2017 AMWA

Medical Writing & Communication Conference

NOVEMBER 1-4 | ORLANDO, FL

Trends and Opportunities for Medical Communicators

REGISTRATION BROCHURE

Keep pace with the field.

Develop your skills.

Build your network.

Make **#AMWA2017** your happy place.

Join AMWA at the **2017 Medical Writing & Communication Conference** and take advantage of the best education available for medical communicators. Our conference education program will provide you access to highly rated sessions in several different tracks with content leaders presenting best practices, lessons learned, innovative ideas, and more.

Spark your creativity, engage in live interactive learning, and connect with leaders in the industry.

Be happy. Be here.

The 2017 AMWA Medical Writing & Communication Conference will take place at the **Walt Disney World Swan and Dolphin**.

More information and link to a discounted room block is available online.

SCHEDULE AT A GLANCE

WEDNESDAY, NOVEMBER 1	
9:00 AM–12:00 PM	AMWA Workshops (*additional fee*)
9:00 AM–12:00 PM	BELS Examination (*additional fee and registration*)
2:00–5:00 PM	AMWA Workshops (*additional fee*)
2:00–5:00 PM	MWC Examination (*additional fee and registration*)
3:00–5:00 PM	Board of Directors Meeting (*invitation only*)
3:30–4:00 PM	Conference Registration Desk opens
4:00–5:00 PM	New to AMWA and Medical Communication Session
5:15–6:15 PM	Speed Networking Session
THURSDAY, NOVEMBER 2	
8:00 AM–5:00 PM	Registration and AMWA Information Desk Open
8:00–8:45 AM	Continental Breakfast in the Exhibit Hall
9:00–10:30 AM	General Session with Alvarez Award Address
10:30–11:00 AM	Beverage Break
11:00 AM–12:00 PM	Sessions
12:15–1:45 PM	Networking Lunch with Sablack Awards Event featuring the Swanberg Award Address
2:00–3:30 PM	Sessions
2:00–5:00 PM	AMWA Workshops (*additional fee*)
3:30–4:00 PM	Beverage Break
4:00–5:00 PM	Sessions
6:00 PM	Meet in Lobby to depart for Chapter and Regional Networking Dinners
FRIDAY, NOVEMBER 3	
8:30 AM –6:00 PM	Registration and AMWA Information Desk Open
8:00–8:45 AM	Continental Breakfast in the Exhibit Hall
9:00–10:30 AM	Sessions
10:30–11:00 AM	Beverage Break
11:00 AM–12:00 PM	Sessions
12:15–1:45 PM	Roundtable Lunch in the Exhibit Hall
2:00–3:30 PM	Sessions
3:30–4:00 PM	Beverage Break
4:00–5:00 PM	General Session with McGovern Award Address
5:00–6:00 PM	Happy Hour Reception in the Exhibit Hall
6:30 PM	Meet in Lobby to depart for Dine Arounds
SATURDAY, NOVEMBER 4	
8:00 AM–4:00 PM	Registration and AMWA Information Desk Open
8:30–9:30 AM	Sessions
8:30–11:30 AM	AMWA Workshops (*additional fee*)
10:00–11:00 AM	Sessions
10:00–11:00 AM	Annual Business Meeting with Town Hall
11:45 AM–12:45 PM	Luncheon for Saturday AMWA Workshop participants
1:00–4:00 PM	AMWA Workshops (*additional fee*)
1:00–4:00 PM	Intensive: Success Strategies for Showcasing Your Personal Brand (*additional fee*)

REGISTRATION INFORMATION

Your full conference registration includes admission to education sessions, general sessions with award winning speakers, lunch, breakfast, a reception, and access to the exhibit hall. Enhance your conference participation by taking advantage of AMWA Workshops. These are highly-rated, small group, intensive 3-hour programs led by industry experts. Register early for best pricing.

Supersaver rates available May 1 – June 30!

Save $100 on full conference registration, plus $25 off each AMWA Workshop!

Regular Registration Rates	AMWA Member	Nonmember	Student or Retired
Full Conference	~~$750~~ $650	~~$850~~ $750	~~$400~~ $300
Thursday or Friday Only	~~$375~~ $325	~~$425~~ $375	~~$225~~ $175
AMWA Workshop	~~$200~~ $175	~~$250~~ $200	~~$200~~ $175

HOTEL INFORMATION

Staying at the conference hotel gives you a better conference experience. Reserve your room now.

IMPORTANT DEADLINES

Regular registration rates: July 1 – September 31

On-site registration rates apply October 1

Last day to cancel conference registration and receive a partial refund: October 11

AMWA Workshop homework is due to the leader by October 11

CANCELLATION POLICY

Email AMWA at conference@amwa.org no later than October 11, 2017 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 11, 2017. Conference registration and workshop fees are nonrefundable after October 11, 2017. 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, 2017 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.

AWARD SPEAKERS

Helen Osborne M.Ed, OTR/L, 2017 Alvarez Award Winner

Award presentation and address will be during the Thursday General Session, November 2, 9:00–10:00 AM.

Helen is president of Health Literacy Consulting, founder of Health Literacy Month, and producer/host of the podcast series Health Literacy Out Loud. Helen also is a member of the national Patient Centered Outcomes Research Initiative (PCORI) Advisory Panel on Communication & Dissemination Research.

Helen brings clinical experience, educational training, and patient perspective to all her work. She speaks about health literacy at conferences worldwide.

Steven Woloshin, MD, MS; and Lisa Schwartz, MD, MS 2017 McGovern Award Winners

Award presentation and address will be during the Friday General Session, November 3, 4:00–5:00 PM.

Professors of Medicine, of Community & Family Medicine; and Co-Directors, Medicine and the Media Programs, Dartmouth Institute for Health Policy & Clinical Practice

Dr. Woloshin and Dr. Schwartz have done extensive research on the quality of medical communication to the public, patients, physicians, and policymakers. Their work has two main approaches: improving the quality of messages presenting health information to people, and preparing audiences to make sense of the messages they receive.

Brian Bass, MWC®, 2017 Swanberg Award Winner

Award presentation and address will be during the Networking Lunch on Thursday, November 2, 12:15–1:45 PM

The Harold Swanberg Distinguished Service Award is named in honor of Harold Swanberg, MD, the founder of the American Medical Writers Association. This award is presented to an active member of AMWA who has made distinguished contributions to medical communication or rendered unusual and distinguished services to the medical profession.

SCHEDULE

WEDNESDAY, NOVEMBER 1

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

WS-10 Writing Clinical Evaluation Reports for Medical Devices

Felicia R. Cochran, BS, PhD, CMPP, Associate Director, Regulatory and Scientific Affairs, CTI Clinical Trial and Consulting Services, Cincinnati, OH

Practical advice and tips for increasing your value to device manufacturers seeking regulatory approval outside the US. Learn about the many differences in reporting processes and requirements.

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

- Define the regulatory framework governing creation of Clinical Evaluation Reports (CERs), which are mandatory for all medical devices sold within the European Economic Area.
- Distinguish between different types of CERs and their regulatory requirements.
- Demonstrate key concepts/strategies to develop the CER: Conformity with relevant "Essential Requirements"; Sources of "clinical data" (eg, scientific literature, clinical investigation, post-market follow-up); Analysis of quality, suitability, and adequacy of clinical data; When and how to establish device "equivalence"; "State of the Art" comparison vs. therapeutic alternatives and competitor products; Risk/benefit analysis whether foreseeable risks are acceptable when weighed against potential clinical benefits.

