REGISTRATION BROCHURE

Join us in San Diego

#AMWA2019
WELCOME TO SUNNY SAN DIEGO! I am proud to present the registration brochure for AMWA's 2019 Medical Writing & Communication Conference. This year you can "dip your toes" or "dive in" this medical communication ocean of opportunities to explore the trends and diverse platforms in our field. This year's conference program is packed with content you need to succeed as a professional medical communicator. The strong educational, leadership, and technical programs have reached a new height this year. With so many excellent options at each time slot, the only disappointment attendees will have is that they cannot be in two places at once.

In response to a request from the AMWA membership, you will find sessions on mindfulness, organization, self-care, health, and fun. The schedule also includes morning walk/run and yoga activities to get your day started out right! San Diego will be the perfect city to serve as a host and backdrop to a conference that is sure to reinvigorate attendees in professional and personal ways.

We are also excited to present a new format of talks this year—Med Write Talks. Similar to the popular TED talks, these 10- to 15-minute presentations will be dynamic, inspiring, and thought provoking. Focusing on discrete, medical communication-related topics with a novel insight or angle, these engaging talks are sure infuse the conference with a positive energy. Overall, this year's conference will also encourage you to walk in the sun, literally and metaphorically. We hope you will walk away with a more “sunny” disposition and new, positive relationships and ideas will take root.

Register now and plan to join us November 6-9. Prepare your professional and personal self for an experience that only AMWA can deliver.

R. Michelle Sauer, PhD, ELS, CRA
2019 AMWA Conference Chair
The AMWA Medical Writing & Communication Conference is like no other educational event for people who write and edit in medicine and health. Whether you’re a regulatory writer, an author’s editor, or a health communicator, or at the beginning, middle, or later stage of your career, you will find sessions that meet your professional interests and goals.

Compared with other association conferences, the AMWA Medical Writing & Communication Conference offers:

- A wider range of choices in educational sessions—pick from nearly 60 different sessions led by medical communicators with expertise on timely topics and trends
- Unique immersive educational experiences—choose from 32 different 3-hour workshops on a wide variety of topics, including seven new workshops (additional fee)
- More roundtable discussions—more than 60!—participate in a roundtable discussion to learn more or to exchange ideas about a subject
- A new delivery format—AMWA’s new Med Write Talks, 10- to 15-minute presentations of compelling stories and calls to action
- Greater networking opportunities—meet medical communicators across all settings to make new connections and gain fresh insights and perspectives

Set aside time to browse the program and select the sessions you want to attend. It won’t be simple with all the choices, but your career will thank you! To make it easier for you to find the sessions of most relevance to you, we’ve assigned color-coded focus areas to the education sessions and included the target audience for education sessions and workshops. We define “mid-career” as 5 to 9 years of experience.

This year’s robust program was developed with close attention to feedback from AMWA members and other documented sources of educational needs in our community. We hope you take advantage of the many opportunities to advance your professional development—all under one roof.

I look forward to seeing you in San Diego!

Lori Alexander, MTPW, ELS, MWC
AMWA Education Director
# Schedule at a Glance

## WEDNESDAY, November 6

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>8:00 AM–5:00 PM</td>
<td>Conference Registration Desk Open</td>
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<tr>
<td>9:00 AM–12:00 PM</td>
<td>BELS Exam <em>(additional fee and separate registration)</em></td>
</tr>
<tr>
<td>9:00 AM–12:00 PM</td>
<td>AMWA Workshops <em>(additional fee)</em></td>
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<tr>
<td>12:00–5:00 PM</td>
<td>Medical Writing Executives Forum with Lunch <em>(by invitation)</em></td>
</tr>
<tr>
<td>12:45–1:45 PM</td>
<td>New to AMWA and Conference Orientation Program</td>
</tr>
<tr>
<td>2:00–5:00 PM</td>
<td>AMWA Workshops <em>(additional fee)</em></td>
</tr>
<tr>
<td>3:00–6:00 PM</td>
<td>Exhibits and Poster Set Up</td>
</tr>
<tr>
<td>5:00–7:00 PM</td>
<td>Meet and Greet at Lobby Bar</td>
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## THURSDAY, November 7

<table>
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<tr>
<th>Time</th>
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<tr>
<td>7:00 AM–5:30 PM</td>
<td>Conference Registration Desk Open</td>
</tr>
<tr>
<td>6:30–7:15 AM</td>
<td>Sunrise Networking Walk</td>
</tr>
<tr>
<td>7:00–3:30 PM</td>
<td>Exhibit Hall Open</td>
</tr>
<tr>
<td>7:15–8:45 AM</td>
<td>Breakfast with Exhibitors and Poster Presenters</td>
</tr>
<tr>
<td>9:00 AM–12:00 PM</td>
<td>AMWA Workshops <em>(additional fee)</em></td>
</tr>
<tr>
<td>9:00–10:30 AM</td>
<td>Education Sessions</td>
</tr>
<tr>
<td>10:00–11:00 AM</td>
<td>Morning Break in Exhibit Hall</td>
</tr>
<tr>
<td>11:00 AM–12:00 PM</td>
<td>Education Sessions</td>
</tr>
<tr>
<td>12:00–1:30 PM</td>
<td>General Session with McGovern Award Address and Lunch</td>
</tr>
<tr>
<td>1:45–2:45 PM</td>
<td>Education Sessions</td>
</tr>
<tr>
<td>2:45–3:15 PM</td>
<td>Afternoon Break in Exhibit Hall</td>
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<tr>
<td>3:15–4:15 PM</td>
<td>Education Sessions</td>
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<tr>
<td>4:30–5:30 PM</td>
<td>Education Sessions</td>
</tr>
<tr>
<td>5:30–6:30 PM</td>
<td>Reception Sponsored by JAMA Network/Oxford University Press</td>
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<tr>
<td>6:00–6:30 PM</td>
<td>Meet-up in Lobby for Chapter Dinners</td>
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## FRIDAY, November 8

<table>
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<th>Time</th>
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<tr>
<td>7:00 AM–5:30 PM</td>
<td>Conference Registration Desk Open</td>
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<td>6:30–7:15 AM</td>
<td>Sunrise Networking Walk</td>
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<tr>
<td>7:15–8:45 AM</td>
<td>Roundtable Discussions with Breakfast <em>(additional fee)</em></td>
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<tr>
<td>9:00–10:30 AM</td>
<td>Education Sessions</td>
</tr>
<tr>
<td>10:00 AM–4:00 PM</td>
<td>Exhibit Hall Open</td>
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<tr>
<td>10:00–11:00 AM</td>
<td>Morning Break in Exhibit Hall</td>
</tr>
<tr>
<td>11:00–11:30 AM</td>
<td>General Session with Alvarez Award Address</td>
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<tr>
<td>11:30 AM–12:30 PM</td>
<td>Lunch with Exhibitors and Poster Presenters</td>
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<tr>
<td>12:45–1:45 PM</td>
<td>Education Sessions</td>
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<tr>
<td>2:00–5:00 PM</td>
<td>AMWA Workshops <em>(additional fee)</em></td>
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<tr>
<td>2:00–3:00 PM</td>
<td>Education Sessions</td>
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<tr>
<td>3:00–3:30 PM</td>
<td>Afternoon Break in Exhibit Hall</td>
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<tr>
<td>3:30–4:30 PM</td>
<td>Education Sessions</td>
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<tr>
<td>4:00–6:30 PM</td>
<td>Exhibit and Poster Breakdown</td>
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<tr>
<td>4:45–5:30 PM</td>
<td>Sunset Networking Walk</td>
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<tr>
<td>6:00 PM</td>
<td>Meet-up in Lobby for Dine-Arounds</td>
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## SATURDAY, November 9

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<tr>
<th>Time</th>
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<tr>
<td>7:00 AM–3:30 PM</td>
<td>Conference Registration Desk Open</td>
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<tr>
<td>7:00–8:00 AM</td>
<td>Breakfast on Your Own</td>
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<tr>
<td>8:00–8:30 AM</td>
<td>Swanberg Award Address</td>
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<tr>
<td>9:00 AM–12:00 PM</td>
<td>AMWA Workshops <em>(additional fee)</em></td>
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<tr>
<td>9:00–10:30 AM</td>
<td>Education Sessions</td>
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<tr>
<td>9:00–11:30 AM</td>
<td>AMWA Board of Directors Meeting <em>(by invitation)</em></td>
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<tr>
<td>10:45–11:45 AM</td>
<td>Education Sessions</td>
</tr>
<tr>
<td>12:00–1:30 PM</td>
<td>Roundtable Discussions with Lunch <em>(additional fee)</em></td>
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<tr>
<td>1:45–2:15 PM</td>
<td>Annual Business Meeting for Members</td>
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<tr>
<td>2:00–3:30 PM</td>
<td>Education Sessions</td>
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<tr>
<td>2:30–4:00 PM</td>
<td>Chapter Leader Orientation <em>(by invitation)</em></td>
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<tr>
<td>2:00–5:00 PM</td>
<td>AMWA Workshops <em>(additional fee)</em></td>
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Registration Information

The registration fee gives attendees access to all education sessions, general sessions, networking events, beverage breaks, Thursday breakfast and lunch, and Friday lunch.

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<tr>
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<th>AMWA Member</th>
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<tr>
<td>First Advantage Rates</td>
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<tr>
<td>Full Conference Registration</td>
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<td>September 1 – November 9</td>
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<td>Workshops</td>
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<td>September 1 – November 9</td>
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<td>Breakfast Roundtable</td>
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<td>Lunch Roundtable</td>
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Further discounted rates available for student and retired members.

Cancellation Policy

Cancellation requests must be sent to conference@amwa.org no later than October 16, 2019, in order to be eligible for a refund. Event registrations are nontransferable. Refunds will be issued through your method of payment, less a $75 cancellation fee. A cancellation fee of $50 will be charged for workshop cancellations/changes made before October 16, 2019. A cancellation fee of $10 will be charged for roundtable cancellations/changes made before October 16, 2019. Conference registration and workshop fees are nonrefundable after October 16, 2019. 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, 2019, to indicate your requirements and/or request accommodations.

Hotel and Travel

AMWA has secured a discounted room block at the Sheraton San Diego Hotel & Marina. Please note, to receive the discounted rate and AMWA benefits, you must book through the AMWA hotel block. More information about hotel and travel is available online.

