: Ensure Success with an Effective Strategy (Core Knowledge/Skills)
Crystal Herron, PhD, ELS, Redwood Ink, LLC

Writing with your colleagues can be an efficient and valuable process. But collaborative writing can also be cumbersome and frustrating. You need to find common ground among different writing styles, working practices, and personality traits. Whether you’re working with writers across the hall or the globe, you can set your team up for success. Learn valuable strategies that can guide your team in completing a writing project collaboratively and efficiently. You can then focus on blending complementary strengths, generating new ideas, sharing the workload, and building trust—all while working toward the same goal.

Target Audience: All levels

Knowing Which Button to Push: Communicating the Value Proposition of Medical Writing (Career Development)
Robin Whitsell, Whitsell Innovations

As medical writers, we intersect with a wide variety of potential stakeholders within and across our organizations. Some of our team members value our contributions and understand the expertise, quality, and soft skills we use to author-by-committee. On the flip side, some team members consider medical writers to be scribes or typing trolls and have minimal understanding of our contributions, the demands on our time, or, possibly, the physical and mental limitations of the human body. In this session, we’ll momentarily acknowledge those collaborative colleagues and then discuss ways to mitigate less helpful team behaviors. This session will focus on strategies for providing respectful disagreement, defusing combative coworkers, and, importantly, asserting the medical writer value proposition.

Target Audience: 2 to 5 years’ experience

Navigating Potential Ethical Pitfalls in Research Publications (Scientific Publications)
Anne Murray, PhD, Methodist Health System
Damiana Chiavolini, MS, PhD, UT Southwestern Medical Center

Researchers, publishers, and medical communicators are responsible for ensuring that dissemination occurs in an ethical manner. However, in an effort to rapidly produce manuscripts, some aspects of publication ethics (eg, data manipulation, reporting guidelines, regulatory approvals, predatory publishers, multiple submissions) may be overlooked, leading to the publication of subpar and/or incorrect information. Alternatively, authors may not be aware of some ethical aspects of publishing. What ethical issues do we need to inform our colleagues about to ensure successful publication? Learn about potential ethical obstacles that medical communicators encounter during the publication process and how to overcome these obstacles.

Target Audience: All levels
EDUCATION SESSIONS
US FDA Real Time Oncology Review Program and FDA Assessment Aid: Early Provision of Data and Authoring of a New Summary Document for Efficient FDA Review (Regulatory Writing)
David Sorscher, PhD, RAC; Norman Heyden RPh, MS; and John Busillo, PhD, Merck & Co. Inc.

The Real Time Oncology Review (RTOR) and Assessment Aid (AAid) are FDA pilot programs to facilitate review of oncology submissions. The RTOR involves early submission of data prior to a submission. The AAid is jointly authored by the applicant and FDA reviewers, thereby providing a chance to present critical results in an FDA review template. Medical writers play an important role in writing the AAid. Best practices, experiences, and tools will be shared for medical writers to author an effective AAid, including instructions and examples from previous AAids and direct transference and reuse of text/data from submission documents. Both pilots have reduced the time to approval of new therapies.

Target Audience: All levels

PLENARY SESSION
Plenary Session with Welcome from the AMWA President, 2020 Awards Recognition, and Alvarez Address
Recognition of recipients of AMWA Fellowships, President’s Award, John P. McGovern Award, and Walter C. Alvarez Award.

2020 AMWA Walter C. Alvarez Award Address
Every Person Is a Patient: Finding the Story in the Science
Mary Elizabeth Williams, journalist and author, A Series of Catastrophes and Miracles: A True Story of Love, Science, and Cancer.

Ms. Williams is a New York-based writer and mother of two. Listen to her inspiring story about her fight against malignant melanoma.

Live question-and-answer period.

BREAK
Grab a bite to eat, visit the exhibitors, browse the posters, or engage with other attendees on the Discussion Boards.
1:00 to 2:00 PM

ROUND TABLE DISCUSSIONS

Roundtable Discussions are held live on a Zoom platform. They are limited to 20 participants (unless otherwise noted), and **attendees may sign up for only 1 Roundtable Discussion per day**. For informational (I) Roundtables, the leader assumes a lecturer role to inform participants about the topic, leaving time for questions and discussion. For participatory (P) Roundtables, the leader facilitates discussion among participants who have knowledge of the topic.

Certification of Editors in the Life Sciences [I]
**Norman Grossblatt, ELS(D)**

Credentials, such as certification, are increasingly important in various fields of communication. This roundtable discussion will address what certification of editors is, its purpose and value, and how to obtain it. Learn more about the credentials offered by the Board of Editors in the Life Sciences (BELS), the origin and history of BELS, and the certifying examinations that it offers.

**Target Audience:** At least 2 years’ experience in life sciences editing

Hosting Medical Communication Interns in Person and Remotely: Key Tips [P]
**Barbara Gastel, MD, MPH, Texas A&M University**

Internships can benefit both intern and host. This discussion will offer guidance on helping medical communication internships achieve this potential. Get advice on recruiting interns, orienting them, supervising them, and wrapping up. Tips on remote internships will be included. Participants will have chances to ask questions and share suggestions.

**Target Audience:** At least 2 years’ experience

Is That What You Do?! Improving Collaboration through Cross-functional Rotations [I]
**Brian Rekoske, PhD, and John Busillo, PhD, Merck & Co. Inc.**

Medical writers provide documents to stakeholders across a wide variety of departments, including clinical development and regulatory affairs; however, most medical writers have little or no experience working in these departments or an understanding of how these documents are used once delivered. Join us for a discussion of the immense benefits gained and lessons learned from a cross-departmental rotation in clinical development. This career development opportunity is invaluable and should be strongly considered, especially by newer medical writers. Hear the manager’s perspective on the benefits of this experience and tips for negotiating opportunities between departments.

**Target Audience:** 2 to 5 years’ experience


ROUND TABLE DISCUSSIONS

Jam Session for Seasoned Freelancers [P]
Brian Bass, MWC, Bass Global Inc.

When accomplished musicians jam, their combined talent, energy, and experience make a special kind of synergy. A similar kind of magic happens when seasoned freelancers get together to discuss their ideas, concerns, and challenges with peers who have the same or more experience. These rare gems of collegial conversation and commiseration happen spontaneously and usually unpredictably. This discussion will provide a supportive space for experienced freelancers 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. This discussion is lightly structured to permit a free flow of discussion without getting stuck for too long on a single topic. (This roundtable discussion is offered twice; the limit is 25 participants.)

Target Audience: Freelance medical writers with at least 8 years’ experience

Putting the Pieces Together: Best Practices for Taking Ownership of Your Documents [I]
Stephanie Hreha-Phillips, MS, Merck & Co. Inc.

Do you often have difficulties getting what you need from stakeholders? Are you unsure of the content required for your document? Most regulatory documents require input from various stakeholders, and writers rely on this to move documents forward. Delays in receiving the necessary information cause timelines to slip. Realize the power of suggestion to take control of your documents. Learn to apply content reuse to regulatory documents and put together proposed text for sections requiring stakeholder input. Various resources for understanding content requirements will be discussed. Become the expert in getting the feedback you need! (This roundtable discussion is offered twice.)

Target Audience: 2 to 5 years’ experience

The Times They Are a Changin’: How to Manage Change Effectively in Every Role [P]
Jenni Pickett, PhD, Whitsell Innovations, Inc.

Change is a way of life for medical writers. Regulations, client needs, and best practices are constantly evolving. Developing skills to manage this change builds your leadership capability. Discuss a past, present, or future change experience with the group and learn change management techniques that apply to your situation. Learn about the roles involved (initiator, expert, leader, advocate, and participant) and how to leverage each of those roles to execute change. Discover how to break down complex changes into manageable steps to maximize your chances of enacting successful lasting change. (This roundtable discussion is offered twice.)

Target Audience: All levels
ROUND TABLE DISCUSSIONS

Tips for Writing Common Sections of Needs Assessments for Accredited Continuing Medical Education [P]
Katherine L. Molnar-Kimber, PhD, KMK Consulting Services of Kimnar Group LLC

Transitioning scientists and health care professionals can use their skills for writing continuing medical education (CME). Writers of accredited CME often deliver needs assessments, conference programs, webinars, monographs, and cases. Learn about the common 10 elements in grant proposals, Bloom’s hierarchy of verbs, several important agencies, societies, and free resources. We’ll discuss tips for writing the five common sections in a needs assessment (gap analysis, learning objectives, expected outcomes, alignment with National Quality Strategy, and references). This roundtable discussion will address several finer details of writing these sections. Bring nonconfidential questions and share your expertise.