WS-11 Clinical Study Report Writing: From Tables Listings, and Graphs to Text

Kathy Spiegel, PhD, Regulatory Writing Senior Manager, Amgen, Inc., Sharon Township, MI

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 Writing and Editing NIH Grants

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

Help organizations overcome the challenges of applying for NIH grants by learning about their general structure and honing your ability to craft key portions of the NIH application.

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

- Define the components of an NIH grant that contribute to the grant's impact score.
- Assess grantsmanship within a proposal.
- Summarize the value added to a proposal by grant editor.

WS-13 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 this workshop, the participant will be able to

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

WS-14 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 this workshop, the participant 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-15 Pharmacokinetics in Clinical Practice and Drug Development

Gayle Nicholas Scott, PharmD, ELS, Principal Medical Writer, Envision Pharma Group, Chesapeake, VA

Andrea S. Gundlach, PharmD, MPH, Richmond, VA

You don't need to be in research to understand pharmacokinetics, the absorption, distribution metabolism, and elimination of drugs. This workshop will help medical communicators with no formal PK training understand principles for better writing and editing.

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

- Define basic pharmacokinetic (PK) terms such as absorption, volume of distribution, metabolism, half-life, elimination rate constant, etc.
- Describe basic PK principles and terminology.
- Describe how genetics may affect drug metabolism.

9:00 AM–12:00 PM **BELS Examination (*additional fee and registration*)**

(Registration is available through the Board of Editors in the Life Sciences.)

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

WS-20 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®, Medical Writing Manager, QuintilesIMS, Durham, 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).

- 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-21 Writing the Investigators Brochure

Jane Stephenson, Director, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT

Increase your knowledge and enhance your value by learning how to provide an uninterrupted information flow between the Sponsor and Investigators at this initial stage of the drug development process.

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

- Identify relevant regulations and guidances.
- Explain how the IB changes from phase 1 to phase 4.
- Describe how an IB can be prepared using subject matter experts.

WS-22 Macroediting

Elliott Churchill, MS, MA, President, A World of Words, Tucker, GA

The techniques employed to ensure a document paints the big picture clearly and sensibly is the art of macroediting, and this advanced workshop will help you elevate your craft.

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

- Differentiate macroediting and microediting tools and techniques.
- Utilize the logic of Aristotle's Scientific Method to guide an author or editor in creating the architecture of a scientific report.
- Demonstrate how the components/sections of an effective scientific report fit together like the pieces of a completed jigsaw puzzle.

WS-23 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 this workshop, the participant 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.

WS-24 Ethical Standards in Medical Publications

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

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 this workshop, the participant 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-25 Plain Language

Sharon Nancekivell, MA, MWC®, Freelance Medical Editor, Writer, Educator, and Plain Language Consultant, Guelph, ON, Canada

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 this workshop, the participant 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-26 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 this workshop, the participant 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.

2:00–5:00 PM **Medical Writing Certification Exam (*additional fee and registration)***

(Application and exam registration information is available online.)

3:00–5:00 PM **Board of Directors Meeting (*invitation only)***

3:30–4:00 PM **Conference Registration Desk opens**

4:00–5:00 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.

5:15–6:15 PM **Speed Networking Session**

This session allows you to get acquainted with colleagues in a structured way. You'll sit with another person at a small table and have 5 minutes to share your professional and personal interests. Then one of you will quickly move to the next table. This is NOT job-hunting; participants will not be divided between job seekers and hiring managers. Rather, this session fosters serendipity—you never know whom you'll meet, what interests you'll share, and whether you might develop a business relationship or friendship! Bring lots of business cards. Please arrive on time and stay for the whole session. Both newer and established professionals are encouraged to attend.

THURSDAY, NOVEMBER 2

8:00 AM–5:00 PM **Registration and AMWA Information Desk Open**

8:00–8:45 AM **Continental Breakfast in the Exhibit Hall**

9:00–10:30 AM **General Session with Alvarez Award Address**

This session features a welcome from AMWA President Lori Alexander, MTPW, ELS, MWC®, the presentation of the President's Award, Fellowships, and the Alvarez Award Address by Helen Osborne M.Ed, OTR/L.

Presentation of 2017 Fellowships: 2017 Fellowship Committee chair, Karen Potvin Klein, MA, ELS, GPC, MWC®, will present Fellowship Awards to Noelle H. Demas, MSTC, Vicki Forester, MD, MSc, and Julie Phelan, MD, MBA, for significant contributions to the goals and activities of the association.

Presentation of the Golden Apple Award: Hope J Lafferty, AM, ELS, administrator of the 2017 Education Committee, will present this award for excellence in workshop leadership to Dominic De Bellis, PhD.

10:30–11:00 AM **Beverage Break**

11:00 AM–12:00 PM **Sessions**

Ready or Not – The New European Medical Device Regulations Are Here!

The Evolving Regulatory Landscape

Felicia R Cochran, BS, PhD, CMPP, Associate Director of Regulatory and Scientific Affairs, CTI Clinical Trial and Consulting Services, Covington, KY

Imagine that the Code of Federal Regulations for medical devices was completely re-written and brand-new regulations were enforced. Sound crazy? In Europe, this is not a hypothetical scenario. Come hear about robust changes imposed by the current European Medical Device (MDRs) and In Vitro Diagnostic Device (IVDRs) Regulations that have replaced the former Medical Device Directives (circa 1990's). Instead of having to read more than 1,000 pages of combined legislation, medical writers can update their knowledge on new, critical provisions affecting the development and market authorization of European medical devices and in vitro diagnostic devices.

Targeted Level of Experience: All Levels of Experience

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

Essential Medical Communication Skills (Writing and Editing)

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 how-to session 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. Session 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.

Targeted Level of Experience: All Levels of Experience

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

Staying Current (Professional Development Topics)

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

Catherine A O'Connor, Senior Communications Analyst, 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 teach you the basics of HEOR and provide tips for medical writers from both technical and nontechnical backgrounds. Topics will include: •HEOR overview (What is HEOR? Why is it growing?) •Real-world evidence (RWE) and patient-reported outcomes (PRO) •Payer/HTA-focused writing •Types of HEOR content (AMCP and global value dossiers, literature reviews, economic models, manuscripts, review articles, slide decks, posters) •International differences (US vs EU vs AP) •What's the future of HEOR? Will it be different in different markets?

Targeted Level of Experience: All Levels of Experience

Realizing the Benefits of Structured Content Management in a Step-wise Fashion

New Media Channels, Writing, Technology, and Software

Mitzi Allred, PhD, Director, Clinical Operations, Merck, North Wales, PA
Angela Horowitz, MPH, Practice Director, Structured Content Management, ArborSys Group, Lawrenceville, NJ

Organizations are faced with managing massive amounts of content. A significant amount of that content is unstructured, as much as 80% in some cases. All this unstructured content can significantly limit your productivity, increase costs and time-to-market, and reduce profits. So, are you interested in realizing some benefits of structured content, but are not ready to implement a full a Structured Content Management (SCM) solution? If your answer is "yes," then join our interactive session where you will learn how Merck, one of the TransCelerate member companies, adopted the technology-enabled TransCelerate Common Protocol Template and then extended it to meet their specific needs. We will demonstrate how the new Merck Structured Authoring Tool (MStAT) provides an authoring interface – using advanced Microsoft Word features – that separates out required document content from related instructional text. In addition, library content is either automatically pre-populated into the document or manually inserted during the authoring process. Finally, we will demonstrate how a content model

was developed to structure a set of clinical documents to enable automated content re-use from one document to another. The session will end with a content mapping exercise where participants can begin to learn how to create their own content model.