The Sheraton San Diego Hotel & Marina is conveniently located across from the San Diego Airport and a short drive from Downtown San Diego. A complimentary shuttle service to and from the San Diego Airport is available.
NEW WS-12 Best Practices for Developing Journal Manuscripts
Ann L. Davis, MPH, CMPP, Independent Contractor
Development of a robust, balanced manuscript with a high likelihood of acceptance is a complex process, and the medical writer should oversee every facet of it to ensure successful publication. This workshop offers a step-by-step approach, beginning with an overview of industry standards, journal editors’ expectations, good writing practices, project management, and potential issues that may arise during manuscript development. Other topics include guidance on everything from outlines and story flow to managing relationships with authors and journal editors. The "anatomy of a manuscript" is also addressed, with particular attention to objectives and content of each section. In addition to enhancing their writing skills, participants will learn how to channel their inner project manager and take global accountability for the development process. In-workshop activities will include interactive case studies and discussions of how to manage barriers to timely, compliant manuscript development.

Target Audience: Writers with less than 5 years of experience with scientific manuscripts

NEW WS-11 Principles and Practices for Developing Needs Assessments for Continuing Education Activities
Johanna Lackner, MPH, MSW, President, Avant Consulting, LLC
The number of continuing medical education (CME) programs created to help clinicians stay current with evolving developments in medicine and science is at an all-time high. Medical writers can have an impact on medical education by gaining knowledge and skills about the development of needs assessments. This workshop focuses on creating needs assessments, including gap analyses, according to best practices. In-workshop activities: participants will engage in several exercises to apply new knowledge of the steps in the process of developing a needs assessment.

Target Audience: Writers with no or little experience with the topic

NEW WS-13 Writing the Clinical Study Abstract
Yeshi Mikyas, PhD, ELS, RAC, Pfizer, Inc.
Preparing clear, concise abstracts for conferences and journal articles is important because decisions are often made on the basis of abstracts. For example, conference committees make acceptance decisions on abstracts, and readers determine whether the article that follows is worth reading. Although abstracts are short pieces, they are packed with information and sometimes the most challenging to write. Topics include how to structure an abstract and how to be concise. The workshop addresses both conference and journal article abstracts for clinical research. However, attention will be given to conference abstracts because they independent, self-contained documents and require other activities in addition to the writing process. In-workshop activities: participants will discuss abstracts developed in pre-workshop activities.

Target Audience: Writers at all levels
Wednesday, 9:00 AM – 12:00 PM continued

WS-14 Introduction to Health Economics for Medical Communicators
Bart Harvey, MD, PhD, Associate Professor, Dalla Lana School of Public Health, University of Toronto

As cost becomes an increasingly important factor in health care decisions, medical communicators need a basic understanding of the terms and concepts of health economics. Topics covered in this workshop include applicable study designs, cost determination, sensitivity analysis, discounting, perspective and time horizon, all of which are presented in a simple, nonmathematical manner. Key terms are defined, and issues relevant to the preparation and review of health economic analyses and publications are described. In-workshop activities: participants will engage in group discussion on applying these principles to examples taken from the published literature.

Target Audience: Writers and editors with little or no familiarity with the topic

WS-15 Basic Grammar I
Loretta Bohn, Senior Editor/Writer, RTI International

Thorough knowledge of parts of speech is the foundation of good writing and editing. This workshop focuses on parts of speech and their use in the sentence. Among the primary topics covered are the types of nouns and pronouns, verb tense, pronouns and case, phrases and clauses (with special emphasis on verbals and on noun, adjective, and adverb clauses), and the types of sentences. In-workshop activities: participants will complete exercises to identify correct grammar. Note: persons who took Basic Grammar II and Usage for credit may still take this workshop for credit if additional grammar review is needed.

Target Audience: All writers and editors

12:45 – 1:45 PM
NEW TO AMWA AND CONFERENCE ORIENTATION PROGRAM
2:00 – 5:00 PM
AMWA WORKSHOPS (additional fee)

WS-20 Writing and Editing NIH Grant Proposals
Kristina Wasson-Blader, PhD, ELS, Clearly Communicating Science, LLC

The National Institutes of Health (NIH) is the largest public funder of medical research in the world, granting more than $32 billion each year. This workshop is designed to provide medical communicators the knowledge and tools needed to help researchers gain funding through the NIH Project Grant Program, typically called an R01. In-workshop activities: participants will work on editing exercises for key portions of a grant application and review and discuss samples of R01 proposals. Note: private (e.g., foundation) proposals are not addressed in this workshop.

Target Audience: Writers and editors with no or little experience with the topic

WS-21 Electronic Common Technical Document
Nancy Katz, PhD, MWC, President, Illyria Consulting Group, Inc.

Common to the United States, Europe, Japan, and other countries, the electronic common technical document (eCTD) is the primary tool used in industry to transfer regulatory information. As such, mastering eCTD-based submissions is an essential skill for regulatory writers. The focus of this workshop is on what writers need to know to prepare regulatory documents for inclusion in an eCTD-based drug application such as the Investigational New Drug Application, Biologics License Application, or New Drug Application. Topics include the rationale, structure, and key features of the eCTD; associated global and US regulations, guidances, and guidelines; and best practices for writers on an eCTD-based submission team. In-workshop activities: participants will complete hands-on exercises. Note: this workshop does not address technical aspects of assembling an eCTD for electronic submission.

Target Audience: Writers with minimal or moderate experience with the eCTD
WS-22 Assessing and Communicating Benefits and Risks of Medicines
Lawrence Libert, PhD, RPh, RAC, Executive Director, CIRS-Centre for Innovation in Regulatory Science

Everyone balances benefits and risks for activities in daily life. Regulators, drug developers, clinicians, patients, payers, and other stakeholders attempt to apply benefit-risk (B-R) assessments to medicines. Despite intuitive approaches, the formal evaluation of a medicine’s B-R is a relatively new, continually emerging science. A common framework for assessing and communicating B-R is quickly approaching. This workshop is an introduction to the concepts that underlie techniques to assess the B-R of medicines. In-workshop activities: participants will discuss ways writers can approach more effective B-R communications with stakeholders.

Target Audience: writers and editors with no or little experience with the topic

WS-23 Lean Authoring
Kimberly Jochman, PhD, Managing Medical Writer, Merck & Co., Inc.
Elizabeth Brown, MS, PMP, Managing Medical Writer, Merck & Co., Inc.

In today’s medical writing environment, medical writers are routinely faced with writing about highly complex studies and overwhelming amounts of data. When writing a deliverable, be it a protocol, clinical study report, poster, or peer-reviewed manuscript, it is imperative to develop a document that focuses on the key messages. This workshop provides recommendations on how to get out of the way of the data and implement various lean authoring techniques to ensure that the target audience comes away with the intended key messages. In-workshop activities: participants will engage in exercises to revise text to make it more fit-for-purpose, more lean and message-driven, more concise, more effective, and less biased.

Target Audience: Writers with no or little experience with the topic

WS-24 Sentence Structure and Patterns
Michael Schneir, PhD, Professor, Herman Ostrow School of Dentistry of the University of Southern California

Well-structured sentences say what they mean clearly, concisely, and coherently, ensuring that readers receive the intended message—a necessity for effective medical communication. This workshop provides an overview of the main elements of sentence construction, accommodation to the reading process, and the management of emphasis—all with a view toward matching structure to purpose. In-workshop activities: participants will review and discuss examples of flawed and improved sentences.

Target Audience: All writers and editors

WS-25 Writing Clinical Evaluation Reports for Medical Devices
Karen Bannick McQuoid, MA, RAC, FRAPS, President and Founder, Bannick LLC

While the US Food & Drug Administration extensively overhauls its submission process for medical devices, American companies are seeking European market authorization. However, there are major differences between the review and approval processes for medical devices in the European Union and the United States. In particular, a clinical evaluation report (CER) is required for all European medical devices (except diagnostic tools). This workshop provides practical advice for gathering and reporting valid clinical evidence in compliance with European Directive 2007/47/EC. In-workshop activities: participants will engage in interactive discussion and hands-on exercises. Note: experience with critical appraisal of the scientific literature and knowledge of medical device development are helpful.

Target Audience: Writers with moderate experience with clinical regulatory documents

San Diego Zoo
**Thursday, November 7**

6:30 AM – 5:30 PM  
CONFERENCE REGISTRATION DESK OPEN

6:30 – 7:15 AM  
SUNRISE NETWORKING WALK

7:00 AM - 3:30 PM  
EXHIBIT HALL OPEN

7:15 – 8:45 AM  
BREAKFAST WITH EXHIBITORS AND POSTER PRESENTERS – Enjoy breakfast in the Exhibit Hall and browse the posters on display. See page 32 for a list of poster titles.

9:00 – 10:00 AM  
EDUCATION SESSIONS

**Can Fitting in Fun Make Us Better Medical Writers?**  
Monica Nicosia, PhD, Principal, Nicosia Medical Writer, LLC  
Julie A. Gelderloos, PhD, Principal, Gelderloos Medical Writing, LLC

Many of us freelance because we love and/or need the flexibility and independence. However, sometimes we trap ourselves in a cycle of work and family obligations that leaves no time for our own physical and mental health. We know that all work and no play makes for a grumpy medical writer, but could that play actually make us better medical writers? Explore the benefits of making time for activities considered fun, enjoyable, and/or healthy, and learn how those benefits relate to career success.

**Focus Area: Health and wellness**

**Target Audience: All writers and editors**

**You Can Find a Diamond in the Rough: Medical Writing Opportunities in Rare Diseases**  
Christina Ohnsman, MD, President, CMO Medical Communications, LLC

Why should medical writers consider working in the rare disease space? Although each rare disease is individually rare, in total they affect an estimated 25-30 million Americans. This startling statistic has captured the attention of pharmaceutical and biotech companies, government agencies, advocacy groups, news outlets, medical education companies, and more. It also presents a relatively untapped business opportunity for medical communicators. Like many medical communication niches, the rare disease space has its own idiosyncrasies. Explore the rare disease landscape, learn how to identify entry points, gain insight on the needs of the field, and discuss the key qualities and skill sets for success.