Target Audience: All levels

Transitioning to Full-Time Regulatory Writing [P]
Cody Nichols, PhD, Whitsell Innovations

Whether you are transitioning into regulatory writing from academia, the pharmaceutical sector, or another world entirely, this roundtable discussion is for you. As a growing and developing writer, you may have the opportunity to work on a wide range of projects, each with its own unique challenges. Discussion topics will include various types of documents in regulatory writing and where to gain valuable training and experience needed for each; some tips and tools to ease the transition into regulatory writing; how to adapt transferable skills to current roles; and the importance of soft skills and resources for perfecting them. (This roundtable discussion is offered twice.)

Target Audience: 0 to 2 years’ experience

Writing for Patients: When and How [I]
Lisa Chamberlain James, Trilogy Writing & Consulting

The demand for better information for patients and the general public is increasing, and this is being reflected and responded to by regulatory authorities. Producing complex scientific and medical information in health-literate language that is appropriate and helpful for the general public requires additional skills to those usually required for communicating with health care professionals and regulatory authorities. Translating this information into plain language for readers who may have low health literacy and/or no scientific or medical knowledge, is a significant challenge. We will discuss the role of medical writers in carrying these initiatives through and make sure that the information produced is what patients want and need.

Target Audience: All levels
**EDUCATION SESSIONS**

**Bridging the Gap: Best-Evidence Strategies for Health Literate, Public-Facing Clinical Trial Materials** *(Health Communication)*  
*Catina O’Leary, PhD, LMSW, Health Literacy Media*

Engagement in clinical research relies on patient access to and understanding of the processes and materials connected to clinical trials. Until very recently, most clinical trial materials were developed without meaningful consideration of patient preferences. Recent regulatory guidance mandates communication of clinical trial results to participants in plain language. This provides an impetus for development of participant-friendly materials across the clinical trial process. Operationalizing the processes to develop public-facing materials between study sponsors and medical writers is a challenge and opportunity. Learn to bridge the gap between science writing and medical writing to produce health literate public-facing clinical trial materials.

**Target Audience:** All levels

**Low-Cost and Low-Effort Ways to Create Infographics and Visually Appealing Slides** *(Core Knowledge/Skills)*  
*Kelly Schrank, MA, ELS, Bookworm Editing Services LLC*

Many clients and employers are ramping up expectations for slide design and many are requesting infographics. Are you ready to move past words in a Word document to presenting concepts in a more visually appealing manner in PowerPoint or PDF? Many people still think you need to be a graphic designer to create infographics or visually appealing slides, but apps such as Canva and templates in PowerPoint can move you forward. Exposing yourself to new ideas and good design can go a long way. Come to this session for resources and ideas for how to get started!

**Target Audience:** 5 to 8 years’ experience

**Umbrella Protocol Toolkit for Early Drug Development** *(Regulatory Writing)*  
*Shawn Watson, PharmD, PhD, BCPS, Bicycle Therapeutics*

Umbrella protocols include multiple studies in a single protocol and provide a great deal of leverage because they allow different cohorts to run concurrently, accelerate overall clinical development, and reduce development costs. Nonetheless, their designs are complicated and present unique challenges to a regulatory writer. This session focuses on these challenges, with an emphasis on single-ascending dose-escalation (SAD) and multiple-ascending dose-escalation (MAD), drug-drug interaction (DDI), pharmacokinetic lead-in, bioavailability, and thorough QT studies. The discussion includes what information these studies provide, the rationale for combining these studies into a single protocol in early development, strategic consideration for combining these studies, and tactical guidance for writing these protocols.

**Target Audience:** 5 to 8 years’ experience
EDUCATION SESSIONS

Value of Medical Writers: What Do the Data Show? (Career Development)
Laura J. Ninger, ELS, Ninger Medical Communications, LLC

Professional medical writers generate content that is scientifically accurate, properly targeted, readable, completely referenced, ethically sound, and compliant with journal instructions. Beyond receiving a published acknowledgment, however, many writers and editors work in a vacuum, with little evidence of our effect on the scientific literature. Several quantitative studies have explored the value of medical writers in areas such as text readability, guideline compliance, time until manuscript acceptance, effect on impact factor, and adherence to ethical guidelines. This session presents data on the value that medical writers (and editors) provide so that attendees can evaluate their own performance.

Target Audience: All levels

BREAK

Grab a bite to eat, visit the exhibitors, browse the posters, or engage with other attendees on the Discussion Boards.

ROUNDTABLE DISCUSSIONS

Avoiding Rejection: Tips for Manuscript Writing Success [I]
Andrea Gwosdow, PhD, Gwosdow Associates Science Consultants, LLC

Writing manuscripts can be challenging. This roundtable discussion will focus on the primary reasons manuscripts are rejected from journals and how to improve one’s chance of success when preparing manuscripts for publication. Come learn practical tips for writing each section of a journal manuscript effectively and efficiently, helping to ensure acceptance. Strategies for dealing with manuscript reviews and responding to reviewers’ comments will also be discussed. Participants will be asked to share their experiences and tips for manuscript writing and publication. (This roundtable discussion is offered twice.)

Target Audience: 2 to 5 years’ experience

Best Practices for Training Writers New to Clinical Trial Protocols [P]
Katie Provost-Javier, PhD, Merck & Co. Inc.

Join us to discuss best practices in training and mentoring novice protocol authors to help them maximize their value. Protocol authors are most effective when they understand the entire continuum of drug development and clinical trial documentation. Recognizing how target label indications drive endpoint selection and how endpoints inform trial design brings focus to protocol authoring. Envisioning how protocol content is used and reused allows the writer to construct a document with foresight and purpose. How do you teach this? Participants will be asked to share their experiences and ideas on training writers who are new to protocol authoring. (This roundtable discussion is offered twice.)

Target Audience: More than 8 years’ experience
ROUNDTABLE DISCUSSIONS

Clinical Evaluation for CE Marking of Medical Devices: Context and Compliance [I]
Isabelle Searcy, PhD, Network Partners

In light of the new Medical Device Regulations (MDR), medical writers have a unique opportunity in helping manufacturers demonstrate compliance of their devices through a thorough Clinical Evaluation. Learn about the requirements of clinical evaluations for medical devices in compliance with the Meddev 2.7/1 Revision 4 and 2020 MDCG guidance and how to conduct, structure, and write clinical evaluation plans and reports. Specificities of clinical evaluations for Class II and Class III devices, and tips for postmarket surveillance and literature search and analysis will also be discussed. (This roundtable discussion is offered twice.)

Target Audience: 0 to 2 years’ experience

Creating a Strategic Plan for a Medical Writing Department [I]
Jeanette Towles, Synterex, Inc.

Effective leadership of a medical writing department involves advocating as well as educating other stakeholders on the value proposition of medical writers. Learn to translate the vision and goals for your group into language that your executive team can easily understand, including assessment of strengths, weaknesses, opportunities, and threats (SWOT) and communication of critical success factors. Learn practical tips to ensure that your short-term and long-term initiatives dovetail with the plans of the company as a whole. (This roundtable discussion is offered twice.)

Target Audience: More than 8 years’ experience

Creating the Ideal Map for Cat Wranglers, aka Grant Application Checklist—What Works and What Doesn’t [P]
R. Michelle Sauer Gehring, PhD, ELS, RnA Editing, LLC

Are you a cat wrangler—a grant/research administrator? Are you tired of triple-checking the folders to ensure you have everything needed in the latest version of the National Institute of Health forms? Are you frustrated that you missed a key element found in the 87-page solicitation? You are not alone. As our subspecialty of grantsmanship takes root, clients and/or bosses often seek funding from multiple sponsors, with different terminology and rules for each, on top of individual institutions’ internal processes. We will review a grant application checklist as a baseline and discuss elements that have worked (and epically failed) so that you can walk away with a flexible and individualized “deliverable” that will hopefully make your wrangling days easier.

Target Audience: All levels
ROUND TABLE DISCUSSIONS

Grow Your Own Local Network of Communication Professionals [I]
Joanne M. McAndrews, PhD

Online networking (LinkedIn, Twitter, Facebook, AMWA Engage, etc.) is wonderful, but nothing really beats live 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, meeting formats and virtual meeting strategies, meeting topics, maintaining a membership list, and the many benefits of connecting in real time on a regular basis with professionals in your field.

Target Audience: All levels

How to Find a Job [I]
Kelleen Nora Flaherty, University of the Sciences

Job hunting is a daunting, overwhelming task for medical writers, whether they are new or experienced and freelance or full-time. However, there are several approaches to and considerations for job hunting that can make your hunting more efficient and successful. Come learn how to undaunt your job search with tips, techniques, approaches, resources, record-keeping, and essential skills! (This roundtable discussion is offered twice.)