Targeted Level of Experience: All Levels of Experience

Professional Development for Medical Writers: Create, Promote, and Monitor Programs and Tools for Growth

Staying Current (Professional Development Topics)

Linda Yih, BSc, Director, Medical Writing Services, PAREXEL International, Lyme, CT

The opportunity for professional development is central to employee retention in today's work environment. By offering pertinent programs and tools to staff, you can facilitate growth, foster engagement and energize your team, setting them up for success. This presentation describes tools that have been created expressly for the development of medical writers. Multiple options are offered to suit personal preference: formal mentoring programs, medical writing skill standards, and individual development plans. Medical writing managers also benefit from similar tools, plus onboarding guides for new hires and a manager's toolkit. A soft-skills training program expands key competencies at all levels, and ideas for collaboration amongst subject matter experts create greater efficiency, teamwork, and a solid knowledge base. A directory ties all of these tools and programs together for easy access. Newsletters and other electronic means promote their availability throughout the group and keep team members informed of new activities. Users contribute feedback to make adjustments as needs change and metrics exhibit the value of professional development throughout the group. With similar development tools in your repertoire, you can invigorate your medical writing team toward learning and growth.

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

Zika—The Bite Heard Round the World

Staying Current (Professional Development Topics)

Larry Lynam, Principal, The Lynam Group, LLC, Coral Springs, FL

R Michelle Sauer, PhD, ELS, CRA, Research Development, Office of Research & Graduate Studies, Prairie View A&M University, Prairie View, TX

Zika! Are you scared? Public information on this virus has ranged from nearly nonexistent to overzealous and misinformed, which has sometimes resulted in more harm than protection. In an age of fake news, this seminar will provide you the facts that you need to know on both a personal and professional level regarding the Zika virus. We will guide you through the fascinating history of the disease and its mosquito vector, Aedes Aegypti, and we will discuss how the public health crisis has been handled in Florida and Texas—the two states with endemic infections. Attendees will leave armed with the facts regarding how the virus is transmitted, how it attacks hosts, and the methods available for combating the spread of the disease so that they can aid in slowing the spread of inaccurate information.

Targeted Level of Experience: All Levels of Experience

12:15–1:45 PM **Networking Lunch with Sablack Awards Event featuring the Swanberg Award Address**

Presentation of the Harold Swanberg Distinguished Service Award and Swanberg Address: Art Gertel, 2017 Swanberg Committee Chair, will present the Swanberg Distinguished Service Award, given for distinguished contributions to medical communication and the medical profession, to Brian Bass, MWC®, who will then present his award address.

2:00–3:30 PM **Sessions**

Awkward to Awesome: How Powerful Construction Can Transform Your Writing

Staying Current (Professional Development Topics)

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

Have you ever gotten the helpful comment of "awkward"? How about the supportive suggestion to "re-write"? While those specific reviewer comments may require some "reviewer-coaching", understanding of writing construction methods and the neuroscience behind powerful writing are tools that can transform "awkward" to "awesome." As most medical writers have scientific backgrounds, we often learned to write as a secondary interest to our science educations or with on-the-job training. Even if we know how to write well, we may not know the best ways to talk about writing methodology, readability, and organization of presentation. This session will discuss scientific storytelling: how to construct a readable and accessible deliverable at the level of the document, the paragraph, and the sentence. It will detail the neuroscience behind good writing and advocate for plain English (brief, precise, audience-centric) in scientific writing. It will also give you the tools to do the same, including how to coach your reviewers to make more actionable comments. This presentation will provide examples from and be applicable to: regulatory documents, patient narratives, and publications.

Targeted Level of Experience: All Levels of Experience

Medical Writer's Guide in ClinicalTrials.Gov Results Postings

The Evolving Regulatory Landscape

Shawn Watson, PharmD, PhD, ON Clinical Consulting, Revere, MA

The presentation will detail the medical writer's role in ClinicalTrials.Gov results postings and position the writer to author these postings successfully. The presentation will discuss the key collaborators and the primary resources used to prepare these postings and the guidelines governing results postings. There will be an additional focus on the timelines for posting clinical study results, how disclosure affects other documents, and the workflow of a successful posting.

Targeted Level of Experience: All Levels of Experience

The Freelancer's Guide for a Successful Social Media Journey: How to Keep Up with Recent Changes, Overcome Obstacles, and Get Optimal Results

The Business of Freelance

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

Larry Lynam, Principal, The Lynam Group, LLC, Coral Springs, FL

As a freelance, social media can help you build your authority, and connect with colleagues and potential clients. Investing time online can lead to new business referrals, but if you don't use social media properly, it can be a waste of time and even damage your personal brand. In this interactive session, we will explore LinkedIn and Twitter –

the two most effective social media platforms for freelance medical writers and editors. We will highlight the significant changes to both of these platforms in 2017 and explore how you can make them fit with your other marketing initiatives. Our session will use actual cases studies to show you how freelances are getting results with social media and to help you identify and avoid communication disasters. We will discuss strategies that can help you recover should a social media miscommunication occur. We will help you sharpen the social media skills needed for a successful and enjoyable social media journey so you can enhance both your personal network and your freelance business.

Targeted Level of Experience: All Levels of Experience

Intermediate Health Economics and Outcomes Research (HEOR) & Real World Evidence (RWE) Elements, Concepts and Writing Constructs

Staying Current (Professional Development Topics)

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

Patti Peeples, RPh, PhD, CEO and Principal Researcher, HealthEconomics.Com, Ponte Vedra Beach, FL

Intermediate HEOR & RWE writing – Building upon foundational elements to enhance utilization of key elements, concepts and writing constructs for effective HEOR and RWE writing and communication. Attendees will be given tools and resources to understand and initiate a plan to enhance writing skills for this growing area of medical writing. Review similarities and differences between HEOR and RWE content and medical/scientific content. Detailed and hands-on working with HEOR and RWE elements including: QALY (Quality-Adjusted Life Years), CEA (Cost-Effectiveness Analysis), CER (Comparative Effectiveness Research, and Value Assessment Framework. Review several types of HEOR deliverables – manuscripts, review articles, dossiers. Resources to use to gain experience and understanding for effective HEOR writing.

Targeted Level of Experience: All Levels of Experience

A Conversation About Podcasting

New Media Channels, Writing, Technology, and Software

Helen Osborne, M.Ed., OTR/L, President, Health Literacy Consulting, Natick, MA

Are you curious to know what podcasting is? Or thinking about starting your own series? In this informal yet informative session, Helen is prepared to address questions and encourage conversation about how podcasting can enhance your practice as a medical writer. Topics not only will include practical aspects such as equipment, costs, and time. But also needed skills including the art of interviewing others. If participants are interested, Helen is happy to also focus on the business side including ways to promote podcasts and measure success. Bring your questions and join this conversation about what podcasting is, why it matters, and ways to get started.

Targeted Level of Experience: All Levels of Experience

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

WS-30 Summarizing Clinical Efficacy Data for a New Drug Application

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

Thomas 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 this workshop, the participant 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-31 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 this workshop, the participant 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-32 Regulatory Aspects of the Drug Development Process for Medical Writers

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 this workshop, the participant 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-33 Microediting

Elliott Churchill, MS, MA, President, A World of Words, Tucker, GA

The art of communication lies in the details, and this advanced workshop will help you hone your microediting skills in the preparation of manuscripts for medical journals.

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

- Differentiate microediting and macroediting tools and techniques.
- Utilize the logic of English grammar and composition to clarify and emphasize the logic of the science being presented.
- Describe the "difference between the right word and the almost right word is like the difference between lightning and a lightning bug" (attributed to Mark Twain).