**Focus Area: Career development**

**Target Audience: Writers and editors at all levels of experience**

**Augmenting Medical Writing with Artificial Intelligence and Natural-Language Generation**  
Jeff Mccrindle, Vice President, Yseop  
Abie Craiu, PhD, Principal Regulatory Documentation Scientist, F. Hoffmann la Roche, Ltd.  
Nishchal Sehgal, MBA, Senior Vice President, Life Sciences, Orion Business Innovation

Conducting clinical studies during the drug development process involves tremendous effort. At the end of these studies, statistical results need to be documented in clinical study reports and patient safety narratives. This authoring step remains a highly manually intensive process that can take several weeks. To assist medical writers’ efficiency and effectiveness, artificial intelligence/natural-language generation (AI/NLG) solutions exist to analyze the statistical results of adverse event data and to automate the process of authoring compliant content. An automated AI/NLG solution seamlessly integrated into the medical writer’s environment can result in considerable savings in time and cost, improvements in quality of reports, and substantial reduction in time to market for new drugs. The results of three real AI/NLG projects to assist medical writers will be presented.

**Focus Area: Regulatory writing**

**Target Audience: Writers and editors at all levels of experience**
Thursday, 9:00 – 10:30 AM continued

**Interviewing Potential Employers and Clients**
Damiana Chiavolini, MS, PhD, Instructor, UT Southwestern Medical Center
J. Kelly Byram, MS, MBA, ELS, CEO/Medical and Scientific Communications Lead, Duke City Consulting, LLC
Anne Murray, PhD, Medical Writer, Clinical Research Institute at Methodist Health System

This highly interactive session focuses on interviewing to land jobs in the medical writing field. Learn how to prepare for interviews to be hired as in-house writers and how to consult with potential clients for freelance assignments. A range of topics will be addressed, including using different interview strategies, asking questions, creating portfolios, negotiating salary and fees, and making decisions. The discussion will target academic and freelance settings, but many of the lessons can be applied to industry and other employment areas.

**Focus Area:** Career development

**Target Audience:** Writers and editors new to the field

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**Narrative Know-How: Streamlining the Writing, Quality Control, and Assembly Processes**
Jennifer Clemens, ELS, Clinical Technical Editor, Merck & Co., Inc.
Kathleen Oxberry, RN, MS, PMP, Lead Safety Medical Writer, Merck & Co., Inc.
Aldo Ramina, Business and Systems Analyst, ArborSys Group

Patient narratives are a vital component of the clinical study report, but they can be a rate-limiting factor in timelines. A polished narrative package that is easily navigable, comprehensive, and free of errors is the ideal deliverable for any regulatory process. Learn about a procedure for developing patient narratives that is based on feedback from the US Food and Drug Association and satisfies the need for consistency among complex projects. The infrastructure, collaborative platform, and document flow that allowed for automating the population of narrative data and the compilation of individual narratives will be discussed.

**Focus Area:** Regulatory writing

**Target Audience:** Writers and editors at all levels of experience

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**Style and Substance: The AMA Manual of Style, 11th Edition**
Stacy Christiansen, MA, Managing Editor, JAMA
Annette Flanagan, MA, Executive Managing Editor, JAMA Network

At last, the 11th edition of the AMA Manual of Style has arrived, complete with policy changes, updates, and new entries. Topics to be covered include new reference entries and standards for authorship; updates to nomenclature, usage guidance, and data presentation; expanded coverage of statistical terms; and recommendations for publication of supplementary online material. Also discussed will be ethical and legal issues that many writers and editors face, such as data sharing and corrections and retractions. Bring your style questions.

**Focus Area:** Writing/Editing

**Target Audience:** All writers and editors

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

**NEW**
**WS-30 Writing for Visual Media: Best Practices**
Ann L. Davis, MPH, CMPP, Independent Contractor

With the increasing variety of venues available for data presentation and scientific messaging, the ability to create visual content is in great demand. Writing for visual media requires simultaneous use of the left and right sides of the brain to get the point across verbally and visually, thereby holding the attention of the target audience. This workshop focuses on the components of effective visual communication, including conceptual development, scriptwriting style, use of animation and other interactive features of digital video, as well as on tips for making didactic slide presentations more visually appealing and engaging. Participants should come away with a better understanding of how to develop and use visual media to effectively convey medical information. In-workshop activities: participants will develop and discuss effectiveness of brief scripts for digital video, discuss appropriate means of illustrating samples of medical text, and evaluate sample slides for effectiveness in presenting medical information.

**Target Audience:** All writers and editors

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WS-31 Writing Clinical Study Report Lay Summaries – a Survivor’s Guide
Lisa Chamberlain James, PhD (cantab.), Senior Partner, Trilogy Writing & Consulting Ltd.

Writing plain language summaries of clinical trial results (the lay summary) is challenging but is now legally required in the European Union, with the United States set to follow suit. This workshop provides an overview of the problems with writing in plain language, a discussion of the challenges of describing real data for a nonspecialist audience, and a summary of practical tips and explanations for how to approach the requirements. In-workshop activities: participants will develop specific sections of a lay summary. The workshop focuses on the requirements of the EU regulation specifically, but the skills and principles taught can be applied to any plain language document.

Target Audience: Writers of all levels of experience in the pharmaceutical industry

WS-32 Writing the Investigator’s Brochure
Kathy Spiegel, PhD, Regulatory Writing Senior Manager, Amgen, Inc.

The purpose of the investigator’s brochure (IB) is to provide a comprehensive summary of the clinical and nonclinical data on an investigational product so that the investigator can best protect the subjects enrolled at his or her site. This workshop focuses on the regulatory and informational needs of the audience for IBs and how to use best practices to communicate information on the drug. Other issues discussed include relevant regulations, required topics, the evolution of the IB from phase 1 to phase 4, and how to prepare an IB with the input of subject matter experts. In-workshop activities: participants will work in small groups to write a section of a model IB.

Target Audience: Writers at all levels of experience in the pharmaceutical industry

WS-33 Introduction to Cancer Pharmacology
Gail Flores, PhD, Principal Writer, Encore Biomedical Communications LLC

The oncology marketplace is expanding at what seems like an exponential rate, with dozens of new agents approved each year. How can a medical communicator keep up? This workshop covers the mechanisms of action and US Food & Drug Administration-approved indications of currently marketed cancer drugs, from the chemotherapy agents discovered in the 1950s that are still used today to the revolutionary immunotherapies introduced in the last few years. Participants will learn about the drug discovery processes for chemotherapy agents and the drug design processes for biologic therapies. In addition to a discussion of the evolution of the oncology drug landscape, trends in indication language, companion diagnostics, and co-approvals are highlighted, as is the fact that despite these advances, today’s patients may receive novel therapeutics in combination with old-school chemotherapy. Participants will leave with a general understanding of currently marketed cancer drugs and the confidence to use this knowledge at work. In-workshop activities: participants will engage in molecule/drug role-playing, demonstrations, and games.

Target Audience: Writers and editors at all levels of experience

10:00 – 11:00 AM
MORNING BREAK IN EXHIBIT HALL

11:00 AM – 12:00 PM
EDUCATION SESSIONS

Demonstrating Presence Regardless of Work Location
Jennifer Thayer, Head, Medical Writing and Scientific Communications, BioBridges

Today, many of us work remotely, whether we are freelancers or full-time employees. While many love the flexibility that remote working provides, there are risks we all must manage, including the risk of being (or being perceived as) passive, indifferent, unavailable, or disconnected. Learn about the results of a survey asking medical communicators (both freelances and full-time employees) what various communication solutions they have used to stay relevant, engaged, and perceived as “present” on projects and program teams despite not working onsite or directly with their counterparts. Attendees will be invited to comment and/or offer their personal perspectives and experience on the topic.

Focus Area: Career development

Target Audience: Writers and editors at all levels of experience, especially those who work remotely
Influence of Leaders and Servant Leadership
Linda Yih, BSc, Senior Director, Medical Writing Services, PAREXEL International Corporation

Sources of influence are all around us. As a result, our behavior is often shaped by how others communicate with us and how we perceive them. If you are a leader or manager, are you aware of how you influence others? Influence also plays an important role in today’s approach to leadership, which has evolved from an authoritarian style to one that is collaborative and supportive. This is the foundation of servant leadership, which embodies nine qualities that can energize employees by cultivating diverse perspectives and trust, facilitating meaningful work opportunities, fostering autonomy, and promoting professional development without compromising personal time. In short, it can create a work environment that is too good to leave. Learn how influence, when used wisely, is an important asset for leaders and how servant leadership can help pave the way.

Focus Area: Leadership/Management
Target Audience: Managers of medical writers

Introduction to Medical Writing Project Management in Smartsheet
Michael Baker, PhD, President & Principal, Samorn Biosciences
R. Jordan Porter, Senior Medical Writer, Samorn Biosciences

Medical writers face many challenges in managing multiple timelines, cross-functional teams, and a variety of writing projects (primary focus on clinical development, regulatory, and scientific communications) to ensure high-quality, scientifically justified, and timely deliverables. Learn how project management in Smartsheet can address these challenges. The presentation is targeted to in-house medical writing managers, medical writers on the service side, and freelance writers seeking to hone their management skills. Attendees will have the opportunity to use Smartsheet and explore its management features.

Focus Area: Regulatory Writing
Target Audience: Mid-career writers

Making Money while You Sleep (or Don’t): The Promises and Pitfalls of Subcontracting
Brian Bass, MWC, President, Bass Global, Inc.
Emma Hitt Nichols, PhD, ELS, CEO and Founder, Hitt Medical Writing, LLC/Nascent Medical, LLC

Taking the daunting first step of starting a freelance business is like stepping out of a perfectly good airplane without a parachute. There’s an exhilaration of boldly freefalling toward an uncertain future, then discovering you can fly. But once a freelance finds his or her wings, what’s next? Subcontracting can take you soaring to new heights—at a price. Just as becoming a successful freelance requires skills far beyond simply being a very, very good medical communicator, subcontracting requires skills that make freelancing look easy. Learn from two freelances with substantial subcontracting experience who will share their stories of making the transition from freelancing to subcontracting and creating income-generating powerhouses. The lessons learned will enable you to fly to that next level.