Target Audience: All levels

The Journey from Vendor to Trusted Partner [P]
Demetrius Carter, Synchrogenix, a Certara Company

In this roundtable discussion, we will review several business cases and outcomes, leading to key lessons learned regarding customer behavior. This knowledge will help you improve collaboration with your teams and drive more effective client relationships. The discussion is based on experience as a Project Management Institute-certified project management professional, a certified Lean Six-Sigma Green Belt, and 20+ years of clinical development and regulatory sciences experience working with pharma companies and contract research organizations.

Target Audience: 5 to 8 years’ experience

Steps to Building a Successful Multidisciplinary Continuing Education Forum for a Regional Health System [P]
Diane Morton, MS, SSM Health

Meaningful interdisciplinary or specialty continuing education (CE) can be difficult for frontline clinicians and practitioners of rural or community hospitals when resources are restricted and opportunities are limited. Learn the strategies of mobilizing teams through group communication, developing CE materials that retain value, avoiding miscommunication mishaps, and building momentum for a successful event. Whereas the examples given are from a health care setting, the principles can be applied to any group. Come prepared to share successes, failures, and ideas for your next big CE event.

Target Audience: All levels
4:00 to 5:00 PM

**ROUNDTABLE DISCUSSIONS**

**Virtual Networking: How to Build a Strong Network** [P]
*Lori De Milto, MJ, Lori De Milto Writer for Rent, LLC*
*Mia DeFino, MS, ELS, DeFino Consulting, LLC*

Right now, virtual networking is the only way we can network. In light of the SARS-CoV-2 pandemic, virtual networking is central to connecting with new people and strengthening relationships with people we already know. When the pandemic ends, virtual networking will be an important supplement to in-person networking. Join us for this interactive discussion of our experiences with virtual networking and ways to network effectively when we can’t be together in person. We'll cover one-on-one virtual networking/staying connected with colleagues, starting your own networking group, attending or hosting virtual networking events, and attending virtual conferences.

**Target Audience:** All levels

5:15 to 6:15 PM

**ROUNDTABLE DISCUSSIONS**

**Building Your Expertise in Unfamiliar Clinical Areas** [P]
*Larry Lynam, DSc, MA, RM, SM, The Lynam Group, LLC*

Oftentimes, freelance writers say they turn down opportunities to build their portfolio because they have no experience in a specific clinical area. The good news is there are many effective ways to build your knowledge and develop your expertise in an area that interests you. Come join our discussion about the variety of resources that you can explore to help build your personal portfolio. We’ll also share tips we have found effective for expanding our capabilities.

**Target Audience:** All levels

**Developing and Retaining the Seasoned Writer** [P]
*Mary Ellis Bogden and Jane White, Whitsell Innovations, Inc.*

As medical writers approach mid- to senior-level career positions, they often look for opportunities to build their skills beyond writing and document-specific expertise. While management opportunities may exist, not all medical writers desire this career path. What strategies do medical writing departments employ to retain, engage, and develop their more experienced writers? We will discuss the challenges and success stories associated with managing mid- to senior-level writers.

**Target Audience:** More than 8 years’ experience
**ROUNDTABLE DISCUSSIONS**

**The Empowered Medical Writer: A Prerequisite for Optimal Deliverables [I]**
*Nancy R. Katz, PhD, MWC, Illyria Consulting Group, Inc.*

The hypothesis of this roundtable is that medical writers must wield power so they can create optimal deliverables. This is especially true because the designation “medical writer” does not automatically confer authority or respect. In fact, in some environments the expertise of medical writers is routinely ignored or denigrated; in turn, this creates a situation that can result in incomplete, inconsistent, unclear, and noncompliant medical writing deliverables. This roundtable discussion will provide tips that enable a medical writer to overcome a lack of inherent positional power. Topics include self-management and management of others, both of which allows the creation of medical writing deliverables of the highest possible caliber.

**Target Audience:** All levels

**Ensnared by Ennui? Staying Engaged in your Professional Development [P]**
*Jennifer Bridgers, MS, MWC, Merck and Co. Inc.*

As a new writer many years ago, I saw the ennui from the experienced members and wondered about it. Now I see this in some of my colleagues. AMWA has been focused on new ways to educate and to share knowledge. We will discuss ways to stay engaged in your professional medical writing development after 8+ years in the field, both within AMWA and through other opportunities. Participants are encouraged to bring their ideas and share their experiences. (With permission, the speaker will consolidate the discussion and post a general summary of the roundtable to Engage.) *(This roundtable discussion is offered twice.)*

**Target Audience:** More than 8 years’ experience

**From Audience to Authors: Insights and Advice for Collaborating with Patients in Medical Communications [I]**
*Thomas Gegeny, MS, ELS, MWC, CMPP, Envision Pharma Group
Kristin I. Carman, PhD, MA, Patient-Centered Outcomes Research Institute, Washington DC
Dawn P. Richards, PhD, Chronic Pain Network, McMaster University*

Writing for patient and lay audiences is familiar ground for many medical communicators, but the role of patients has been growing as new partnerships and collaborations focus on their contributions as advisors, reviewers, and consultants. The perspectives and recommendations of patients and caregivers not only inform study designs, assessments of product benefit and risk, and communication strategy, but also add context to research results. The intrinsic value of patient participation in research and reporting is widely recognized, and now journals, pharmaceutical companies, government agencies, and other groups are embracing these opportunities. The age of the patient author is upon us!

**Target Audience:** All levels
5:15 to 6:15 PM

ROUNDTABLE DISCUSSIONS

Health Habits: Stress Less, Feel Great, Work Better [I]
Reggie Wilson, MS, Fit for Freelance

Back hurts, can’t concentrate, and always feel stressed out? I bet that’s not why you started freelance or remote work. Big companies focus on employee wellness to increase productivity, attendance, and retention, while reducing health care costs. Home-based writers can barely focus while they work themselves sick. Are you ready for energy to enjoy the reasons you work? Join the discussion for simple food, activity, workspace, and lifestyle choices you can make right away to feel great while you work! (This roundtable discussion is offered twice.)

Target Audience: All levels

How to Successfully Transition from a General/Clinical Background into Medical Writing [P]
Julian Barrera, MS, Merck & Co. Inc.

Coming from a nonregulatory or nonmedical writing background into a professional medical writing career poses distinct challenges. How can writers adapt and be successful? This roundtable discussion will focus on the opportunities, obstacles, and positive practices that medical writers need to manage as they make transitions from strictly clinical or a non-health-related backgrounds into writing. Through listening to the real-life experiences of roundtable participants, new writers can anticipate those potential obstacles, share positive practices, and learn strategies to make the evolution efficient, smooth, and beneficial.

Target Audience: 0 to 2 years’ experience

Networking Discussion: Regulatory Writing Executives
TBD

Join other regulatory writing executives to share common issues and explore solutions.

The Trend toward Collaborative Authoring: Pros and Cons vs Fixed Steps for Document Development [I]
Mark R. Bowlby, PhD, Synchrogenix

The near-universally adopted method for document development, namely, the draft-review-revise process, is increasingly being questioned as best practice. As demands for shortening process timelines have continued to increase and software advances have made many interactions continuous, there appears to be a concurrent push for a more collaborative approach to authoring. Collaborative authoring can indeed speed the development of expert content in documents; however, it also poses new issues for authors, especially in the case of continuous collaborative authoring. Learn about the extent of this trend, variants in its implementation, impacts on authors, and techniques for managing collaborative authoring. (This roundtable discussion is offered twice.)

Target Audience: All levels
EDUCATION SESSIONS

Addressing Legislative Efforts to Limit the Livelihood of Freelance Medical Communicators
(Freelance)
Tim Day, Innovative Strategic Communications, LLC
Agnella Matic, PhD, CMPP, AIM Biomedical, LLC
Carol Keys, PhD, CMPP, Thinking Cap Medical Communications, LLC

Recent activities by state and federal legislative bodies (eg, California AB5) will have an adverse impact on the livelihood of freelance writers. Although the specific impact of each legislative activity will vary, these actions will have the effect of imposing limits on the amount and type of work freelancers can do. The nature of these legislative efforts has caught many by surprise. The ripple effects of the resulting limitations will affect an expansive swath within the publications sector, including writers, publishers, and medical communication agencies, as well as pharmaceutical, biotech, and medical device firms. The fluid nature of the situation will be addressed, and an interim status of legislative activities will be presented. (In addition to a question-and-answer period, there is also a Roundtable Discussion on this topic, Wednesday, 4:00 to 5:00 PM.)

Target Audience: All levels

Mentoring Programs: One Size May Not Fit All (Career Development)
Mary Burder, PhD, Parexel International

Mentoring programs have become a best practice, as they promote the sharing of knowledge and experience and facilitate growth and development. However, one size may not fit all, as each mentee may be in a different stage of career and/or development at the onset of mentoring. Thus, mentoring programs should be tailored to the mentees’ needs and career objectives. Three different mentoring programs will be discussed: new-hire mentoring, which facilitates transition into a new company/new position; project mentoring, for acquisition of client/project-specific skills and processes; and role shadowing, which enables exposure to new roles and skills for career development.