WS-34 Preparing CME Materials: Concepts, Strategies, and Ethical Issues

Marcello Morgan, MD, MPH, CHCP, Associate Medical Director, Haymarket Medical Education, Paramus, NJ

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

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 this workshop, the participant 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-35 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 this workshop, the participant 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.

3:30–4:00 PM **Beverage Break**

4:00–5:00 PM **Sessions**

Crib Notes for CMC Module 3: Content, Organization, and Post-Approval Impact

The Evolving Regulatory Landscape

Mary Ellis Bogden, BA, Senior CMC Regulatory Consultant, Whitsell Innovations, Inc., Chapel Hill, NC

Karry Smith, PhD, MPH, Medical Writer and Consultant, Whitsell Innovations, Inc., Des Moines, IA

Module 3 (Quality) of the Common Technical Document (CTD) includes the Chemistry, Manufacturing, and Controls (CMC) information for the intended marketed drug product. Information about development, characteristics, standards, and packaging for the drug substance(s) and product are contained in this module. Module 3 is present in the IND and the content is initially developed and managed by subject matter experts or CMC functional area heads in the early stages of development. As development of a drug moves through Phase 3, a higher level of collaboration between CMC experts and regulatory writers is required to prepare the NDA submission. Familiarity with the source documentation supporting Module 3 enables the regulatory writer to be efficient and strategic when compiling an NDA, as many sections in other modules cross-reference data contained within Module 3. Understanding the location of content and life-cycle strategy for Module 3 during NDA compilation is essential for managing the dossier

post-approval. In this session, attendees will be guided through the development and content of Module 3, using the example of an oral dosage formulation. Attendees will also receive helpful color-coded handouts that describe how Module 3 is sourced, organized, and cross-referenced to other NDA sections.

Targeted Level of Experience: All Levels of Experience

Getting Down to Business: The Nuts and Bolts of Starting (and Maintaining) Your Freelance Writing Business

The Business of Freelance

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

You love science, you love to write, and you would love to say goodbye to office politics and set your own work schedule. But let's be level-headed about this: When you choose to freelance, along with office politics you also leave behind a regular paycheck, paid time off, and benefits. What kind of a financial cushion should you have when you start out? How do you obtain health insurance? Do you need business insurance and if so what kind? What do you need to do about taxes? How do you decide what to charge? How do you handle contracts with clients? What about time management, record keeping, invoicing? Attend this session for a 60-minute crash course on the business aspects of freelancing. Please note that the predominant focus of this session is on the logistics of freelancing, not on marketing.

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

How to Shorten Abstracts Effectively

Essential Medical Communication Skills (Writing and Editing)

Ursula Lehner-Mayrhofer, MMag., Medical Writer, MED-EL GmbH (Medical Electronics), Innsbruck, Tyrol

This session aims to convey useful techniques to shorten abstracts in order to meet word limit requirements without compromising completeness, clarity or readability of the text. The introductory lecture will focus on core elements and key characteristics of a good abstract; the subsequent hands-on training will comprise different types of practice-oriented writing exercises and group discussions. The overall focus will be on the elimination of non-essential information and expressions, the replacement of 'wordy' expressions by short and succinct phrases, the deletion of useless words and phrases, the use of parallel constructions, the elimination of nominalizations, the avoidance of repetition, and other helpful writing techniques. Further, the use of numbers, logical operators and hyphenated and compound nouns to improve linguistic efficiency will also be discussed. This interactive session targets all people entrusted with abstract writing, including researchers and scientific, medical and technical writers from both the pharmaceutical and the medical device fields.

Targeted Level of Experience: All Levels of Experience

Clinical Trial Transparency for Writers

The Evolving Regulatory Landscape

Elizabeth Schiavoni, Owner and Primary Writer, Life Science Writing Solutions LLC, Buffalo, NY

Whether we are writing, reviewing, or managing a project, AMWA members are trusted to provide the most accurate information available to our target audiences. Our ability to scrutinize the reliability of publications while conducting literature searches and creating cutting edge strategies makes us dependable professionals. Publication bias against negative clinical trial results contributes to the abundance of inaccurate data affecting

the quality of biomedical research and medical practice. Credible communicators play crucial roles in ensuring clinical trial results are properly reported. In this one hour topic session, an ambassador from the AllTrials Clinical Trial Transparency Campaign will address current clinical trial registration and reporting requirements, the impacts of non-compliance for patients and professionals, and how writers can influence transparency and grow their reputation.

Targeted Level of Experience: All Levels of Experience

Body Systems Overview for Medical Writers

Staying Current (Professional Development Topics)

Anne Erlich, Pharmacist and Medical Writer, Write Market Access, East Brunswick, NJ

Not all medical writers hold degrees in clinical medicine, pharmacy, or other healthcare related occupations. Although it may be helpful to have a background in the life sciences, it is not mandatory. In fact, some very successful medical writers have backgrounds in English literature and history. However, communicating medical data or distilling the essential points of clinical studies can be a daunting task without a basic understanding of some common body systems disorders. Whether you are new to the industry of medical communications or a seasoned medical writer, this tutorial will crystalize core cardiovascular concepts that you are likely to encounter on a regular basis. Medical writers have a responsibility to craft clear messages that are factual and objective. Understanding the cardiovascular systems will enhance your ability to produce robust medical communications for readers. The following tutorial is designed to broadly cover cardiovascular system disorders that will be useful to medical communication professionals.

Targeted Level of Experience: All Levels of Experience

6:00 PM — **Meet in Lobby to Depart for Chapter and Regional Networking Dinners**

Meet up with your colleagues before heading out for dinner.

FRIDAY, NOVEMBER 3

8:00 AM–6:00 PM — **Registration and AMWA Information Desk Open**

8:00–8:45 AM — **Continental Breakfast in the Exhibit Hall**

9:00–10:30 AM — **Sessions**

Are You Picking Up What I'm Putting Down? The Communication Conundrum

Staying Current (Professional Development Topics)

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

In every project management training course or session, communication is rated as critically important. Clear communication among team members allows for an understanding of process, alignment of clear, key messages, and successful hand-offs between stakeholders. According to a 2015 survey by Accenture, most people think they are excellent communicators and listeners. However, that same survey also demonstrated that our actual skills at relaying information and listening don't live up to our expectations or our perceptions. The Harvard Business Review (HBR) sited that effective listeners (the top 5% of those they surveyed) have specific actions that make them more effective – most of these are related to interactions that seem commonplace. And yet, breakdowns in communication are common and most teams experience them at some point in a project's lifecycle. This session will discuss communication styles—how we can be more mindful of how our messages are interpreted and how we can help ensure that our communication

is clearly and thoroughly understood. To address the ways that communication breakdowns happen, we will: discuss ground rules for solid communication (based on recommendations from the Accenture data and the HBR data), participate in in-class exercises (the fun kind!), collaborate on tips for being a better communicator and listener (including those offered by the audience), and share ideas for modification of our communication styles to support understanding of non-native speakers.

Targeted Level of Experience: All Levels of Experience

Trash Talk: Drug Waste in the 21st Century

The Evolving Regulatory Landscape

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

Thousands of metric tons of pharmaceutical waste are produced annually, but where does it all go? The associated environmental, economic, and public health risks continue to mount global interest. Currently, regulations classify pharmaceutical waste and define proper disposal/destruction; drug companies and health care institutions are putting more effort into developing waste reduction methods. Also, while recommendations are offered to the public about disposal of personal medications, awareness is limited. In this session, we will explore these issues and information resources for medical writers.