Focus Area: Freelancing
Target Audience: Writers and editors at all levels of experience

Navigating Workplace Incivility as a Medical Writer
Emmaly Schwartz, Medical Writer, GE Healthcare

Medical writers often wear many hats. They are usually experts in regulations, medical knowledge, foundations of language, clinical research, and project management, and when working alone or in large teams, it is not uncommon for the medical writer to assume multiple roles. Because of their central role and broad knowledge base, they are often the intermediary between other members of various teams. This intermediary position can put them at the center of conflict. The discussion focuses on the causes and predictors of workplace incivility from an industrial/organizational psychology perspective and will include strategies for dealing with experienced incivility and stopping the propagation of negative environments.

Focus Area: Health/Wellness
Target Audience: All writers and editors
“X” Marks the Spot: Creating an Annotation “Treasure Map” for Quality Control Review
Mandy Pennington, BS, MWC, Quality Reviewer and Medical Editor, Whitsell Innovations, Inc.
Ashley Khan, PharmD, Medical Writer and Consultant, Whitsell Innovations, Inc.

A quality control (QC) specialist reviews and verifies all aspects of a document. Now, more than ever, it is vital that scientific materials are accurate and foster trust from the public. Thus, QC specialists take time and effort to ensure that a document is supported by source documents, which can go beyond the expected tables, listings, and figures to include emails, protocols, and training materials. With the sheer amount of material available, it is only fair to give your QC personnel a “treasure map” to any document...otherwise known as annotation. Annotation will be defined, best practices will be described, and strategies for creating treasure maps will be discussed.

Focus Area: Regulatory writing
Target Audience: Writers at all levels of experience

12:00 – 1:30 PM
MCGOVERN AWARD ADDRESS, WITH LUNCH

Award recipient: Paul A. Offit, MD, Director of the Vaccine Education Center, Children’s Hospital of Philadelphia, Maurice Hilleman Professor of Vaccinology and Professor of Pediatrics, Perelman School of Medicine at the University of Pennsylvania, Philadelphia

1:45 – 2:45 PM
EDUCATION SESSIONS

Communication Strategies: Learning How to Promote Programs and Navigate Media
Katrina Burton, MS, Program Manager, Public Relations Office, The University of Texas MD Anderson Cancer Center

An effective communications strategy is important for promoting medical discoveries, research and clinical news, and patient programs. A strategic communications plan serves as a road map for getting your message delivered to your target audience. Media can play a crucial role in awareness and external promotion. Combining these three elements—a strategy, a plan, and media—can help medical writers and communicators be successful in promoting research and programs. Learn how to develop and implement an internal and external communications plan incorporating internal stakeholders and various tools, how to engage an external audience, and how to navigate media.

Focus Area: Public relations/health care marketing
Target Audience: Writers and editors at all levels of experience

Effective Networking Skills for Medical Writers
Jeannene Butler, BSc, Associate Director, Medical Writing Services, PAREXEL International Corporation

Research has shown that face-to-face networking is the most effective method of establishing a mutually beneficial relationship with other business people and/or potential clients. Yet, in our current age of virtual communications, many medical writers work remotely and may feel out of practice or inexperienced with making connections with new people at conferences or other meetings. All writers, whether they are freelance or employed, should take the time to develop and practice the art of business networking. Learn best practices and tips for effective networking at business conferences and events, including preparation before the event, managing conversations at the event, and following up after the event has ended. Gain tips on creating an elevator pitch, to be prepared for those rare, unexpected moments to sell your skills or an idea.

Focus Area: Career development
Target Audience: Writers and editors at all levels of experience
How to Build a Medical Writer: Medical Writing Apprenticeships - New Training for a New Breed
Julia Forjanic Klapproth, PhD, President and Senior Partner, Trilogy Writing & Consulting

Training medical writers has never been an easy task – a successful medical writer needs to master a specific and demanding set of skills, including teasing out the crucial messages from data, writing in a clear and compelling way, managing stressed and pressured teams effectively, and keeping up with the constant changes in the regulations and updates to templates. Many different methods are available to train medical writers, and they have had varying degrees of success and are aimed at slightly different outcomes. Learn about a more holistic approach of medical writing apprenticeships that is based on the principle that medical writing is a craft not defined by a checklist, and that the best way to learn any craft is to become an apprentice from a skilled and experienced master craftsperson.

Focus Area: Regulatory writing
Target Audience: Managers of medical writers

The Science and Art of Project Stakeholder Management
Becky Nuttall RN, BSN, Submission Medical Writer, Pfizer, Inc.

Do you groan when you see the word stakeholder? Did you know there really is a science behind it? And, like medicine, stakeholder management is an art. Regrettably, most medical writers get no training in this key area, and as demand increases, it is even more important for medical writers to understand the basics of project stakeholder management. When medical writers are called on to use project management skills, an organized approach will lead teams to success. Learn pragmatic tools to categorize stakeholders, tips for negotiations, and steps to get buy-in when you must lead without authority.

Focus Area: Leadership/Management
Target Audience: Mid-career regulatory writers

Text Recycling in Scientific Research Writing: Recent Findings from the Text Recycling Research Project
Cary Moskovitz, PhD, Director of Writing in the Disciplines, Duke University
Susanne E. Hall, PhD, Campus Writing Coordinator, Hixon Writing Center, Caltech

Text recycling refers to the reuse of material from one’s previous work in a new work without identifying the material as a quotation. As increasing numbers of journals have adopted the practice of screening submissions with plagiarism-detection software, the practice has become more visible and contentious. Critics of text recycling claim that authors should avoid reusing material from their prior publications, while others contend that recycling material is sometimes justified—especially in Methods and Introduction sections. The need for more consistent and explicit guidance for authors and editors requires a better understanding of the practice itself. Learn about the recent findings from the project, including (1) the beliefs and practices of journal editors regarding text recycling, (2) text recycling practices of researchers, and (3) copyright and contract law. Implications for medical writers and editors will be discussed.

Focus Area: Scientific publications
Target Audience: Writers and editors at all levels of experience
ment. Learn the major differences between small molecules and monoclonal antibodies and their impact on drug development.

**Focus Area: Science and medicine**

**Target Audience:** Writers and editors at all levels of experience

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**Herding the Cats: The Medical Writer’s Survival Guide for Regulatory Submissions**

Mary Ellis Bogden, Senior Writer & Manager, Whitsell Innovations, Inc.

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

Authoring the components of regulatory submissions requires cross-functional collaboration among research and development (nonclinical, clinical, biostatistical, pharmaceutical), marketing, regulatory, senior management, and other key stakeholders. Medical writers are often tasked with authoring more than one Common Technical Document module, organizing and working across teams with competing resources and timelines, and ensuring key stakeholders stay informed during the process. Learn about methods, tips, and tools for tracking your document’s progress and the flow of source materials, balancing your own timelines with the overall submission plan, managing cross-functional team activities, and aligning key messages and style across documents and authors. The writer’s role in maintaining regulatory compliance and mitigating critical path emergencies during the authoring phase will also be addressed, along with essential skills for establishing boundaries, communicating clearly, leading review meetings, and resolving team conflict, all of which contribute to the success and quality of the submission.

**Focus Area: Regulatory writing**

**Target Audience:** Mid-career writers

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**Med Write Talks I**

**Career Burnout: We Didn’t Start the Fire...or Did We?**

April Reynolds, MS, ELS, President, Write/Correct, Inc.

Is burnout a phenomenon among just Millennials or did our grandparents feel it too? What do the current thought leaders on burnout say? Listen to a personal journey through burnout and beyond and learn practical ways to improve work/life balance and explore whether making a hobby a career is a good idea or a trap.

**The CMEpalooza Story: Lessons for the Medical Writing Community**

Scott Kober, President, MedCaseWriter, Inc.

CMEpalooza, a free, semiannual online conference for CME professionals, launched in 2014 and is unquestionably a success story. The two conference co-creators coordinate everything: session planning, promotion, sponsorship sales, back-end production, website development, and much more. Learn how nontraditional opportunities such as this can be used to market yourself and your business to broad industry communities.

**Disrupting Our Profession: A Medical Writer’s Call to Action**

Joan Affleck, Executive Director, Head of Medical Writing, Merck & Co., Inc.

It’s time to reimagine the role of medical writing. As all else in medicine blazes new trails, we risk losing ground, losing relevance, without visionary change. We risk betraying our writers. We risk having industry disengage unless we reconvince leaders of the unique resource they have in medical writers. We must disrupt our profession. Disrupting our profession gives a clear call to action: Develop and train medical writers to reinvent the profession. Our work must provide indispensable ... not incidental ... value to our companies. We must lead, not follow. We must energetically embrace the very technology so many fear. Disrupting our profession will empower medical writers to reimagine who ... and how ... we are.

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**We the People: Making Government Biomedical Information Understandable for Everyone**

Shauna Bennett, PhD, Science Writer, Palladian Partners

Karen Eddleman, MT(ASCP), Senior Science Writer, Palladian Partners

According to the Centers for Disease Control and Prevention (CDC), when health information is unfamiliar, complex, or filled with jargon, nine out of 10 adults will struggle to understand and use it. For that reason, federal law now requires the use of plain language in a variety of consumer-facing health content from US government sources, such as the National Institutes of Health, CDC, Food and Drug Administration, and others. Topics will include the guiding principles of plain language writing,
Thursday continued

Section 508 compliance, and best practices for interactions with federal government clients. Gain insights and resources that are useful for creating clear, accessible content.

**Focus Area: Health communication**

**Target Audience: Writers and editors at all levels of experience**

4:30 – 5:30 PM

**EDUCATION SESSIONS**

**The ABCs of Stress Management**
Reggie Wilson, MS, Wellness Coach and Medical Education Writer, Fit for Freelance/Wilson Medical

On a scale from 1 to 10, how stressed are you? Tight deadlines, annoying clients, and your forever long to-do list—when you’re stressed out, you lose productivity and feel exhausted. Unchecked, stress destroys sleeping, eating, and exercising habits, causing the weight gain that leads to chronic disease. Go beyond slowly counting to 10 by discovering the ABCs of Stress Management. Practice Positive Behavior Support strategies that let you feel great, work better, and enjoy what you love in life and work.

**Focus Area: Health and wellness**

**Target Audience: All writers and editors**

**Jam Session for Mid-Level Managers**
Kimberly Jochman, PhD, Managing Medical Writer, Merck & Co., Inc.

Do you wonder whether your management challenges are unique? Join other managers to find out by sharing experiences and tips on managing people, deliverables, and career.