Target Audience: All levels

Roll-out of a Medical Writing Artificial Intelligence Tool: The Future is Here (Core Knowledge/Skills)
Julia Forjanic Klapproth, Trilogy Writing & Consulting

Artificial intelligence will be the future of generating initial drafts of documents by pulling raw material together from various sources. This session provides an overview of what artificial intelligence can and cannot do in the context of medical writing to set expectations for what we can hope to get from such a system. The session will include a live demo of what the system is now able to do: what you put in, how you interact with the tool, how long the process takes, how it helps the writer, and ultimately, what is the final product.

Target Audience: All levels
**10:00 to 11:00 AM**

**EDUCATION SESSIONS**

**What the Best Medical Writers Know About Nonclinical Data (Regulatory Writing)**
Beth Krause, MS, MBA, RRD International, LLC

The nonclinical realm is often unfamiliar territory for medical writers, despite being an integral component of drug development. Essentially all drugs are supported by some nonclinical studies, the results of which will follow the compound through to the product label. Learn about the types of nonclinical data included in an initial investigational new drug submission and how these data influence clinical development; the impact of nonclinical information in common clinical documents, such as protocols, clinical study reports, and investigator’s brochures; and the importance of nonclinical studies beyond the initial investigational new drug application and how they impact drug development through approval.

**Target Audience:** All levels

**11:15 AM to 12:15 PM**

**PLENARY SESSIONS**

**Plenary Session with Special Bioethics Address**

**Structural Injustice in the Time of COVID: Vaccines Globally and Nationally**
Beth R. Faden, PhD, MPH, Founder, Berman Institute of Biomedical Ethics at Johns Hopkins University, inaugural Andreas C. Dracopoulos Director, and Philip Franklin Wagley Professor of Biomedical Ethics

As in other crises, the most disadvantaged groups globally as well as within countries are suffering the most from the COVID-19 pandemic. The root causes of these disproportionate burdens are long-standing structural injustices in well-being, power, and advantage that have been laid bare and, in some cases, exacerbated by the pandemic. In her presentation, Dr. Faden will highlight two areas of particular immediate concern: access to COVID-19 vaccine globally and nationally.

Live question-and-answer period.

**12:15 to 12:45 PM**

**BREAK**

Grab a bite to eat, visit the exhibitors, browse the posters, or engage with other attendees on the Discussion Boards.
ROUNDTABLE DISCUSSIONS

Communicating Science through Social Media [I]
Abbie Roth, Nationwide Children’s Hospital

Medical misinformation runs rampant in social media. Medical communicators have the opportunity and responsibility to advocate for evidence-based health information. Whether you are using social media for business or personal use, you can help support high-quality health information. If you’re new to social media, you might just find out that it’s not so scary after all. From Facebook to Twitter, TikTok to Instagram – the social media landscape is always changing, but by learning some best practices, you can be a voice for good.

Target Audience: All levels

The Importance of Empathetic Language in Scientific Publications (P)
Mary E. Knatterud, PhD, University of Minnesota Medical School (retired)

In these increasingly divisive times, medical writers and editors can help ensure language in scientific articles and related materials that shows appropriate empathy for patients in particular, regardless of age, gender, race, disease, or any other classification. Participants are encouraged to bring an example or two, from your own workplace or reading, of health-oriented terms or sentences that struck you as lacking empathy.

Target Audience: All levels

Jam Session for Editors [P]
Kristina Wasson-Blader, PhD, Clearly Communicating Science, LLC
James Cozzarin, ELS, MWC, ProEd Communications, Inc.

Need a break from writer-focused content? Join your fellow editors for a lightly structured discussion of all things editorial: from software to soft skills, from wresting with grammar to wrangling with writers. This judgment-free zone will be for editors of all professional ages and occupations to ask questions, find answers, and talk shop with editorial colleagues. (The limit on participants is 25.)

Target Audience: Medical editors at all levels of experience

Key Insights for Writing an Effective Clinical Overview (Module 2.5) for a Marketing Application [I]
Elaine B. Taylor, Synchrogenix

Clinical Overviews are meant to be a critical assessment of the clinical data that support the marketing application for a drug product. This discussion will focus on how to fulfill the International Council for Harmonisation M4 guidance requirements and meet regulator’s current expectations. Learn practical tips for achieving a well-thought out and effective Clinical Overview. Each major section of the Clinical Overview will be broken down and evaluated; however, the product development rationale and the benefits/risks sections will be the main focus. (This roundtable discussion is offered twice.)

Target Audience: At least 5 years’ experience and familiarity with Module 2.5
1:00 to 2:00 PM

ROUND TABLE DISCUSSIONS

Leveling up: How Using Emotional Intelligence Will Make You a Better Communicator [I]
Gretchen Griffin, MS, MBA, Trilogy Writing & Consulting

The world of medical communication changes as frequently as the styles, guidance, and standards that accompany it. The expectations of what a medical writer can and will do are evolving and growing. The perceived value of a medical writer is not based solely on the document quality, but on how well they partner with and support the team. This roundtable will include a brief background on emotional intelligence (EI), relevant EI skills, and the benefits of successful EI skill application.

Target Audience: All levels

Leveraging Artificial Intelligence in Medical Writing—“Localizing” the Patient Connect [I]
Dr. Nimita Limaye, CSOFT Health Sciences

Medical writers bring in rich expertise in authoring complex documents containing a prodigious amount of information and significant duplication of content. While structured authoring has helped, artificial intelligence (AI) has significantly improved the return on investment in the authoring of documents and enabled rapid data redaction, content development, and document translation. AI is an invaluable enabler, allowing writers to focus on high-end tasks. Yet, the localization of language can make all the difference in building the patient connect in the case of documents such as lay summaries.

Target Audience: All levels

Looking Back for Future Medical Writing Success [I]
Manasi Kher, PhD, Merck & Co. Inc

Medical writers can use every document as an opportunity for continuous improvement through a "lessons learned" approach. This discussion will focus on practical ways medical writers can use lessons learned to implement positive changes on future projects. Gain tips and understand best practices to effectively gather lessons learned and use the information to build trusting relationships, modify communication strategies, uncover potential tool/process changes, and achieve desired team behaviors. Also discussed will be characteristics of a successful lessons-learned implementation in which a medical writer was able to move improvements forward by effectively looking back.

Target Audience: All levels
1:00 to 2:00 PM

**ROUNDTABLE DISCUSSIONS**

**Tips for Studying for the MWC Exam**
*Brian Bass, MWC, Bass Global, Inc.*

The Medical Writer Certified (MWC) examination is administered in June and December each year via computer-based testing at IQT testing centers near major cities around the world. While many people have already earned their MWC certification, some people worry about sitting for the exam because they don’t work in all areas of medical communication or are unsure of how best to study for the exam. The Applicant and Candidate Handbook and Study Guide developed by the Medical Writing Certification Commission (MWCC) are essential tools for anyone thinking of sitting for the MWC exam. This roundtable discussion will focus on how candidates from a range of backgrounds as medical communicators can best prepare themselves to sit for the exam.

**Target Audience:** At least 2 years’ experience

**Where Do You Find Your Story Topics?**
*Larry Lynam, DSc, MA, RM, SM, The Lynam Group, LLC*

When you’re at the “mature” stage of your career, other medical writers often ask advice; and a recurring topic of late is, “where do you get your story ideas?” That question has led to great discussions about interests, passions, and how to incorporate and tell stories. Stories can play a powerful role in making your work more memorable. If you are interested in stretching your creativity, or even just expanding your portfolio of offerings, join us for this discussion and let’s share ideas to help us each other progress along the path toward communicating more effectively with storytelling.

**Target Audience:** All levels

2:15 to 3:15 PM

**EDUCATION SESSIONS**

**3 Easy Steps to Get More Freelance Clients on LinkedIn** *(Freelance)*
*Lori De Milto, MJ, Lori De Milto Writer for Rent LLC*
*JoAnna Pendergrass, DVM, JPen Communications LLC*
*Kelly Schrank, MA, ELS, Bookworm Editing Services LLC*

More and more clients are using LinkedIn to find freelance medical writers and editors and to check them out before deciding whether to contact one. But many freelancers don’t know what to do on LinkedIn to get found by clients and impress them. Once you know the three easy steps to success on LinkedIn, attracting more clients will be easier and less time-consuming. Learn how to get found and impress clients with a complete profile focused on their needs and rank higher in search results by building a big, relevant network and being active (posting and commenting on other people’s posts).