Targeted Level of Experience: All Levels of Experience

Biologics & Biosimilars: Regulations, Rules of Trial Design, and Rising Approvals

The Evolving Regulatory Landscape

Rochelle Mills, PhD, Medical Writer & Consultant, Whitsell Innovations, Inc., Raleigh, NC

Are you hearing the term "biologic" with increasing frequency and need more details on this corner of the pharmaceutical world? Biologics are a rapidly growing sector of the drug market, composing 10% of new FDA approvals in 2005 and 32% of approvals in 2016. Biologics and copycat biosimilars are complex protein-based pharmaceuticals that cannot be manufactured as easily as their conventional drug counterparts. Biologics are costly to produce, and are a big part of the current national drug-pricing conversation. Before 2010, there was no FDA provision for licensing cheaper analogous versions of biologics. The 2010 Biologics Price Competition and Innovation Act introduced a path for biosimilar approval, but standards for achieving interchangeability status (allowance for the biosimilar to be substituted for the original reference biologic by a pharmacist) were strict and vague. In January 2017, the FDA issued new interchangeability guidelines for biosimilars, making it easier to develop a biosimilar that can be ordered at the pharmacy like a generic. This guidance discusses clinical trial designs unique to the arena of biologics/biosimilars.

Targeted Level of Experience: All Levels of Experience

Winning the Work: Grant Writing Basics

Grant And Proposal Writing and Editing

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

Do you want to learn the basics of grants and write persuasively for reviewers? Improve your writing with proven techniques and best practices that will help you sell the overall story, win more work, and stay (mostly) sane while you're doing it. You will learn how to apply the six C's of grant writing to impress potential clients. We'll also help you navigate the requirements for the most common types of grants and show you how to use time-tested strategies to compose a convincing, well-written grant submission.

Targeted Level of Experience: All Levels of Experience

Tech Tools to Help you Run Your Freelance Business

The Business of Freelance

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

This session will help new and experienced freelancers expand and upgrade their office toolbox to manage routine business-related tasks such as bookkeeping and invoicing. More traditional approaches to some of these tasks include cumbersome spreadsheets and piles of receipts. Techie solutions include software, apps, and online services. Given the large number of available options, you could spend countless unbillable hours researching and reading reviews to help you decide which tools to try out, buy, or download for free. To save you some effort, during this session I will share my own recent experience with re-equipping my freelance business after realizing that some of my tools were not that user-friendly or were out-of-date and discuss ways to identify viable options and narrow down choices. Highlight results from the 2016 Freelance Medical Communicators Tools of the Trade online survey to show the wide spectrum of solutions used by fellow freelances. These data might help you narrow down your choices and spark ideas for new ways of doing things. Categories of tools to be addressed include: computer back-up options; business website hosting; and software/apps for accounting, invoicing, time tracking, email, and citation/reference management. The session will offer plenty of opportunity for audience participation.

Targeted Level of Experience: All Levels of Experience

What Should You Know About Public Relations and Marketing in Medicine?

Staying Current (Professional Development Topics)

Erin L. Boyle, Senior Editor, Remedy Health Media, Arlington, VA
Katrina R Burton, BA, Senior Communication Specialist, The University of Texas MD Anderson Cancer Center, Houston, TX
Hilary Graham, MA, Senior Manager, Scientific Marketing, Luminex Corporation, Austin, TX

How can you use writing and editing skills to enhance your career opportunities in PR and marketing? Find out from three senior professionals in the medical communications field with backgrounds in medical journalism, public relations, and marketing. The panelists will discuss hot topics and trends in the "marcomm" (marketing + communications) field and why it matters to you as a medical communicator.

Targeted Level of Experience: All Levels of Experience

10:30–11:00 AM **Beverage Break**

11:00 AM–12:00 PM **Sessions**

The Ticking Clock: Maintaining Sanity for QC

Essential Medical Communication Skills (Writing and Editing)

Amanda Pennington, BS, Quality Reviewer and Medical Editor, Whitsell Innovations, Inc., Oxford, PA
Ashley Khan, PharmD, Medical Writer and Consultant, Whitsell Innovations, Inc., Pittsboro, NC

The quality control (QC) process is a critical step in finalizing regulatory documents. Medical writers may have personal preferences on how to send documents for QC, and companies often have checklists to ensure the QC process is complete. However, what about the finer details that impact timelines and sanity for the QC specialist? How should a medical writer annotate a document for QC? How do you accurately estimate time to complete QC? What are the downstream effects of shifting timelines? In this session, a medical writer and QC expert will discuss what it takes to make QC run smoothly and how to tackle common dilemmas.

Targeted Level of Experience: All Levels of Experience

You Can Do It Too! Creating Science Videos for the Public

New Media Channels, Writing, Technology, and Software

Jessica Meade, MFA, Writer-Editor, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, Bethesda, MD

Whether for patients or the public, videos can help people understand scientific and medical concepts more quickly and easily and drive more traffic to your article or website. But creating short science videos to accompany scientific writing can seem intimidating and expensive. The truth is, there are so many software options out there now that almost anyone can edit together a video relatively cheaply. But the biggest problem is often just getting started. How long should the video be? What if you don't have any interesting visuals? How would a video relate to this topic? Can you come up with something that would be understandable, relevant, and interesting? Do you even have an application to edit videos on your computer? This session will answer all these questions and more (the answer to the last question is yes, you do have access to video editing software!) but will focus on the first part of video creation—concept development—by walking participants through the process of brainstorming and storyboarding video concepts. We will talk about how writing and producing videos is not all that different from writing anything else—it starts with audience, purpose, and voice.

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

CORE Reference: A Year of Experience Preparing CSRs for Multiple Audiences

The Evolving Regulatory Landscape

Aaron B. Bernstein, PhD, Principal Regulatory Writing Consultant, Aaron Bernstein Consulting, LLC, Millburn, NJ

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

CORE Reference (see http://www.core-reference.org/) was launched in May 2016, to provide interpretational guidance on ICH E3-based CSR authoring that incorporates real-world insights. These include guidance on writing CSRs that share clinical trial data responsibly, and in accordance with current public disclosure requirements. Data disclosure and transparency have become an important concept in new guidance from FDA and EMA. Since its introduction, CORE Reference has been downloaded over 5,400 times. Additionally, there have been a number of other important developments in the area of clinical trial disclosure. Redacted CSRs for over ten products have been published on the EMA's website. This past December, EMA held a webinar to provide an update on the implementation of the clinical data publication Policy 0070. In February 2017, the Transcelerate Clinical Data Transparency team published three papers on practical implementation of clinical data transparency. Using CORE Reference, along with information from these other recent developments, attendees will be given strategies that can be applied to proactive preparation of CSRs for uses that require redacted personally-identifiable information and company confidential information.

Targeted Level of Experience: All Levels of Experience

The SCE (Section 2.7.3, Summary of Efficacy Safety): Data from the Trenches

The Evolving Regulatory Landscape

Nancy R. Katz, PhD, MWC®, President & Principal Medical Writing Consultant, Illyria Consulting Group, Inc., Soda Springs, CA

The session will present original research, namely the results of a survey whose objective is to describe the tasks and roles involved in creating an SCE (Section 2.7.3 of the CTD). Specifically, it focuses on the amount of de novo, repurposed, and extant writing used by writers who create an SCE. It also reports on whether the write of an SCE plays a reactive or proactive role when creating that document.

Targeted Level of Experience: All Levels of Experience

What Instructional Design Skills do you Need to Learn to Develop Effective Educational Communications?