**Focus Area: Leadership/Management**

**Target Audience: Mid-level managers of medical writers**

**Preparing Module 3 (Quality) Content for Complex Biologic Early-Phase Investigational New Drug Applications**
Carrie Eklund, BSE, MEd, CMC Senior Manager, Global Medical Writing and Translation

Writing the Chemistry, Manufacturing, Controls (CMC) section for early-phase Investigational new drug (IND) applications is typically left to the sponsor’s technical team. However, a skilled CMC regulatory writer can facilitate the completion of a strategically positioned IND application to support future regulatory filings while liberating technical staff for development activities. US Food and Drug Administration (FDA) estimates for future cell and gene therapy submissions and the 2018 FDA Guidance for cell and gene therapy product INDs will be reviewed. Elements of successful early-phase IND submissions to be discussed include assessment of sponsor readiness through availability of key source documents (including strategies to address rolling availability and incomplete source documents); engagement of primary stakeholders; and execution of IND preparation under accelerated timelines.

**Focus Area: Regulatory writing**

**Target Audience: Writers at all levels of experience**

**Reviewer Coaching: Increasing Efficiency through Communicating Reviewing Best Practices**
Lima Chutkan, PhD, RAC, Senior Manager, Medical Writing, Alnylam Pharmaceuticals

Do you spend more time asking reviewers to clarify their comment than writing? It can be daunting to see hundreds of comments and wade through conflicting viewpoints. Reviewer training can help by improving reviewers’ ability to convey specific and constructive feedback. Effective reviewing is a skill, and everyone can benefit from coaching. Discussion will focus on best practices for reviewing, with an emphasis on strategic reviewing and guidelines on how to work within a review system. Learn how to engage and educate reviewers and how to set expectations on resolving comments for a smoother process later on. Multiple options will be presented to allow you to customize the best approach for your circumstances.

**Focus Area: Regulatory writing**

**Target Audience: Writers at all levels of experience**

**Tools to Enhance Your Productivity as an Editor**
Kelly Schrank, MA, ELS, Medical Editor and Technical Writer, Bookworm Editing Services

Anyone writing, editing, or managing any type of communications for a living is feeling the crunch. There
is less time to create, review, and edit; more types and formats of content; and an increasing number of applications, software, and systems. Become a more productive editor by learning how to better use the most ubiquitous office software, Microsoft Word, and by addressing a multitude of modern dilemmas with a relatively old-school hack, an editing checklist. Learn how to make an Editing Tools tab in Word, customize the Spell Check to work harder for you, and automate some editing tasks using find and replace with wild cards and simple macros. Examples will be shown in Microsoft Office 365 version of Word, but should be applicable to earlier versions.

Focus Area: Writing/Editing
Target Audience: Mid-career editors

Using Narratives to Improve Health Literacy and Communicator Credibility
Rachel Adams, PhD(c), MS, RD, LD, Health Communication Strategist, Rachel Adams, LLC

Researchers and scientists may be recognized as experts, but the public perception is that they lack warmth, which decreases trust. Building narrative into our messaging and coming from a posture of sharing or teaching has the potential to grow both trust and credibility. In addition, research indicates that programs with a narrative component not only improved the likability and recall of the messages but also reduced barriers to positive health behaviors in distinctly disadvantaged populations. Evidence-based examples will demonstrate how perceptions of trustworthiness and credibility improve with narrative, authenticity, transparency, and warmth to have a positive impact on health literacy and behavioral outcomes while reducing health disparities.

Focus Area: Health communication
Target Audience: Writers and editors at all levels of experience

Friday, November 8

6:30 AM – 5:30 PM
CONFERENCE REGISTRATION DESK OPEN

6:30 – 7:15 AM
SUNRISE NETWORKING WALK

7:15 – 8:45 AM
ROUNDTABLE DISCUSSIONS WITH BREAKFAST
(additional fee) – Titles with an asterisk (*) are also offered as a Lunch Roundtable Discussion on Saturday.

All Aboard the MentorShip: Effective Mentoring in Medical Writing: Mentor Perspective
Elise Eller, PhD, Senior Medical Writer and Consultant, Whitsell Innovations, Inc.

Art of Writing Accredited and Nonaccredited Continuing Medical Education (CME)
Katherine Molnar-Kimber, PhD, President, KMK Consulting Services of Kimnar Group LLC

Avoiding Rejection: Tips for Manuscript Writing Success
Andrea R. Gwosdow, PhD, President, Gwosdow Associates Science Consultants, LLC

Being Informed in the 21st Century
Joan Affleck, Executive Director, Head of Medical Writing, Merck & Co., Inc.

Benefits of Dynamic Product Information Delivery for Life Sciences
Elizabeth Fraley, CEO, Single-Sourcing Solutions

Certification of Editors in the Life Sciences
Norman Grossblatt, ELS(D), Editor

CSR Section 13 or: How I Learned to Stop Worrying and Love Writing the Discussion Section
Trisha L. Houser, Manager, Houser Clinical Research Writing and Consulting, LLC

*CTD Structure: From IND to NDA
Michael G. Baker, PhD, President & Principal, Samorn Biosciences

Don’t You Forget It! Using an Editorial Project Checklist
Laura J. Ninger, ELS, President, Ninger Medical Communications, LLC

The Elusive Pursuit of Work/Life Balance
Anita Misra-Press, PhD, Independent Medical Writer

Finding the Wild Side: An Introduction to Using Wildcard Find and Replace in Microsoft Word
Kate McKiernan, Freelance Editor

Formal Communication with Regulatory Agencies: After Discovery and Before Development
Priyanka B. Ingle, Translational Clinical Pharmacologist, CRC Pharma, LLC
Freelance's Guide to Cybersecurity
J. Kelly Byram, MS, MBA, ELS, CEO/Medical and Scientific Communications Lead, Duke City Consulting, LLC

*From Benchtop to Laptop: Streamlining the Transition to Full-Time Regulatory Writing
Cody Nichols, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc.

Get up, Stand up ... for Your Health!
Eva Stabenow, MA, Wordplay Translations

Grow Your Own Local Network of Communication Professionals
Joanne M. McAndrews, PhD, Freelance Medical Writer

*How Did I End up Working Here?
Lisa Carricaburu, MBA, Managing Editor, Decision Support Products/Informatics-Decision Support, ARUP Laboratories

How to Improve Editing and Writing Skills in a Multilingual Environment
Natalia Andrea Abdelnur León, Assistant Clinical Technical Editor, MSD

HTAs and AMCP Dossiers: Find Out What They Are in Five Easy Steps!
Linda Rice, Medical Writing Senior Manager, Amgen Inc.

I Have the Abstract: How Do I Make It into a Poster?
Michelle E. Stofa, Research Communications Manager, Nemours/Alfred I. duPont Hospital for Children

It's Been X Years, Now What Do I Do?
Mari Welke, Director, US Operations, Trilogy Writing & Consulting

The Location-Independent Medical Writer: How to See the World while Doing What You Love
Bryce Marquis, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc.

Managing Cross-Functional Teams
Julia Forjanic Klaproth, PhD, President and Senior Partner, Trilogy Writing & Consulting

Medical Writer Burnout: How Leadership Plays a Vital Role
Lyne Pauley, MS, Manager of Medical Writing – Early Clinical Medical Writing, PRA Health Sciences

A Medical Writer's Guide to Single- and Multiple-Ascending Dose-Escalation Combination Studies
Shawn Watson, PharmD, PhD, BCPS, Associate Director, Clinical Sciences, Vertex Pharmaceuticals

Medical Writing in Marketing and Communications
Valerie Sjoberg, MAc, MWC, Medical Writer and Content Manager, DaVita, Inc.; Owner, BioWrite LLC

Nonclinical Recall: The Total Reality of Writing CTD Sections 2.4 and 2.6
Rochelle Mills, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc.

Pricing Strategies for Freelances
Heather Gorby, Freelance Medical Writer, Gorby Consulting

Seven Habits of Highly Successful Medical Writers
Kimberly Newton, Senior Director, Medical Writing, Veristat, LLC

Simplify the Document Review Process and Get Your Life Back!
Kristi Boehm, MS, ELS, Manager, Medical Writing, Lexicon Pharmaceuticals, Inc.

*Taking EU Medical Device Teams into the Year 2020
Stephanie Knighten, MS, Senior Medical Writer and Associate Manager, Whitsell Innovations, Inc.

Tech, Travel, and Data Security
Kathy Boltz, PhD, Owner and Principal, On Point Scientific, LLC

Think Like a Grant Reviewer
Madison Hedrick, MA, Senior Medical Writer, Wilson Carroll Research Services, LLC

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

Transitioning from Freelance Medical Writing to Retirement
Barbara T. Zimmerman, PhD, Owner/Manager, Biomedical Communication & Consulting

Translators Networking
Matthew McKeelhan, MA, ELS, Translator, Chugai Pharmaceutical Co., Ltd.

Use It, Don't Lose It: Strategies for Better Time Management
Melissa Christianson, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc.

Veterinary Medicine Expertise: Challenges and Opportunities in Medical Writing
Suzanne Pratt, MBA, DVM, MS, DAVCP, ELS, Principal, Suzanne Pratt Works, LLC

Women in Medical Writing and Communications: A Discussion of Challenges and Successful Life Hacks
Tara Gupta, PhD, Principal, Medical Writer, 2G Consulting and Services
Work/Life Integration for Freelances and Full-Time Employees Alike: Staying Balanced while Working Remotely
Jennifer Thayer, Head, Medical Writing and Scientific Communications, BioBridges

"Writing while Female: A Discussion of Gender Disparity/Bias in the Medical Writing Industry
Stephanie Leveene, ELS, CMPP, Senior Market Access Writer, Evidera

7:30 – 8:30 AM
EDUCATION SESSIONS

Yoga at Your Desk: Stretch, Breathe, and Relax
Mary Kemper, Yoga Instructor, TriYoga

Start your day with a TriYoga practice sure to leave you sitting taller and feeling energized. Be guided through basic yoga stretches to release neck and shoulder tension, wrist and finger strain, and back stiffness. Along with classic yogic eye exercises, learn the Daily 5, moving with wave-like flows to free the spine and hips. Practice rhythmic breathing practices for calm and creativity, dynamic concentration for focus, and a guided meditation for relaxation.