**Target Audience:** All levels
EDUCATION SESSIONS

Beyond the Needs Assessment: Creative Perspectives on Continuing Medical Education Content Development (Education for Professionals)
Don Harting, MA, MS, ELS, CHCP, Harting Communications

This session offers an advanced look into writing for accredited continuing medical education (CME). The session begins with a discussion of a few key industry trends that are driving greater creativity in CME writing. After a brief mention of the needs assessment, which is considered a basic assignment, we’ll delve into how to work with clients and faculty to develop more advanced assignments, including digital monographs, polling questions, test questions, interactive case studies, outcome reports, meeting posters, and peer-reviewed journal articles. The session will end with a look ahead at additional types of CME writing assignments that may become common in the future, including software and games.

Target Audience: 5 to 8 years’ experience

A Powerful Combination: The Value of the Writer-Editor Partnership (Career Development)
Crystal Herron, PhD, ELS, Redwood Ink, LLC

Every writer can benefit from partnering with a good editor. Even the best writers. A good editor will dive deep into your writing, tear it apart objectively, and then help you put it back together in a clear and compelling way. They will invest time in refining your writing to elevate it to a higher standard than you thought possible. They will become your partner, teacher, and collaborator. Learn the benefits of partnering with a professional editor and how you can find the best editor to complement your writing skills and style.

Target Audience: All levels

Tricks and Tips for Time Management (Core Knowledge/Skills)
Melissa Christianson, PhD, Whitsell Innovations

Time is one of a writer’s most valuable resources, and managing this resource in the face of competing challenges can be among the most complex parts of a writer’s job. However, most writers receive little or no training on effective time management skills and, consequently, lose a sizable fraction of their working time to inefficiency. Fortunately, making purposeful changes in working habits can help writers improve their time management skills. This session will address 6 common time management problems and explore specific solutions for each one. Participants will learn actionable strategies for improving their time management skills and increasing productivity.

Target Audience: All levels

BREAK

Grab a drink, visit the exhibitors, browse the posters, or engage with other attendees on the Discussion Boards.
ROUNDTABLE DISCUSSIONS

By the Numbers: Health Numeracy and Communication Strategies that Work for Patients and the Public [P]

Genevieve J. Long, PhD, PC

We’ve all heard of health literacy, but what does health numeracy mean? How much do patients and other members of the public understand from the statistics, charts, and graphs in health information? In this roundtable, we will discuss the latest evidence-based strategies for communicating risk, sharing numerical information in graphics, and more. Bring your questions and strategies, connect with other medical communicators who are passionate about helping people use numbers, and leave with new ideas for sharing health information using numbers.

Target Audience: All levels

Cardiovascular Disease Pharmacogenomics [I]

Shawn Watson, PharmD, PhD, BCPS, Bicycle Therapeutics

Pharmacogenomics is a frequent component of clinical studies and patient care. During this roundtable discussion, we will evaluate the validity (analytic and clinical) and clinical utility of pharmacogenomic (PGx) testing in patients treated with medications to manage cardiovascular (CV) disease. We will apply a CYP2C19 genotype to individualize antiplatelet therapy selection for patients undergoing percutaneous CV interventions and apply CYP2C9, VKORC1, and CYP4F2 genotypes to establish an anticoagulation regimen for patients taking warfarin. Lastly, we’ll assess the role of PGx testing in hyperlipidemia, hypertension, heart failure, arrhythmia, and with direct oral anticoagulants. These examples will provide medical communicators with a better foundation and relevant insights into contemporary clinical considerations with pharmacogenomic data.

Target Audience: 5 to 8 years’ experience

Clinical Evaluation for CE Marking of Medical Devices: Context and Compliance [I]

Isabelle Searcy, PhD, Network Partners

In light of the new Medical Device Regulations (MDR), medical writers have a unique opportunity in helping manufacturers demonstrate compliance of their devices through a thorough Clinical Evaluation. Learn about the requirements of clinical evaluations for medical devices in compliance with the Meddev 2.7/1 Revision 4 and 2020 MDCG guidance and how to conduct, structure, and write clinical evaluation plans and reports. Specificities of clinical evaluations for Class II and Class III devices, and tips for postmarket surveillance and literature search and analysis will also be discussed. (This roundtable discussion is offered twice.)

Target Audience: 0 to 2 years’ experience
**ROUNDTABLE DISCUSSIONS**

**Discussion of Legislative Efforts to Limit the Livelihood of Freelance Medical Communicators [P]**

*Tim Day, Innovative Strategic Communications, LLC*

*Agnella Matic, PhD, CMPP, AIM Biomedical, LLC*

*Carol Keys, PhD, CMPP, Thinking Cap Medical Communications, LLC*

Join a discussion about the effects of recent activities by state and federal legislative bodies that are poised to affect the livelihood of freelance medical writers. It’s best to first listen to the Education Session, Addressing Legislative Efforts to Limit the Livelihood of Freelance Medical Communicators, on Wednesday, 10:00 to 11:00 AM.

**Target Audience:** All levels

**Networking Discussion: New to AMWA**

*Sharon Ruckdeschel, AMWA Membership Director*

Are you new to the organization? Is this your first AMWA conference? Learn more about how to get the most out of your membership and your conference experience.

**Quality through Automation: Improving Document Quality with PerfectIt—An Enterprise Case Study [I]**

*LaShanda Gordon, Merck & Co. Inc.*

From interactive voice response systems to IBM Watson, automation technology offers the promise of improved quality and workflow productivity within the medical sciences. PerfectIt is a novel software tool that gives medical communication organizations a consistent means for ensuring quality standards across the document portfolio. Join us for a discussion about Merck Medical Writing’s implementation of PerfectIt. We will discuss our implementation process from concept to steady state and share some of the benefits, challenges, and lessons learned from the experience.

**Target Audience:** All levels

**The Self-Empowered Medical Writer [I]**

*Anand Devasthanam, PhD, Syneos Health*

Have you ever wanted to grow laterally and build experience in different settings within medical writing? Do you think knowledge and experience are the only determinants of success? Think again. This discussion introduces self-empowerment as a skill that can be developed, honed, and applied effectively to dissolve internal barriers, strategize lateral movement, and be poised for success. Self-empowerment means recognizing and using our innate strengths to achieve our highest and best use as medical writers. This discussion aims to captivate and inspire medical writers at all experience levels to re-examine the transformational power of self-empowerment in their professional paths.

**Target Audience:** All levels
4:00 to 5:00 PM

ROUND TABLE DISCUSSIONS

Working Remotely: Adapting to the New Norm [P]
Jenny Thayer, MBA, EdM, MA, BioBridges

Many medical communicators have worked remotely for years, but many of us found ourselves suddenly working remotely this year. How have we adapted to this new norm? At this roundtable discussion, seasoned remote workers can share their tried-and-true techniques for a successful career working remotely while those newer to working remotely can share their recent successes, including the inevitable bumps in the road and resultant adaptations allowing them to work remotely successfully. (This roundtable discussion is offered twice.)

Target Audience: All levels

5:15 to 6:15 PM

ROUND TABLE DISCUSSIONS

Creating a Strategic Plan for a Medical Writing Department [I]
Jeanette Towles, Synterex, Inc.

Effective leadership of a medical writing department involves advocating as well as educating other stakeholders on the value proposition of medical writers. Learn to translate the vision and goals for your group into language that your executive team can easily understand, including assessment of strengths, weaknesses, opportunities, and threats (SWOT) and communication of critical success factors. Learn practical tips to ensure that your short-term and long-term initiatives dovetail with the plans of the company as a whole. (This roundtable discussion is offered twice.)

Target Audience: More than 8 years’ experience

Freelancer’s Guide to Cybersecurity [I]
J. Kelly Byram, MS, MBA, ELS, Duke City Consulting, LLC

For freelancers, reputation is everything, and cybersecurity can be something they don’t think about until tragedy strikes: viruses and malware attack or data are taken for ransom. This can be heartbreaking when personal data are lost or destroyed, but the loss, destruction, or theft of data can be devastating for a professional managing ongoing projects and clients’ confidential data. Learn about common vulnerabilities facing freelance professionals and the inexpensive tools and best practices for maintaining privacy and cybersecurity—at home and on the road.

Target Audience: All levels
ROUND TABLE DISCUSSIONS

Jam Session for Early-Career Freelancers [P]
Andrea R. Gwosdow, PhD, Gwosdow Associates Science Consultants, LLC
Theresa E. Singleton, PhD, Singleton Science, LLC

If you’re an early-career freelance with 3 to 7 years of experience, you won’t want to miss this roundtable discussion. Come exchange information on the common challenges that arise during the early years of freelancing, as well as share ideas and lessons learned. Discuss your successes and toughest problems with other early-career freelancers and make new connections to continue the conversations once you're back home. (The limit on participants is 25.)

Target Audience: Freelance medical writers with 3 to 7 years’ experience

Jam Session for Seasoned Freelancers [P]
Brian Bass, MWC, Bass Global Inc.