Essential Medical Communication Skills (Writing and Editing)

Deborah Anderson, PhD, Medical writer/Medical instructional designer, DGA Medical Communications, Bucks County, PA

Medical writers are increasingly responsible for instructional designs skills. However, they are often not trained nor qualified to perform effective instructional design. As this is a demonstrated and published issue, this presentation would seek to inform the audience of the problem as well as provide suggestions and resources to overcome the issue. First the presentation would identify the many facets of an educational program, as well as how one piece fits into the whole of a program. Second, the presentation would provide guidelines for considering different approaches to presenting data, such as when to use audio, visual, and written content. Thirdly, it would review sections within educational pieces and demonstrate the essential links between goals, objectives, and assessment and how the content falls into place once these are established.

Targeted Level of Experience: All Levels of Experience

Molecular Biology of Cancer

Staying Current (Professional Development Topics)

Janet Novak, PhD, ELS, Senior Editor/Grant Writer, Memorial Sloan Kettering Cancer Center, New York, NY

In the past few decades we have learned a great deal about how cancer originates and progresses at the level of molecules. This session will begin with a quick review of the salient molecules (DNA, RNA, and proteins). Alterations to these molecules can disrupt the cell's control systems in a way that results in cancer. By investigating these alterations and their consequences at the molecular level, researchers can sometimes find new ways to treat cancer. We will look at two examples: •Chronic myelogenous leukemia: This disease is caused by a chromosome rearrangement that gives rise to an abnormal protein, which promotes cell proliferation and disrupts the cell's normal quality control system. Drugs that inhibit this protein have been remarkably effective in treating the disease. •Breast cancer: Inherited mutations in BRCA1 can increase the risk of breast cancer in part by hindering the cell's ability to repair damage to its DNA. Paradoxically, one way to treat the cancer is to use a drug that worsens the cancer cells' DNA repair defect. Finally, we will look at new techniques used to find the abnormalities behind other types of cancer.

Targeted Level of Experience: All Levels of Experience

12:15–1:45 PM	**Roundtable Lunch in the Exhibit Hall**
2:00–3:30 PM	**Sessions**

Writing Pediatric Plans: Experiences and Challenges

The Evolving Regulatory Landscape

Jennifer Rilstone, PhD, Senior Regulatory Documentation Scientist, Hoffmann-La Roche Limited, Mississauga, Ontario

Children are not small adults! The evolving pediatric regulatory landscape is focused on ensuring that medicines are adequately studied for use in children. Over the last decade, pediatric regulations in the US and EU have introduced additional documentation requirements for drug development programs. This session will provide an overview of EU Paediatric Investigation Plans (PIPs) and US Pediatric Study Plans (PSPs), and discuss how the medical writer can contribute to the development of these documents.

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

Time Saving Techniques for Microsoft Word – Best Tips, Shortcuts, Ideas and Guides

Staying Current (Professional Development Topics)

Zoe Wright, Product Specialist, PleaseReview, Malmesbury, Wiltshire

Do you want to increase your proficiency with Microsoft Word? If you spend more time in Microsoft Word than any other software application, learning how to use it as efficiently as possible will save you significant time and increase your productivity. Learn how to navigate Word and use advanced features to become more confident, efficient and effective when producing large, complex Word documents. Writing submissions and other important documents are reliant on a good understanding of Word, but Medical Writers may not have the depth of knowledge to use its functionality to their best advantage. This session builds on previous lessons learnt with the key focus on making your experience of Word the most productive and efficient as possible. Covering a range of topics, including keyboard shortcuts, fields, customization features, embedding and linking, document map outline view and other tips and tricks, we will demonstrate how to make Word work for you, rather than against you.

Targeted Level of Experience: All Levels of Experience

Writing and Editing CME Needs Assessments

The Future of Continuing Medical Education

Donald Harting MA, ELS, CHCP, President, Harting Communications, LLC, Downingtown, PA
Katherine Molnar-Kimber PhD, President, KMK Consulting Services of Kimnar Group LLC, Worcester, PA
Nathalie Turner, MS, ELS, Senior Grant Developer, Medscape Education, Seattle, WA

We will start by reviewing highlights from our latest annual survey on best practices for writing CME needs assessments (NAs). After a brief review of the basics, such as why NAs are important and how they fit within the system of accredited CME, we will focus on sources of evidence, overcoming key practice barriers, and criteria for selecting references when performing a literature review. Then we will break up into small groups for a hands-on editing activity, taking a jumbled mass of data about leukemia and organizing it according to one of three “recipes” from our recent article published by the. Every participant will receive a copy of the recipes and a synopsis of recent survey results.

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

Strategic Grantsmanship Principles for Academic Medical and Scientific Writers

Grant And Proposal Writing and Editing

Kelly Byram, MS, MBA, ELS, CEO, Duke City Consulting, LLC, Albuquerque, NM

Over the past fifteen years, the research funding paradigm has shifted and the financial terrain has dramatically changed in myriad biomedical research areas and institutions. As competition for extramural research funding increases, medical and scientific writers and editors increasingly find themselves assigned to sprawling grant development project teams. Moreover, they are often asked to manage these projects, too. The challenge is that grant writing and editing can be very different from many other types of medical and scientific writing and editing. In this session, we will discuss the basics of funding for research, tech transfer, and commercialization. We will lightly touch upon the basics of grant writing mechanics, but mainly we will focus on an important value proposition for grant writers and editors: strategic grantsmanship. Strategic grantsmanship techniques introduced will include how to: identify the audience for your proposal, define what makes a proposal competitive for the funding opportunity, leverage your research experience in the project development process, optimize your proposal for the review process, and manage the project and team. The principles of strategic grantsmanship introduced here are designed to provide academic writers a strategic framework within which they can expertly manage their additional emerging role in their workplace.

Targeted Level of Experience: All Levels of Experience

Jam Session for Seasoned Freelances

The Business of Freelance

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.) In the most magical place on Earth we're looking to make some jam session freelance magic! 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. Based on last years' experience, this session will be lightly structured to permit a free flow of discussion without getting stuck for too long on a single topic. Sorry, there won't be any wine during the session. But those who are interested can continue your conversations over happy hour and/or dinner and wherever the journey takes you.

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

FDA Expedited Regulatory Approval Programs

The Evolving Regulatory Landscape

Monique Pond, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc., Chapel Hill, NC

The FDA offers four expedited regulatory approval programs for drugs that either target serious or life-threatening conditions that do not have adequate therapy or that offer therapeutic advancement over available therapy: Breakthrough Therapy Designation (since 2012), Accelerated Approval (since 1992), Priority Review (since 1992), and Fast

Track (since 1997). The appropriate use of these approval programs is often misunderstood by both pharmaceutical companies and health care providers. Medical writers seeking to understand the similarities and differences between these approval programs are encouraged to attend this roundtable. Tips on writing documents requesting that a drug be considered for an expedited approval program will be presented. Recent trends in the use of expedited regulatory approval programs within oncology will be discussed to give attendees a deeper understanding of these programs. Trends in conditional marketing authorizations within oncology will also be presented to provide some global context.

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

3:30–4:00 PM	**Beverage Break**
4:00–5:00 PM	**General Session with McGovern Award Address** This session features the presentation of the McGovern Medal Address by Steven Woloshin, MD, MS; and Lisa Schwartz, MD, MS.
5:00–6:00 PM	**Happy Hour Reception in the Exhibit Hall** Be here. Be happy. Join other attendees for a happy hour before enjoying an evening out or relaxing.
6:00–8:00 PM	**Exhibitor Move Out**
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 Orlando. Attendees will be able sign up onsite for a dine-around group and explore the area.