Focus Area: Health and wellness
Target Audience: All writers and editors

9:00 – 10:00 AM
EDUCATION SESSIONS

It’s YOUR Time: A Nonjudgmental Approach to Time Management
Erica Goodoff, ELS, Senior Scientific Editor, Department of Scientific Publication Services, The University of Texas MD Anderson Cancer Center

What does the phrase time management mean to you? Efficiency? Productivity? Frustration? In a deadline-driven field, we all practice time management, whether it works well or not. So how well is it working for you? This session goes beyond the internet listicle style of time management tips to help you devise a more personalized time management strategy: not the way you should manage your time, but the way that actually works.

Focus Area: Health and wellness
Target Audience: All writers and editors

9:00 – 10:30 AM
EDUCATION SESSIONS

Are You a Candle or a Wolf? Medical Writers as Strategic Leaders
Robin Whitsell, President, Whitsell Innovations, Inc.

Irrespective of title, role, or organization, medical writers have the opportunity to become strategic leaders. Are you the type of leader who is out in front of your group or are you leading from the vantage point of your entire team? As medical writers advance in their careers, aspects of leadership inside of their organizations and professional outreach become more and more crucial. We will explore the common traits strategic leaders strive to obtain, reflect on how we can leverage our credibility and expertise to influence and truly shift conversations, share how to characterize and refine our value proposition as strategic leaders, and discuss how to move from awareness to action. Strategic leadership starts with situational- and self-awareness and extends through to creation of a long-term goals and operationalizing those goals. Are you ready to roll up your sleeves and lead?

Focus Area: Leadership/Management
Target Audience: Mid-career writers and editors

Exploring the Diverse and Multidisciplinary Educational
Friday, 9:00 – 10:30 AM continued

Ecosystem for Medical Writing
Tim K. Mackey, MAS, PhD, Associate Professor, UC San Diego, School of Medicine Director - Healthcare Research & Policy
UC San Diego - Extension Director, Global Health Policy Institute, UC San Diego
R. Michelle Sauer Gehring, PhD, ELS, CRA, Principal Writer/Editor and Faculty, UC San Diego Extension, Medical Writing and Editing Certificate Program

Panelists will focus on educational approaches to scientific writing and publication from the perspectives of graduate education, adult learning, and professional development. The discussion will address various types of scientific writing and publication courses (including graduate courses, professional certificates, and other continuing education courses) designed for different audiences, including (1) masters-level students in health care research-related fields seeking to publish academic research; (2) medical writers participating in adult education focused on professional development; and (3) medical writers in in-house corporate training programs. Challenges, development of core competencies, delivery design/format, track specializations, tailoring of content for different levels of medical writers, and opportunities for innovation in curriculum and program design will be explored based on real-world experience from panelists with experience in academia, industry, and consulting firms.

Focus Area: Career development
Target Audience: Writers and editors at all levels of experience

How to Nurture Clients into Long-Term Relationships and Boost Your Bottom Line
Katherine Molnar-Kimber, PhD, President, KMK Consulting Services of Kimnar Group LLC
Deborah Anderson, PhD, MS, MT(ASCP)SH, Medical Writer/Instructional Designer, DGA Medical Communications

Keeping clients happy so they continue to request projects is a win-win for both the client and the freelancer. Learn three exercises to narrow the characteristics of ideal clients and identify efficient recruitment strategies, as well as three topical issues that turn off clients. Lastly, six tips for nurturing clients into long-term relationships will be presented. Attendees will have the opportunity to share experiences and will leave with new insights for nurturing new clients and gaining a steady flow of projects.

Focus Area: Freelancing
Target Audience: Writers and editors at all levels of experience

How to Write Strategic Grant Proposals for Research Collaborations
J. Kelly Byram, MS, MBA, ELS, CEO/Medical and Scientific Communications Lead, Duke City Consulting, LLC
Damiana Chiavolini, MS, PhD, Instructor, UT Southwestern Medical Center

Whether a research question will be explored at the bench, in the clinic, or in the community, funders allow or, increasingly, expect funding proposals to involve shared leadership. Sometimes, an interdisciplinary approach to a question demands team science involving the collaboration of multiple research teams across institutions and countries, while other questions require researchers to combine forces with community stakeholders to perform patient-centered outcomes research or other community-engaged research. The savvy funding seeker realizes that the collaborative and shared-leadership models that support the execution of this research introduce an element of perceived risk not found in the lone-researcher model, and reviewers need assurance that the benefits of the proposed approach outweigh the risks. Learn about common collaborative models and about how to develop strategic grant proposals that will get your team funded. Funding opportunities discussed will include NIH, PCORI, and CPRIT MIRA.

Focus Area: Grantsmanship
Target Audience: Writers and editors at all levels of experience

Medical Writing Techniques in Pharmacovigilance
Mari Welke, Director US Operations, Trilogy Writing & Consulting
Pharmacovigilance is a key term in today’s medical writing field. Learn about key analysis topics in the field (eg, overdose, drug interactions, medication errors, special populations) and about the types of questions that medical writers should ask when reviewing data for aggregate reports, signaling evaluations, and benefit-risk evaluations. Also discussed will be the data sampling breakdowns needed to support the analysis and creation of
pharmacovigilance reports and the reference documents that are applicable to pharmacovigilance.

Focus Area: Regulatory writing
Target Audience: Writers at all levels of experience

10:00 AM – 4:00 PM
EXHIBIT HALL OPEN

10:00 – 11:00 AM
MORNING BREAK IN EXHIBIT HALL

11:00 – 11:30 AM
ALVAREZ AWARD ADDRESS
Award recipient: Daniel J. Siegel, MD, Clinical Professor of Psychiatry, UCLA School of Medicine, Santa Monica, CA

11:30 AM - 12:30 PM
LUNCH WITH EXHIBITORS AND POSTER PRESENTERS
See page 32 for a list of poster titles.

12:45 – 1:45 PM
EDUCATION SESSIONS

Findings from the 2019 AMWA Medical Communication Compensation Survey
Laura Sheppard, MBA, MA, Director, Medical Writing & Quality Control, Endo Pharmaceuticals

For more than 30 years, AMWA salary surveys have been the only surveys that focus specifically on medical writing, editing, and communication professionals. Learn about the latest data on compensation across medical writing settings for both freelance and employed medical writers and editors.

Focus Area: Career development
Target Audience: Writers and editors at all levels of experience

How to Check Consistency and Enforce Your House Style: Using PerfectIt in Submissions and Publications
Daniel Heuman, CEO and Founder, Intelligent Editing

All it takes is one typo for readers to question the underlying science of a submission or publication. Finding time to correct consistency errors or check that each word conforms to the style manual is difficult for any editor, but especially when under the time pressure of a submission. This work can, and should, make use of automation so that you have more time to focus on substantive editing. Learn the basics of PerfectIt software and a quicker way to find and correct consistency mistakes as well as advanced topics, including how to build a PerfectIt style sheet to enforce house style.

Focus Area: Technology
Target Audience: All writers and editors

The Saving Equation: Work + Saving = Yes, You Really Can Have a Life
Loryn Woodard, Financial Advisor, Edward Jones

The savings equation is a test everyone faces. In today’s landscape, retirement and savings are often the last items on a long to-do list. When you’re starting out (or even if you are 20 years in), it can be difficult to find ways to put aside funds for retirement (or emergencies), but not saving can have devastating consequences. Learn about the most common savings and retirement options, adaptable strategies that can fit personal lifestyles and goals, the importance of having a retirement plan and estate plan in place, insurance that can cover unexpected events, buy-sell agreements, and simple saving plans.

Focus Area: Health and wellness
Target Audience: All writers and editors

SharePoint to the Rescue! Using SharePoint as a Tool to Manage Medical Writing Teams and Client Partnerships
Amelia Young, Associate Manager, Medical Writing Services, PAR-EXEL International Corporation

Templates, assignments, and style guides, oh my! In a fast-paced environment, the time medical writers use to locate the correct template, track project assignments, and verify client requirements takes away from the time a writer is able to spend working on project deliverables. Microsoft SharePoint can be used as a tool to manage administrative items for both medical writing teams and client partnerships. Learn how to develop a SharePoint site and how to customize the site to meet specific needs.
TransCelerate's Common CSR Template: A Consistent Approach to Writing Compliant CSRs with Ease
Elizabeth Brown, MS, PMP, Managing Medical Writer, Merck & Co., Inc.

On the heels of TransCelerate’s successful roll-out of the common protocol template (CPT), the organization's common clinical study report (CSR) template was publicly released in December 2018 and is being adopted across the industry. Learn the story behind this new, thoughtfully designed, technology-enabled CSR template, including the collaborative development process and key decisions of the template design. Also discussed are how the template encourages adoption of a streamlined authoring approach, the advantages of the TransCelerate CSR template and structured authoring, and how to implement the template for the next CSR you write.

**Focus Area: Regulatory writing**

**Target Audience: Writers at all levels of experience**

2:00 – 3:00 PM

**EDUCATION SESSIONS**

10 Essential Criteria for Building and Maintaining a Freelance Business
Laura J. Ninger, ELS, President, Ninger Medical Communications, LLC

Earning a living as an independent contractor is an ongoing endeavor involving daily decisions about how to structure your business, allocate time and resources, enhance your skills, market yourself, deal with legal and tax issues, and manage clients—all while actually doing the work and getting paid. Learn 10 key strategies for building, maintaining, and evaluating your freelance business. Both new and experienced freelances can benefit by identifying recommendations relevant to their own businesses and applying these pointers to enhance their careers and grow their bottom line.

**Focus Area: Freelancing**

**Target Audience: Writers and editors at all levels of experience**

In the Green Room with Your Words – MS Word Template Creation
Kelly Crossett, Quality Reviewer and Publishing Specialist, Whitsell Innovations, Inc.

Your words have been written. They are ready for their debut. Backstage, in the Green Room, you must give them the tools they will need to truly shine and impress your audience… a custom set of Word templates! Custom templates can be useful for many documents created by medical writers (eg, protocols, education materials, grant proposals, letterhead, invoices). Templates provide the paragraph styles, page layouts, and basic document formatting that will ensure a consistent production every time the curtain goes up (or a client opens a document)! Learn a step-by-step process for creating your own templates, as well as tips and best practices for saving, accessing, and sharing your custom Word templates. *Note:* The discussion will focus on Windows-based Word 2016.