When accomplished musicians jam, their combined talent, energy, and experience make a special kind of synergy. A similar kind of magic happens when seasoned freelancers get together to discuss their ideas, concerns, and challenges with peers who have the same or more experience. These rare gems of collegial conversation and commiseration happen spontaneously and usually unpredictably. This discussion will provide a supportive space for experienced freelancers 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. This discussion is lightly structured to permit a free flow of discussion without getting stuck for too long on a single topic. (This roundtable discussion is offered twice; the limit is 25 participants.)

Target Audience: Freelance medical writers with at least 8 years’ experience

Managing Medical Writers Virtually [I]
Dylan Harris, PhD, MBA, Takeda

While working remotely has been a routine part of professional life for many medical writers, many additional writers who had been office based have found themselves working remotely in 2020. This has presented a special set of challenges for writers and also for managers who are charged with resource planning, developing and keeping writers engaged, providing necessary tools and technologies for remote working, and ensuring teams that high-quality work will proceed on schedule. We will discuss strategies for successfully managing medical writers and medical writing groups in a virtual setting. (This roundtable discussion is offered twice.)

Target Audience: At least 5 years’ experience
**ROUNDTABLE DISCUSSIONS**

**Medical Journalism Do's and Don'ts: Tips for Successful Reporting and Writing** [I]
*Barbara Gastel, MD, MPH, Texas A&M University*

This discussion 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 chances to share their own tips and ask questions. A resource list will be provided.

**Target Audience:** All levels

**Operating Decisively and Planning Around Uncertainty: Scientific Publication Planning** [P]
*Chirag Shah, PharmD, RPh, Neurocrine Biosciences*

As the novel coronavirus races around the globe, a growing number of conference organizers are cancelling, postponing, or virtualizing their medical meetings. Of course, this is an unprecedented time, but we have learned a lot from this situation. As medical communication professionals, we are adaptable and can meet our customers’ educational needs while operating in a virtual environment. Join this roundtable to discuss key strategies and tactics as they related to publication planning in a virtual environment.

**Target Audience:** All levels

**Poster Discussion: Balancing Expectations while Writing Lay Summaries** [I]
*Madiha Khalid, PhD, Kinapse, a Syneos Health Company*

This roundtable is a discussion of the poster “Lay Summaries: “Translating” Regulatory Documents into Lay Language.” Regulatory writers transitioning to lay summary writing have 3 main areas of development to consider: balancing regulatory requirements with sponsor expectations, maintaining scientific accuracy, and patient-focused presentation that is clear and visually appealing. We will discuss the key points for a successful transition into lay summary writing as they relate to these 3 areas of development.

**Target Audience:** All levels

**What Should Clients and Freelancers Expect from Each Other?** [I]
*Debby Berlyne, PhD, Freelancer*
*Jennifer McCulley, PhD, PMP, IQ Solutions*

Freelance writers and editors and clients often have misconceptions about each other. For example, freelancers do not always make sure, in advance, that they truly understand what the task requires and that they have the appropriate skills and availability needed. They might neglect to determine the resources that they and the client will provide, when the work will start (and whether the start date is firm), and whether the deadline is flexible. Similarly, clients do not always understand that freelancers need advance notice of new tasks or changes in existing ones, what information and resources they need to provide to freelancers, and what a reasonable timeline is. This discussion, led by a freelancer and a client who works with freelancers, will address how to identify reasonable expectations on both sides, how and when to communicate expectations, and what to do when expectations are not met.

**Target Audience:** All levels
EDUCATION SESSIONS

Clinical Evaluation Reports: Requirements, Recommendations, and Reality (Medical Devices)
Karen Bannick McQuoid, Bannick LLC
Denise King, Medtronic

Clinical Evaluation Reports (CERs) are recognized as an invaluable element of any European medical device submission, especially in light of quickly evolving interpretations of the European Medical Device Regulations (EU MDRs). The reality is that there is a science and an art to the preparation of CERs. The bar for the CER content and expectations for the analysis of all clinical evidence available on the device continues to be raised in any unpredictable trajectory. This session will provide a brief overview of key elements of the requirements and hone in on recommendations for avoiding common pitfalls seen during Notified Body Review.

Target Audience: All levels

Editing: Hard Knowledge, Soft Skills (Career Development)
Loretta Bohn, ELS, RTI International
Erica Goodoff, ELS, The University of Texas MD Anderson Cancer Center
Crystal Herron, PhD, ELS, Redwood Ink

The skills and tasks of writers and editors, though they may overlap, are distinct. If you’ve been doing editing tasks for more than a couple of years, either as a freelancer or an employee, you know this, and you seek out other members of your tribe. AMWA is a home for anyone in health or scientific communication, so whether you’re a “real” medical writer who also edits your peers’ work or you work full-time at any form of editing, you belong here! Join us—two staff editors and a freelance editor—for a panel discussion on how to maintain our mental health as editors, how to manage expectations and conflict, and what new trends or new trends or challenges we’re seeing.

Target Audience: 5 to 8 years’ medical editing experience

Regulatory Chemistry, Manufacturing, and Controls Submissions: Lifecycle Decisions (Regulatory Writing)
Nellie Waterland Forwood, MS, RAC, CQE, Synchrogenix

The chemistry, manufacturing, and controls (CMC) information in an initial marketing application needs to be a balance between current manufacturing and testing practices, requirements in the various guidance documents, and the need for some flexibility in the lifecycle management of the marketed product. Learn about the CMC detail necessary in an initial marketing application balanced against the postapproval ramifications of including too much detail in certain aspects of the application.

Target Audience: All levels
10:00 to 11:00 AM

EDUCATION SESSIONS

Strategies for Effective Risk Communication (Health Communication)

Melissa Christianson, PhD, Whitsell Innovations

The rise of patient-centered care and shared decision-making models has created a crucial role for risk communication in health care. Effective risk communication occurs when physicians and other medical communicators share clear and accurate information about health-related risks in a way patients can understand. Failure of this process compromises patient involvement in care decisions. However, obstacles such as variable health literacy rates, attitudes toward science, and data complexity make risk communication difficult.

This session outlines both barriers to and strategies for successfully communicating risk information to nonexpert audiences. Participants will learn proactive methods for clearly and effectively communicating about health-related risks.

Target Audience: All levels

11:15 AM to 12:15 PM

PLENARY SESSION

Plenary Session with Executive Panel

Commentary on the state of the industry in regulatory writing and scientific communications.

Is There Any "New Normal" for Regulatory Medical Writing?

Joan Affleck, MA, MBA, Associate Vice President, Head of Medical Writing, Merck & Co. Inc.

Title TBD

Heather Abourjaily, PharmD, Head of Global Scientific Communications – Pipeline, Vertex Pharmaceuticals

BREAK

12:15 to 12:45 PM

BRAK

Grab a bite to eat, visit the exhibitors, browse the posters, or engage with other attendees on the Discussion Boards.
ROUND TABLE DISCUSSIONS

Best Practices for Writing Continuing Medical Education Needs Assessments [I]
Donald Harting, Harting Communications LLC

Writing needs assessments for continuing medical education can be like solving a puzzle. This hands-on exercise will begin with a brief lesson on what nationwide survey evidence has shown are the most essential sources of evidence to include. Then the group will be given a puzzle to solve, in the form of a jumbled mass of data about leukemia. Working in pairs, roundtable participants will classify the evidence, organize the evidence in a standard format, edit out nonessential evidence, draft 2 learning objectives, share solutions with the group, and discuss alternate solutions.

Target Audience: 0 to 2 years’ experience

Clinical Evidence and Clinical Evaluation Report Strategies in a Medical Device Regulation-Compliant Landscape [P]
Julie Hurt, PhD, Whitsell Innovations, Inc.

The initial release of Medical Device Regulation (MDR) in the European Union created a paradigm shift in clinical evidence collection and clinical evaluation report (CER) strategy. Over the transition period, manufacturers have evaluated safety and performance of their devices alongside state-of-the-art technologies in new and challenging ways (ie, demonstrations of equivalence, formalized postmarket activities, mandatory clinical investigations, clearly delineated safety and performance endpoints, etc). Join us and share our experiences as the CER “storykeepers,” keeping teams focused and organized as they identify the most robust clinical evidence to support their devices.

Target Audience: All levels

Ensnared by Ennui? Staying Engaged in your Professional Development [P]
Jennifer Bridgers, MS, MWC, Merck and Co. Inc.

As a new writer many years ago, I saw the ennui from the experienced members and wondered about it. Now I see this in some of my colleagues. AMWA has been focused on new ways to educate and to share knowledge. We will discuss ways to stay engaged in your professional medical writing development after 8+ years in the field, both within AMWA and through other opportunities. Participants are encouraged to bring their ideas and share their experiences. (With permission, the speaker will consolidate the discussion and post a general summary of the roundtable to Engage.) (This roundtable discussion is offered twice.)