SATURDAY, NOVEMBER 4

8:00 AM–4:00 PM	**Registration and AMWA Information Desk Open**
8:30–9:30 AM	**Sessions**

Designing Your Regulatory Content for Multichannel Targets

New Media Channels, Writing, Technology, and Software

Susan Bairnsfather, CEO, EPharmaTech, Shreveport, LA

The adoption of a content management and content re-use strategy by regulatory writers will expedite various submissions to agencies around the globe. We have already accomplished granularization of our documents with the CTD; it's now time to carry this concept further. The strategy of pharmaceutical documentation should be based on product content archived in much further granularization than whole documents. Software packages that archive whole documents are no longer the most efficient strategy to manage content. And software to archive and re-use the more modular product information has long been available. The content re-use method requires that content appropriately be created with its re-use preconceived and tagged with metadata so that people and software can easily find it. Similar to the strategy of the CTD to modularize and standardize its contents, cost-saving metrics are realized through implementing the appropriate software for maintaining the life cycle of a product within the required modules of the CTD, whether submission is for different indications for the same product or to difference countries with differing submission requirements or to countries in other languages.

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

Precision Medicine, Biomarkers, and NextGen Sequencing – Science, Regulation, and the Future

The Evolving Regulatory Landscape

Karry Smith, Medical Writer and Consultant, Whitsell Innovations, Inc., Chapel Hill, NC

The field of precision medicine (PM) has been growing since the approval of the first PM drug and its companion diagnostic in 1998. PM is the optimization of patient care that takes into account objectively measurable data to define individual patterns of disease. The term "biomarker" encompasses a wide range of medically predictive signs that are well-characterized and can be accurately and reproducibly measured. Many emerging biomarkers are gene sequences that can be decoded by next generation DNA sequencing (NGS). In the context of PM, biomarkers have the potential to predict side effects and efficacy, creating the opportunity for targeted drug delivery. The US Food and Drug Administration (FDA) has signaled an interest in PM, NGS, and the use of biomarkers with the release of 3 draft guidance documents in July 2016. This presentation will provide an overview of PM as it relates to biomarkers and NGS, discuss the 3 (draft) FDA guidance documents, detail current PM approvals based on biomarker use, and distill the guidance landscape using an example PM therapeutic and in vitro diagnostic device (IVD) companion diagnostic as a case study.

Targeted Level of Experience: All Levels of Experience

A Review of Processes and Some Best Practices for Narrative Writing

Essential Medical Communication Skills (Writing and Editing)

Karen L. Campbell, MS, Senior Medical Writer & Consultant, Whitsell Innovations, Cary, NC

In the world of clinical regulatory documents there are two kinds of nonfiction stories to tell: that of the drug and its path to approval (or abandonment) and that of the patient. For most documents (protocols, investigator brochures, clinical study reports), the story of the drug takes center stage. Narratives, however, tell the story of the patient. They are informative documents that can provide Health Authority reviewers with the necessary details to understand an adverse event or other pre-defined situation. To some, writing clinical subject narratives may be perceived as a time-consuming (or daunting) task to be completed for a CSR or other submission document. The source material for narratives can be "messy" and include data that live outside the clean and careful world of the clinical data base. Those sources can also include contradictory or incomplete information. Having written and/or reviewed over 10,000 narratives, the presenter will offer a review of processes and some best practices. Medical writers seeking to understand the narrative writing process and how to manage it are encouraged to attend this session.

Targeted Level of Experience: All Levels of Experience

Freelance Medical Editing, Writing, or Both: Which Path Is Right for Me?

The Business of Freelance

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

Julie Munden, Medical Editor & Copywriter, Blue Ink Communications, Souderton, PA

Medical editing and writing offer freelancers many opportunities. But choosing whether to be an editor or writer, or both, can be challenging. The right path depends on many factors, such as your work experience, the stage of your freelance career, and your skills and interests. In this session, a freelance medical editor and a freelance medical writer will share each of their career paths and offer tips and checklists to help you decide the path that is right for you. We'll also highlight some freelance opportunities in medical editing and writing.

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

8:30–11:30 AM **AMWA Workshops (*additional fee*)**

WS-40 Understanding the Principles of Kaplan-Meier Analysis

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

Used often in drug development, Kaplan-Meier analysis efficiently depicts survival in clinical trials and other time-to-event outcomes. Knowledge of this statistical tool is an asset for every medical writer.

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

- Analyze Kaplan-Meier graphs from publications and reports and other source documents.
- Describe survival analyses in their documents.
- Identify obvious misrepresentations of survival analyses.

WS-41 Ethics of Communicating Regulated Drug Development Activities

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

Hone your ethical knowledge and skills to properly communicate regulated drug development activities to the various stakeholders involved—from scientists and healthcare providers to regulatory authorities.

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

- Find information relevant to communicating regulated drug development activities on the Internet.
- List the steps of a multi-step decision-making model for resolving ethical situations.
- Identify stakeholders involved in the ethical issues of communicating regulated drug development activities.
- Use this model to identify alternative solutions to ethical situations.

WS-42 Advanced Data Presentation: Tables, Graphs, and Charts

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

Good visuals convey specific information more efficiently than text, adding graphic interest to the printed page. Learn how the seamless combination of data and art contribute immeasurably to medical communication.

At the end of this workshop, the participant 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.

WS-43 Medical Journalism: From Choosing a Topic Through Polishing the Piece

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

Medical journalism shapes perceptions and influences research and policy. Writing for general readers requires a sense of audience, and mastery of the subject matter and art of producing easy-to-read text.

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

- Identify types of publication sites for journalistic articles on medical topics.
- Structure query letters (proposals for journalistic articles) appropriately.
- State basics of gathering content for medical journalism through reading and interviews.
- Apply principles of crafting journalistic articles on medical topics.
- Identify resources for further learning on doing medical journalism.

WS-44 Proofreading: Strategy for Document Quality Control

Hope J Lafferty, AM, ELS, Hope Lafferty Communications, Marfa, TX
Damiana Chiavolini, Instructor, University of Texas Southwestern, Dallas, TX

Proofreading is the final check that acheives consistency, by sharpening attention to mechanical errors and identifying and correcting production and layout issues. Hone your technical expertise with these tips and techniques to spot problems awithin even the most complex medical documents.

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

- Differentiate proofreading from other parts of the editorial process (eg, copy editing).
- Use best practices when proofreading documents to ensure quality.
- Assess the value of onscreen proofreading vs hardcopy proofreading.

WS-45 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 this workshop, the participant 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.

10:00–11:00 AM **Sessions**

Transitioning from the Academic Track to Medical Writing: Tips and Tricks for Scholars Looking to Go In House or Strike Out on their Own

Staying Current (Professional Development Topics)

Tamara Powell, PhD, Research Associate, Children's Hospital Colorado, Denver, CO
Brittany DM Hodges, PhD, Owner and Medical Writer, Inkwell Scientific, Denver, CO

This session is for doctoral candidates, graduate students, recent graduates, or researchers who are considering transitioning from traditional academic career trajectories to medical communication professions. The presenters will discuss their own experiences making career transitions and then help participants begin to strategically plan their own transitions.

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

The Elements of a Great Multiple-Choice Test Question

The Future of Continuing Medical Education

Nathalie Turner, MS, ELS, Senior Grant Developer, Medscape Education, Seattle, WA

Multiple-choice questions (MCQs) are important components of medical education activities and medical licensing examinations. You read them; maybe you participate in some of them; and maybe you've been asked to write or edit them. There's more to developing an MCQ than throwing a question and a bunch of answers on a page. In fact, there's an art to constructing high-quality MCQs that effectively test the participant's knowledge and comprehension vs assessing only if they're good test takers (hint: that's not what you want to do). Join my how-to session to learn the science behind a well-written MCQ and add to your skill set as a medical writer/editor.