**Focus Area: Technology**

**Target Audience: Mid-career writers and editors**

Med Write Talks II

It Is Almost Time to Tidy up, but Before I Go
Larry Lynam, Principal, The Lynam Group, LLC
Recipient of 2018 AMWA President’s Award

If we are lucky travelers, we get to reach that sweet spot in our journey where we realize the ultimate destination is far closer than our starting point. But before we jump up to gather our belongings one last time, we are given a minute to enjoy a realization; this wasn’t the journey I planned, but I am so glad it is the one I took. As a bonus, we get to reflect on those crazy experiences, fun times, and even those wild obstacles we overcame along the way. But we have one last obligation and opportunity before we disembark. We need to share what we learned along the way. This is our chance to take time to gather, organize, and craft what could be our best story yet. Our real measure is the roadmap we leave for others. What will your map say?

Overcoming Obstacles: A Nurse with Chronic Illness Shifts Her Career Path
Ashley Hay, BSN, RN, Owner of A Hay Writing - Freelance Health Care Writer, Editor, and Consultant

Hear the personal story of how chronic illness led an experienced oncology nurse to a satisfying path of freelance medical writing/editing, health care consulting, and entrepreneurship. Learn about the value of connection with others in your desired niche as a way to change your professional journey successfully.
Toward More Effective Communication with Science Deniers
Christina Ohnsman, MD, President, CMO Medical Communications, LLC

Science is under attack in our society, with nonscientists denying the facts of evolution, climate change, and the benefits of vaccines. These increasingly loud objections and "alternative facts" are steering public policy in dangerous directions. How can medical communicators effectively respond to these unfounded challenges to established facts? Learn how to recognize and critically evaluate common arguments used on all sides and to identify strategies for more effective communication with science deniers.

Writing Biomedical Research Papers for Publication
Madison Hedrick, MA, US Medical Research Services, LLC

More than 2.5 million new scientific research studies are published each year. How do you make sure the one you’re working on gets published? Learn how to marshal the details of a research study into a clear story with a beginning (the introduction), middle (the methods), end (the results), and the moral (the discussion). Other topics include different types of research papers and their level of medical evidence, features of tables and figures that make for effective reading, and factors that help ensure the best possible chance at publication, such as ethical guidelines, steps for a systematic method of publishing, and CONSORT guidelines.

Focus Area: Scientific publications
Target Audience: Writers with little or no experience

3:00 – 3:30 PM
AFTERNOON BREAK IN EXHIBIT HALL

2:00 – 5:00 PM
AMWA WORKSHOPS (additional fee)

WS-40  Writing and Designing Materials for Patient Education
Genevieve Long, PhD, Freelance Medical Writer - Patient Education, Health Literacy, and Marketing Specialist

In the Google era of health misinformation, writing for patients—and the overall public—has never been more challenging. This workshop focuses on different types of patient education materials and the key principles underlying this type of writing. In-workshop activities: participants will critique sample patient education booklets.

Target Audience: Writers with little or no experience with the topic

WS-41  Essentials of Copyediting
Loretta Bohn, Senior Editor/Writer, RTI International

Copyediting is a basic but essential skill that every professional medical communicator should master to ensure clarity, accuracy, and consistency. The workshop focuses on the elements, principles, and processes involved in copyediting for scientific and medical publications. In-workshop activities: participants will identify typical copy problems and compare various editorial choices.

Target Audience: Beginning copyeditors

WS-42  Proofreading: Strategy for Document Quality Control
Damiana Chiavolini, MS, PhD, Instructor, UT Southwestern Medical Center

Proofreading is the final—and often underappreciated—step in producing professional documents. This introductory or refresher workshop focuses on proofreading as a strategy for document quality, distinct from writing or copyediting. More than catching typos, proofreading strategies include achieving consistency, sharpening attention to mechanical errors, and identifying and correcting production and layout issues. Standard proofreading practices and electronic proofreading methods are discussed. Participants will learn to train both the mind and the eye to determine what to correct, query, or ignore. In-workshop activities: Participants will complete exercises to apply proofreading strategies.

Target Audience: All writers and editors

WS-43  Summarizing Clinical Safety Data for a New Drug Application
Marijke H. Adams, PharmD, PhD, President, MH Adams & Associates, Inc.
Jennifer Bridgers, MS, MWC, Managing Medical Writer, Merck & Co., Inc.

For regulatory writers, it is crucial 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). This workshop provides an overview of the applicable Code of Federal Regulations sections, US Food and Drug Administration guidances, and International Council for Harmonisation (ICH) guidelines associated with the Summary of Clinical Safety (SCS) and Integrated Summary of Safety (ISS). The similarities and differences between the SCS and the ISS are described, as well as the source documents needed to write these regulatory documents. In-workshop activities: participants will engage in exercises and discussion relevant to writing clinical safety documents.

Target Audience: Writers with moderate experience with clinical regulatory documents

WS-44 Strategies for Improving Document Quality for Pharmaceutical Communications Managers
Kathy Spiegel, PhD, Regulatory Writing Senior Manager, Amgen, Inc.

Improving the process of document preparation is crucial for medical writers. Topics discussed include mechanisms for enhancing quality and accountability and for ensuring adequate time allowances. These are organizational issues around which a medical writing group can build policies aimed at ensuring a higher degree of accountability among those with whom they work and upon whose input they depend. In-workshop activities: participants will work in small groups to discuss ways to overcome the enemies of quality.

Target Audience: Regulatory writers in a supervisory role

WS-45 Advanced Writing
Helen Hodgson, PhD, Emeritus Professor of Communication, Westminster College

This workshop offers the opportunity for experienced medical writers to explore ways in which they can become even better. Discussion centers on the cognitive processes used by writers and a few finer points of style, and strategies for successfully approaching (and completing) a writing project. In-workshop activities: participants will share the process they use in their writing and the effect of writer’s block on that process.

Target Audience: Writers with at least 5 years of experience

3:30 – 4:30 PM
EDUCATION SESSIONS

Beyond Happy 😊, Sad 😞, and Mad (*%$#!) – Use Your Words! (Dealing with Life and Stress Using Emotional Granularity)
Kelly Crossett, Quality Reviewer and Publishing Specialist, Whitsell Innovations, Inc.

Think of something that makes you mad. Is it an inconsiderate client; a coworker missing a crucial deadline; a favorite team losing the championship? Would you use “mad” to describe all of these things? If the answer is “no,” you are showing a level of emotional granularity. Being able to use a more specific and varied vocabulary to describe your feelings can help you take a step back from emotionally charged situations and develop a specific, action-oriented response. Learning to use more accurate words to describe our emotions can help us handle stress more directly, process feedback more productively, and deal with our clients and colleagues more effectively. Learn how to express emotions beyond emojis and punctuation marks.

Focus Area: Health and wellness
Target Audience: All writers and editors

By the Hour or by the Project? Straight Talk about Pricing Strategies for Freelancers
Eleanor Mayfield, ELS, President, ELM Communications

Pricing strategies can be a matter of passionate debate among freelance medical writers. Some people swear by project fees, while other are equally vehement that an hourly rate is the only practical approach. In the real world, however, all methods of pricing have advantages and disadvantages. The discussion will focus on the pros and cons of different pricing strategies and factors to consider in determining how to price a freelance project. Attendees will be invited to share pricing conundrums, successes, and lessons learned.

Focus Area: Freelancing
Target Audience: Writers and editors at all levels of experience
Creating Narrative-Writing Software
Danielle St. Pierre, Manager, Medical Writing, PAREXEL International Corporation

Narratives are data-heavy documents, and writing them requires special attention to detail. These documents can be time-consuming, may involve repetitive work, and are often written under tight timelines. On top of that, a single clinical study report might need hundreds of them. Fortunately, writing narratives doesn't have to be done manually. Writing the first draft of a narrative can be automated with a small computer program. With the help of an in-house or contracted software developer, you can create a program that will print the tables, text, and custom safety data for each individual narrative and drastically reduce the time required to write a large batch of narratives.

Focus Area: Regulatory writing
Target Audience: Writers at all levels of experience

Effective Mentoring of Medical Writers: Principles and Practice
Vicki Foster, MSPH, Principal Medical Writer, PAREXEL International Corporation
Michele Vivirito, Medical Writing Consultant

Mentoring can be a crucial step in the training and development of medical writers at all stages of a career. As teacher, advisor, and advocate, a mentor promotes growth of knowledge, shares experiences (both successes and failures), and facilitates a sense of community and teamwork. Learn the principles of effective mentoring, the qualities of a good mentor, three levels of mentoring based on career stage (informational, skills-based, and advocacy), the importance of goals and objectives, and feedback methods. Also discussed will be how principles of effective mentoring have been put into practice in various settings, including a decentralized work environment.

Focus Area: Regulatory writing
Target Audience: Mid-career writers

Managing Complex Regulatory Submissions: A Case Study
Lima Chutkan, PhD, RAC, Senior Manager, Medical Writing, Alnylam Pharmaceuticals
Lori Davis, MS, PhD, RAC, Senior Manager, Medical Writing and Program Management, Impact Pharmaceutical Services

Regulatory submissions can be exciting, complex, and overwhelming. Learn more about managing submissions in the context of a case study, from two perspectives: the sponsor writing lead and the clinical research organization (CRO) project manager. Big-bucket items, such...
as writing, reviewing, and resourcing, will be discussed in terms of the needs of both sides. Specific examples of obstacles that occurred during the project and how each side approached the challenge will also be discussed. A successful regulatory submission team is one in which the sponsor and CRO work seamlessly together, and appreciating the other side’s viewpoint is the first step!

Focus Area: Regulatory writing
Target Audience: Writers at all levels of experience

Open-Faced, Triple-Decker, or Plain Old Peanut Butter and Jelly... Stories and Tips from the Sandwich Generation
Amy Zheng, MD, MPhil, Healthcare Educational Consultant and Expert Witness
Patrice Marcarelli, MD, Senior Physician, VA Office of Inspector General
Dannette Johnson, DO, Senior Physician, VA Office of Inspector General
Sonia Melwani, DO, Medical Director of Healthcare Consult, VA Office of Inspector General

Nearly half of middle-aged adults in the United States provide care for parents and young children. Not surprisingly, this sandwich generation reports feeling stressed and overextended. The day-to-day management of caregiving duties on top of juggling a busy work schedule can be daunting, but you can learn from four professionals who will share their perspectives of how they manage to work full time and travel while still being engaged in their children’s activities and fielding the surprise phone calls about a loved one’s medical emergency. Learn evidence-based tips for carving out time in your busy schedule for self-care.