Target Audience: More than 8 years’ experience
ROUND TABLE DISCUSSIONS

Lay Summaries of Clinical Study Results—Evaluating Current Industry Practice. Are We Meeting Expectations of the Public? [P]
Thomas Schindler, PhD, Boehringer Ingelheim Pharma

This discussion is meant to provide a forum to discuss current practices in the writing of lay summaries. We will be looking at examples from different sponsors and will jointly assess how they are fulfilling the requirements and whether they are appropriate for patients and the public. This will help us to determine potential shortcomings and areas of improvement for lay summaries. Time permitting, we will also review lay summaries for children.

Target Audience: All levels

Networking Is at Least as Important Now as It Was BC (before COVID): We Took Our “First Thursday” Event Virtual [P]
Larry Lynam, DSc, MA, RM, SM, The Lynam Group, LLC

In December of 2016, a small group of AMWA southeastern Florida Chapter members began meeting the first Thursday of each month. Our group, officially christened as “First Thursday,” met live until the COVID-19 shutdown hit Florida in March. Our monthly gatherings are important to our members, so much so, we transitioned to virtual monthly meetings. As a result, we discovered a new range of possibilities and purpose for our gatherings. We are happy to share our story and are interested in hearing your ideas as well. Join us for a discussion on effectively networking—even during these trying COVID times.

Target Audience: All levels

Putting the Pieces Together: Best Practices for Taking Ownership of Your Documents [I]
Stephanie Hreha-Phillips, MS, Merck & Co. Inc.

Do you often have difficulties getting what you need from stakeholders? Are you unsure of the content required for your document? Most regulatory documents require input from various stakeholders, and writers rely on this to move documents forward. Delays in receiving the necessary information cause timelines to slip. Realize the power of suggestion to take control of your documents. Learn to apply content reuse to regulatory documents and put together proposed text for sections requiring stakeholder input. Various resources for understanding content requirements will be discussed. Become the expert in getting the feedback you need! (This roundtable discussion is offered twice.)

Target Audience: 2 to 5 years’ experience
1:00 to 2:00 PM

ROUND TABLE DISCUSSIONS

Transitioning to Full-Time Regulatory Writing [P]
Cody Nichols, PhD, Whitsell Innovations

Whether you are transitioning into regulatory writing from academia, the pharmaceutical sector, or another world entirely, this roundtable discussion is for you. As a growing and developing writer, you may have the opportunity to work on a wide range of projects, each with its own unique challenges. Discussion topics will include various types of documents in regulatory writing and where to gain valuable training and experience needed for each; some tips and tools to ease the transition into regulatory writing; how to adapt transferable skills to current roles; and the importance of soft skills and resources for perfecting them. (This roundtable discussion is offered twice.)

Target Audience: 0 to 2 years’ experience

The Trend toward Collaborative Authoring: Pros and Cons vs Fixed Steps for Document Development [I]
Mark R. Bowlby, PhD, Synchrogenix

The near-universally adopted method for document development, namely, the draft-review-revise process, is increasingly being questioned as best practice. As demands for shortening process timelines have continued to increase and software advances have made many interactions continuous, there appears to be a concurrent push for a more collaborative approach to authoring. Collaborative authoring can indeed speed the development of expert content in documents; however, it also poses new issues for authors, especially in the case of continuous collaborative authoring. Learn about the extent of this trend, variants in its implementation, impacts on authors, and techniques for managing collaborative authoring. (This roundtable discussion is offered twice.)

Target Audience: All levels

Writing Informed Consent Forms in the Era of the Revised Common Rule [I]
Benjamin Snow, MS, ELS, and Katelyn Le, MS, Leidos Biomedical Research, Inc.

In 2018, the regulations that govern most federally funded human subjects research, known as the Common Rule, underwent their first revision since initial publication in 1991. This revision makes several updates to the elements of informed consent, including a description of plans for secondary research on data and biospecimens and a description of plans for returning research results; and a new introductory section called “key information.” As institutions implement the new regulations, medical writers can play a part in helping to provide research participants with the information they need, and in a way they can understand, to provide informed consent.

Target Audience: All levels
EDUCATION SESSIONS

Analysis of Mentoring: From Marginal to Maximal (Career Development)
*Susan Morris, MEd, CPCC, ACC, Susan Morris Coaching*

In today’s life sciences industry, technical professionals are rewarded for their deep expertise, sometimes at the expense of an equivalent excellence in building and maintaining one important business relationship. This important business relationship is the mentoring relationship. This session will provide an analysis of the benefits of mentoring for the mentee and mentor. Learn about a 4-step mentoring process that, when followed, takes mentoring from marginal to maximum rewards.

**Target Audience:** All levels

Enforcing House Style: Customizing PerfectIt for Client, Agency, or Publication Preferences (Core Knowledge and Skills)
*Daniel Heuman, Intelligent Editing Ltd*

Checking that every detail conforms to a house style is time-consuming and it can distract you from ensuring that science is presented correctly. There is an easier way! This session will show how you can use PerfectIt to build a custom style sheet and check your preferences. It will show how you can set up a different style sheet for each agency, client, or publication that you work with; and it will describe show you can share that with colleagues.

**Target Audience:** Some experience with PerfectIt on a PC with Windows

Updates to the *AMA Manual of Style, 11th Edition*
*Stacy Christiansen, JAMA
Tracy Frey, JAMA Network Specialty Journals*

Two members of the *AMA Manual of Style* committee will aim to give AMWA attendees an overview of recently implemented updates since publication of the 11th edition in February. This session will focus particularly on updates to the Correct Usage section on race and ethnicity, additions to the Nomenclature chapter to include COVID-19, and updates to the Capitalization and Punctuation chapters. In addition, important changes to this edition will be reviewed from throughout the manual. There will be time at the end of the session to ask questions.

**Target Audience:** All levels

BREAK

Last chance to visit the exhibitors, browse the posters, or engage with other attendees on the Discussion Boards.
ROUNDTABLE DISCUSSIONS

Avoiding Rejection: Tips for Manuscript Writing Success [I]
Andrea Gwosdow, PhD, Gwosdow Associates Science Consultants, LLC

Writing manuscripts can be challenging. This roundtable discussion will focus on the primary reasons manuscripts are rejected from journals and how to improve one’s chance of success when preparing manuscripts for publication. Come learn practical tips for writing each section of a journal manuscript effectively and efficiently, helping to ensure acceptance. Strategies for dealing with manuscript reviews and responding to reviewers' comments will also be discussed. Participants will be asked to share their experiences and tips for manuscript writing and publication. (This roundtable discussion is offered twice.)

Target Audience: 2 to 5 years’ experience

Best Practices for Training Writers New to Clinical Trial Protocols [P]
Katie Provost-Javier, PhD, Merck & Co. Inc.

Join us to discuss best practices in training and mentoring novice protocol authors to help them maximize their value. Protocol authors are most effective when they understand the entire continuum of drug development and clinical trial documentation. Recognizing how target label indications drive endpoint selection and how endpoints inform trial design brings focus to protocol authoring. Envisioning how protocol content is used and reused allows the writer to construct a document with foresight and purpose. How do you teach this? Participants will be asked to share their experiences and ideas on training writers who are new to protocol authoring. (This roundtable discussion is offered twice.)

Target Audience: More than 8 years’ experience

Key Insights for Writing an Effective Clinical Overview (Module 2.5) for a Marketing Application [I]
Elaine B. Taylor, Synchromix

Clinical Overviews are meant to be a critical assessment of the clinical data that support the marketing application for a drug product. This discussion will focus on how to fulfill the International Council for Harmonisation M4 guidance requirements and meet regulator’s current expectations. Learn practical tips for achieving a well-thought out and effective Clinical Overview. Each major section of the Clinical Overview will be broken down and evaluated; however, the product development rationale and the benefits/risks sections will be the main focus. (This roundtable discussion is offered twice.)

Target Audience: At least 5 years’ experience and familiarity with Module 2.5
4:00 to 5:00 PM

**ROUNDTABLE DISCUSSIONS**

**Managing Medical Writers Virtually [I]**
*Dylan Harris, PhD, MBA, Takeda*

While working remotely has been a routine part of professional life for many medical writers, many additional writers who had been office based have found themselves working remotely in 2020. This has presented a special set of challenges for writers and also for managers who are charged with resource planning, developing and keeping writers engaged, providing necessary tools and technologies for remote working, and ensuring teams that high quality work will proceed on schedule. We will discuss strategies for successfully managing medical writers and medical writing groups in a virtual setting. (This roundtable discussion is offered twice.)