Targeted Level of Experience: All Levels of Experience

Managing Remote Medical Writing Teams for Large Safety Narrative Projects

Staying Current (Professional Development Topics)

Stephanie Matheson, MSc, PhD, Senior Medical Writer, PAREXEL International, Billerica, MA

Coordinating the development of a large number of safety narratives can be challenging, especially if the members of the writing, QC, and review teams are located across several different time zones. As Medical Writing becomes increasingly globalized, the management and preparation of regulatory documents present several benefits and caveats and hence necessitate the adjustment of managing strategy in order to optimize the results. Remote teams require clearly defined deliverables, detailed timelines, a set of ground rules and conventions, adequate training, coaching, and frequent communication (e.g., changing availability, revisions to timelines, modified conventions, review comments feedback) with team members. In some cases, mitigation plans are also needed. This presentation will describe how to set up and manage a remote medical writing team for a narrative project. In addition, we will discuss some of the typical obstacles that may be encountered when managing remote safety narrative teams, and how to resolve them.

Targeted Level of Experience: All Levels of Experience

Helping Non-Native English-Speaking Investigators get Their Research Published in Quality Journals

Essential Medical Communication Skills (Writing and Editing)

William R. Brown, MD, Professor of Medicine Emeritus, Univ Colorado School of Medicine, Denver, CO

Non-native English-speaking (NNES) investigators confront many problems in constructing publishable research papers. The problems go much beyond unfamiliarity with English language. Although all inexperienced authors encounter these problems, they may be more daunting for NNES investigators. Some of the challenging problems, which the editor should help the authors overcome are: • Lack of a clearly stated hypothesis objective(s) • Lack of knowledge of oImpact factor o Science Citation Index o PRISMA check list and flow diagrams o STROBE check list o MOOOSE guidelines o MeSH terms • Failure to follow journals' instructions for authors o Word limit and character limits o Abbreviations o Reference formatting and appropriate number of references o Tables and figures—design and limited number • The manuscript o Clearly stated, concise hypothesis or objective(s) o Conclusion(s) linked tightly to the hypothesis or objective(s) o For an original research paper: discussion focused on the original findings and importance (not an exhaustive literature review).

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

10:00–11:00 AM **Annual Business Meeting with Town Hall**

All AMWA members are encouraged to attend, to get an update on AMWA from 2016-2017 President, Lori Alexander, MTPW, ELS, MWC®, and Treasurer, Julie Phelan, MD, MBA, to witness the passing of the gavel to Kathy Spiegel, PhD, MWC®, the 2017-2018 President, and to meet the 2017-2018 officers and Executive Committee.

11:45 AM–12:45 PM **Lunch for Saturday AMWA Workshop participants**

1:00–4:00 PM **AMWA Workshops (*additional fee*)**

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

Jennifer Bridgers, MS, MWC®, Medical Writing Manager, QuintilesIMS, Durham, 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 this workshop, the participant 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 Advanced Writing

Marianne Mallia, ELS, MWC®, Editor, Scientific Publications, Mayo Clinic, Scottsdale, AZ

It takes more than experience to make a great writer. This advanced workshop provides some tools to help you better understand the process of writing and your individual approach to that process.

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

- Describe the cognitive processes of writing (planning, freewriting, rewriting, and revising) and the importance of using these processes in writing all types of biomedical communications.
- Differentiate between reader-centered and writer-centered prose.
- Define how to use collaborative planning to a maximum advantage in writing projects.

WS-52 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 this workshop, the participant 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-53 Writing and Designing Materials for Patient Education

Sharon Nancekivell, MA, MWC®, Freelance Medical Editor, Writer, Educator, and Plain Language Consultant, Guelph, ON, Canada

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 this workshop, the participant will be able to

- Identify the different types of patient education materials.
- Define the principles of writing and designing effective patient education materials.
- Begin developing patient education materials that audiences can understand and use.

WS-54 Punctuation for Clarity and Style

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

Punctuation is one of the building blocks of a strong grammatical foundation—creating the basis for clear, precise writing that is crucial in health and medical communication.

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

- Assess common grammatical constructions that require use or omission of various marks of punctuation.
- Demonstrate editing techniques--such as shortening or restructuring sentences—to eliminate awkward or excessive punctuation.
- Use varied punctuation to enhance the clarity, effectiveness, liveliness, and elegance of writing.

WS-55 Introduction to Cancer Pharmacology

Sunil Patel, MS, Oakland, 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 this workshop, the participant 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.

1:00–4:00 PM **Intensive (*additional fee*)**

Success Strategies for Showcasing Your Personal Brand

Roz Usheroff, Founder and President, The Usheroff Institute, Toronto, Canada–Chicago, IL–West Palm Beach, FL

Larry Lynam, Principal, The Lynam Group, LLC, Coral Springs, FL

This intensive is designed to help you discover techniques for refining, revitalizing, and reinventing your brand to showcase your best attributes. To advance your career in today's competitive market, you'll need to assess your unique strengths, leverage your points of difference, and ensure that others recognize the powerful contribution you can make. Learn the importance of skillfully employing the art of "self-promotion" to enhance your personal brand.

Objectives

- Discover how to reinvent your personal brand for staying relevant to your business
- Leverage your own unique abilities for recognition and job satisfaction

- Learn how to respectfully use self-promotion with authenticity and ease
- Create a networking roadmap for expanding your visibility
- Manage constructive confrontation to enhance your relationships

You will leave with a customized roadmap of techniques for becoming your own best PR manager. You will feel energized and confident in knowing how to capitalize on your "remarkable" brand. You will be inspired to take greater risks to drive your own development and move your career forward.

POSTERS ON DISPLAY

Authoring Protocols for Different Phases of Clinical Development: Key Differences and Tips for Preparation
Barbara Orban, MS, Medical Writer and Consultant, Whitsell Innovations, Chapel Hill, NC

Best Practices for Writing CME Needs Assessments 2016
Katherine L. Molnar-Kimber, PhD, President, KMK Consulting Services of Kimnar Group LLC, Worcester, PA
Donald Harting, MA, ELS, CHCP, President, Harting Communications LLC, Downingtown, PA

Use of Standards and Automation to Deliver Cost-Effective Patient Narratives
Mary McKenna, MS, Director, Medical Writing, Business Operations and Service Development, Merck, Rahway, NJ
Angela Horowitz, MPH, Practice Director, Structured Content Management, ArborSys Group, Lawrenceville, NJ

Telecommuting and Effective Communication in a Virtual Team
Sharad Wankhade, Principal Medical Writer, Merck, Medina, OH

Write How? Do Writers Have the Instructional Design Skills Necessary to Develop Effective Communications?
Deborah Anderson PhD, Medical writer/Instructional designer, DGA Medical Communications, Bucks County, PA

First Thursdays: Strengthening the FL AMWA Chapter Through Effective Networking
Melory Johnson, President, MJ Medcom, LLC, Boca Raton, FL
Larry Lynam, Principal, The Lynam Group, LLC, Coral Springs, FL

Crash Course in Food and Dietary Supplement Regulations
Kelly Kilibarda, PhD, Medical Writer & Consultant, Whitsell Innovations, Inc., Littleton, CO
Stephen Carlson, PhD, Medical Writer & Consultant, Whitsell Innovations, Inc., Durham, NC