**Target Audience:** At least 5 years’ experience

**Patient Engagement and Cultural Competence: The Common Thread. The Human Experience [I]**
*Mauvareen Beverley MD, mauvareen BeverleyMD, PLLC*

Individuals came to our institutions and were given a disease they did not want, were not prepared for, and cannot give back. Once accurately diagnosed, the disease is non-negotiable and may remain with the individual for life. Come learn why the concept of a non-negotiable disease, inclusive of the elimination of choice, creates a culture of empathy and compassion and how this new concept would help medical communicators be more proficient and emphatic.

**Target Audience:** All levels

**The Times They Are a Changin’: How to Manage Change Effectively in Every Role [P]**
*Jenni Pickett, PhD, Whitsell Innovations, Inc.*

Change is a way of life for medical writers. Regulations, client needs, and best practices are constantly evolving. Developing skills to manage this change builds your leadership capability. Discuss a past, present, or future change experience with the group and learn change management techniques that apply to your situation. Learn about the roles involved (initiator, expert, leader, advocate, and participant) and how to leverage each of those roles to execute change. Discover how to break down complex changes into manageable steps to maximize your chances of enacting successful lasting change. (This roundtable discussion is offered twice.)

**Target Audience:** All levels
4:00 to 5:00 PM

ROUNDTABLE DISCUSSIONS

To Be More Efficient and Consistent, Build a Better Checklist [I]
Kelly Schrank, MA, ELS, Bookworm Editing Services LLC

Come to this roundtable to learn how using a comprehensive checklist created and updated for a specific task can help you differentiate workflows, systems, and activities; increase quality, accuracy, and consistency; spell out details needed at the moment you need them; track your progress; document metrics; and give you a sense of completion and peace of mind. Samples of checklists for editing manuscripts, dossiers, and slide decks; completing business tasks; and writing projects will be shared. Bring your own checklists and/or ideas for tasks where you need help, and we’ll brainstorm together how to make you more efficient and productive.

Target Audience: 5 to 8 years’ experience

Topics and Trends in Scientific Publications [I]
Marianne Mallia, ELS, MWC, Mayo Clinic

Do you want to know more about data sharing, available journal selection tools, duplicate publication, and other ethical issues, such as predatory publishing/editing, as well as trends toward more open access and transparency? This roundtable will explore these issues (and more) in an interactive discussion for editors and writers interested in current topics and trends in scientific publications.

Target Audience: All levels

5:15 to 6:15 PM

ROUNDTABLE DISCUSSIONS

Health Habits: Stress Less, Feel Great, Work Better [I]
Reggie Wilson, MS, Fit for Freelance

Back hurts, can't concentrate, and always feel stressed out? I bet that's not why you started freelance or remote work. Big companies focus on employee wellness to increase productivity, attendance, and retention, while reducing health care costs. Home-based writers can barely focus while they work themselves sick. Are you ready for energy to enjoy the reasons you work? Join the discussion for simple food, activity, workspace, and lifestyle choices you can make right away to feel great while you work! (This roundtable discussion is offered twice.)

Target Audience: All levels
ROUNDTABLE DISCUSSIONS

How to Find a Job [I]
*Kelleen Nora Flaherty, University of the Sciences*

Job hunting is a daunting, overwhelming task for medical writers, whether they are new or experienced and freelance or full-time. However, there are several approaches to and considerations for job hunting that can make your hunting more efficient and successful. Come learn how to undaunt your job search with tips, techniques, approaches, resources, record-keeping, and essential skills! (*This roundtable discussion is offered twice.*)

**Target Audience:** All levels

The Mindset and Art of Writing Effective Response Letter to the Journal Editor [P]
*Katherine L. Molnar-Kimber, PhD, KMK Consulting Services of Kimnar Group LLC*

Writing an effective response letter to the journal editor that addresses the comments of the peer reviewers can move your client’s submitted revised manuscript to the acceptance folder. With authors’ input, medical writers can address straightforward comments and revise the manuscript. We’ll discuss when and how to disagree with the reviewers and still get published in the journal. Our discussion will provide successful ways to address 5 reviewers’ issues. Participants are encouraged to bring (nonconfidential) examples of challenging reviewers’ issues for group discussion.

**Target Audience:** All levels

Networking Discussion: 25-Year Club
*Donna Miceli*

Get together with other AMWA members who have been in the association for 25 years or more.

Networking Discussion: AMWA Past Presidents
*Art Gertel, MedSciCom, LLC*

Join your fellow past presidents and connect!

Plain Language Summaries: Managing Patient Engagement [I]
*Theresa Shalaby, MSN, RN, Synchrogenix, a Certara Company*

Managing the challenges of patient engagement in the development of plain language summaries (PLS) will be discussed. Current challenges include how to identify and recruit patient reviewers, how to manage the engagement/review period, and what to do with the information provided. Synchrogenix has developed a solution to these challenges called the Podium PLS Review Platform. The platform, and some results from patient engagement work will be presented.

**Target Audience:** All levels
**ROUNDTABLE DISCUSSIONS**

**Trust Me on This: How to Build Client Trust** [P]
*Beth Knight, PhD, Whitsell Innovations, Inc.*

Client distrust hampers efficiency by causing version-control issues, work redundancy, disorganization, unclear expectations, rushed timelines, and urgent communications. Fear that the medical writer will be unresponsive or not follow through causes stress for the entire team. How can we build trust with clients who may be anxious with us as their new writer? We will discuss strategies on earning client trust through communication, timelines, delivery, and more. We will share factors that might underlie client behaviors, tips for handling demands for rapid response, and ways to tame team practices for a more efficient project process.

**Target Audience:** All levels

**Working Remotely: Adapting to the New Norm** [P]
*Jenny Thayer, MBA, EdM, MA, BioBridges*

Many medical communicators have worked remotely for years, but many of us found ourselves suddenly working remotely this year. How have we adapted to this new norm? At this roundtable discussion, seasoned remote workers can share their tried-and-true techniques for a successful career working remotely while those newer to working remotely can share their recent successes, including the inevitable bumps in the road and resultant adaptations allowing them to work remotely successfully. (*This roundtable discussion is offered twice.*)

**Target Audience:** All levels

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**GET ENGAGED!**

There are many ways to engage in this year’s conference and interact with your fellow attendees.

**Send a message.**
Connect with colleagues old and new by sending a message to another attendee through the conference platform.

**Sign up for a Networking Discussion.**
Choose the New to AMWA roundtable if you’re new to the association or it’s your first conference. If you’ve been a member for 25 years or more, meet at the 25-Year Club table. And if you’re a Past President, join other past presidents at the Past Presidents roundtable.

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**Post on a Discussion Board.**
- **Daily Questions.** Serious—and fun—questions asked every day. Join the conversation by answering and seeing what your colleagues have answered.
- **Freelance Career Advice.** Have a question about a freelance career? Ask your question and get an answer from an expert.
- **Celebrate AMWA’s 80th!** Share a comment or photo of a particularly fond memory from a previous AMWA conference.
Twelve posters are on display throughout the conference. You will be able to discuss the poster with the presenter by using the Discussion function. You can chat at any time, and presenters will be available during poster discussion times on Wednesday, 4:00 to 5:00 PM (ET), and Thursday, 1:00 to 2:00 PM (ET).

Author Affiliation with Pharmaceutical Companies may Influence Citations: Analysis from the Top 25 Pharmaceutical Companies
Sarah Cross, PhD, et al., AbbVie Inc.

Custom Macro Development: Added Value for Company and Career
Eric Crampton, Merck & Co. Inc

Difficulties Associated with Moving to a New Document Storage System
John W. Kehoe, PhD, Janssen Pharmaceuticals

The Evolution of Clinical Trial Design with Advances in Personal Medicine
Katie Bates, PhD, et al., Whitsell Innovations Inc.

Lay Summaries: “Translating” Regulatory Documents into Lay Language
Madiha Khalid, et al., Kinapse

Navigating Challenges and Excelling in a Cross-Functional Team Environment
Kunwei Cole, et al., Pfizer Inc

New “Jobs” for Medical Writers: Are Digital Enhancements “Worth the Trouble”? 
Patricia Fonesca, Excerpta Medica

On Becoming Human: The Role of Natural Language Processing in Clinical Research
Debra Kessler, MD, PhD, et al., Merck, Sharpe and Dohme

The Paradox of Corrective Communications: Findings from an MMR Vaccine Awareness Strategy
Lindsay Ulrich, et al., INVIVO Communications

The Role of the Medical Writer in the FDA’s Complex Innovative Trial Designs Program
Bryce Marquis, PhD, Whitsell Innovations

Staying Connected and Broadening our Horizons. First Thursday Goes Virtual
Larry Lynam, DSc, et al., AMWA Florida Chapter

Writing for the Future
Vvyvca Walter, PhD, et al., Eli Lilly and Company