Focus Area: Health and wellness
Target Audience: All writers and editors

Plain Language 2.0 and Health Literacy: New Strategies for Better Outcomes
Romina Marazzato Sparano, Translator & Language Consultant

Health literacy is the degree to which individuals can find, understand, and process health information to make health decisions that respond to their needs. Health literacy is affected by input from providers, access to knowledge of health topics, and adaptability. Given that an estimated eight in 10 adults have limited health literacy, plain language has a vital role in aligning audiences, providers, and situations to produce better health outcomes. Learn strategies that address different aspects of the communication situation: audience, purpose, structure, content, and design, as well as readability formulas, versioning, recasting options, signposting, and information structure.

Focus Area: Scientific publications
Target Audience: Writers and editors at all levels of experience

Predatory Publishing: Update on Current Environment
Barbara C. Good, PhD, Director, Scientific Publications, NSABP Foundation
Mary Kemper, BS, Medical Writer/Yoga Instructor, Mayfield Clinic/Glia Media
Donna Simcoe, MS, MS, MBA, CMPP, Medical Publications Consultant, Simcoe Consultants, Inc

This session highlights the recent history and current status of predatory publishing. Expert panelists will discuss this year’s AMWA-EMWA-ISMPP Joint Position Statement on Predatory Publishing and will address recent developments and trending scams in predatory publishing, highlighting the challenges that medical communicators face. The panelists will explore such questions as What is a predatory journal, and how can you identify it? What dangers do predatory journals and publishers pose for researchers and for the body of medical literature? How can universities and other entities implement policies to help slow down the proliferation of predatory journals? What can we do to dissuade authors from publishing, knowingly or unknowingly, in predatory journals? What can you do if you have published by accident in a predatory journal? Participants will also learn what to look for when encountering a potentially predatory journal or publisher and how to identify tools that can help recognize these threats to the publication of legitimate research. The session is designed to be interactive, so participants are encouraged to share their experiences and questions.
9:00 AM – 12:00 PM
AMWA WORKSHOPS (additional fee)

WS-50  Usage: Choosing the Right Word for the Job
Stephen N. Palmer, PhD, ELS, Manager and Senior Scientific Medical Writer, Texas Heart Institute

Medical writing calls for accuracy, clarity, and precision, making word usage a crucial factor in effective documents. This workshop focuses on selecting the precise word to convey the vital and complex information in medical writing. Topics include what is considered correct usage in the academic medical literature (mainly according to AMA style) and how to choose words for maximum precision and conciseness. In-workshop activities: participants will engage in group exercises pertaining to usage. Knowledge of basic grammar and usage principles is helpful.

Target Audience: Writers and editors with some experience

WS-51  The Medical Editing Clinic: Strategies to Hone Your Editing Skills
Marianne Mallia, ELS, MWC, Editor, Scientific Publications, Mayo Clinic Scottsdale
June Oshiro, PhD, ELS, Editor, Scientific Publications, Mayo Clinic

This workshop addresses substantive editing and is designed to expand the skills of medical editors whose work involves improving the content, style, and structure of manuscripts. Topics include common mistakes in writing, the effect of word choice on clarity, and how changing paragraph and sentence structure can instantly improve readability. Numerous editing and writing examples are discussed, as well as strategies to improve the editing of medical documents. The knowledge and skills gained in the workshop should make an immediate difference in participants’ ability to prepare a medical document that is clearer and more concise. In-workshop activities: participants will engage in small-group work on editing exercises.

Target Audience: Developmental editors and writers who also edit their own work

WS-52  Summarizing Clinical Efficacy Data for a New Drug Application
Marijke H. Adams, PharmD, PhD, President, MH Adams & Associates, Inc.

For regulatory writers, it is crucial 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). This workshop provides an overview of the applicable Code of Federal Regulations sections, US Food and Drug Administration guidances, and International Council for Harmonisation (ICH) guidelines associated with the Summary of Clinical Efficacy (SCE) and Integrated Summary of Efficacy (ISE). The similarities and differences between the SCE and the ISE are described, as well as the source documents needed to write these regulatory documents. In-workshop activities: participants will engage in exercises and discussion relevant to writing clinical efficacy documents.

Target Audience: Regulatory writers with moderate experience

WS-53 Introduction to Statistics for Medical Communicators
Bart Harvey, MD, PhD, Associate Professor, Dalla Lana School of Public Health, University of Toronto

Medical communicators with a good understanding of statistics are comfortable, confident, and competent in interpreting and reporting statistical methods and results—the story behind the data. Elementary statistical concepts needed to understand medical and scientific articles are addressed, including types of variables, levels of measurement, summary statistics, estimation and confidence intervals, and Student’s t test. Emphasis is on understanding statistical presentations and on reporting statistical information, not on calculations or mathematical explanations. In-workshop activities: throughout the workshop, participants will identify and discuss the statistical aspects applicable to an example biomedical study. Note: This workshop has been renamed from Statistics for Medical Writers and Editors.

Target Audience: Writers and editors with little or no background in statistics
WS-54 Principles and Practice of Visual Data Presentation
Janet Novak, PhD, ELS, Senior Editor/Grant Writer, Memorial Sloan Kettering Cancer Center

Visual representation of data conveys specific information more efficiently than text, but choosing the best type of table or graph is not always easy. This workshop addresses the roles that tables, graphs, and charts play in the reduction, summarization, understanding, communication, and analysis of data. In-workshop activities: participants will discuss solutions to graphic problems submitted by other participants. Note: previous participation in the Tables and Graphs and Statistics for Medical Writers and Editors workshops is recommended. This workshop has been renamed from Advanced Data Presentation: Tables, Graphs, and Charts.

Target Audience: Writers and editors with moderate experience with graphical displays of data

10:45 – 11:45 AM
EDUCATION SESSIONS

The Art of Personal Branding: How to Tell the YOU Story and Gain New Customers
Elizabeth Fraley, CEO, Single-Sourcing Solutions

Maybe you’re thinking it’s time to branch out on your own, move up in your company, or try something different. No matter the scenario, you (or your company) must be THE solution that fills a NEED for the boss/client. Clarifying your vision and defining your brand will attract customers. Today’s job market requires more than a technical resume or CV; it requires a story, a plan, and a brand. This session is for anyone who is working for a promotion, expanding a business, or trying a new venture. Learn how to identify who your ideal customer is (and is not), and how to gain customers by telling your story well and often. Bring questions and get the answers you seek!

Focus Area: Career development

Target Audience: Writers and editors at all levels of experience

Reporting Drug Metabolism in the Age of Precision Medicine
Teresa McNally, Medical Writer and Consultant, Whitsell Innovations, Inc.

Precision medicine refers to therapies that are targeted to individual patients or groups of patients rather than the entire population. This approach is expected to improve the efficacy and safety of drugs and devices in clinical practice and has already led to changes in clinical trials and drug labeling. An overview of current and future developments will be presented and the impact of these changes on regulatory documentation will be discussed. Learn about the science of individualized drug metabolism and the impact of genetic changes to metabolism enzymes through a series of real-world examples.

Focus Area: Science and medicine

Target Audience: All writers and editors

12:00 – 1:30 PM
ROUNDTABLE DISCUSSIONS WITH LUNCH (additional fee) – Titles with an asterisk (*) are also offered as a Breakfast Roundtable Discussion on Friday.

All Aboard the MentorShip: Effective Mentoring in Medical Writing: Mentee Perspective
Cody Nichols, PhD, Senior Medical Writer and Consultant, Whitsell Innovations, Inc.
Basics of Writing Accredited and Nonaccredited Continuing Medical Education (CME)
Katherine Molnar-Kimber, PhD, President, KMK Consulting Services of Kimnar Group LLC

Breathing New Life into Work/Life Balance
Stephen Carlson, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc.

Building Successful Sponsor and Vendor Relationships
Michelle Lee, Manager, Gilead Sciences

Cross-Cultural Communication Skills as a Key Element for Success
Jennifer Clemens, ELS, Medical Writing Clinical Technical Editor, Global Trial Operations, Merck & Co., Inc.

*CTD Structure: From IND to NDA
Susan Vintilla-Friedman, Senior Director, Development, Samorn Biosciences

*From Benchtop to Laptop: Streamlining the Transition to Full-Time Regulatory Writing
William Buchta, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc.

*How Did I End up Working Here?
Kathi Whitman, MA, Project Consultant, SelectHealth

Instructional Design: Are You Considering Learner Usability in Your End Products?
Deborah Anderson, PhD, MS, MT(ASCP)SH, Medical Writer/Instructional Designer, DGA Medical Communications

Managing Clinical Study Report Development
Jayashree Mitra, PhD, Principal Medical Writer, Merck & Co., Inc.

New Research Shows Freelance Rates Are Lower for Women. Why, and What Can We Do About It?
Laura J. Ninger, ELS, President, Ninger Medical Communications, LLC

SAD or MAD but not Alone: Medical Writing for Small Biopharma Companies
Alex Rohall, Senior Manager, Medical Writing, PROMETRIKA, LLC

Scheduling Dos and Don’ts for Freelances
Debby Berylne, Freelance Writer/Editor

So, You Want to Be a CAM Writer
Priyanka B. Ingle, Translational Clinical Pharmacologist, CRC Pharma, LLC

So, You’re Going to Take the BELS Exam
Leslie Neistadt, ELS, Managing Editor, St Louis University

Strategic Publication Planning
Michael G. Baker, PhD, President & Principal, Samorn Biosciences

Strategies to Structure and Lead Teams through Learning Processes

Catalina Gonzalez Rueda, MSc, MBA, Associate Director, Medical Writing, MSD

*Taking EU Medical Device Teams into the Year 2020
Julie Hurt, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc.

A Tale of Two Contemplations: Impostor Syndrome and Medical Writing Dreams
Anand Devasthanam, PhD, Medical Writer II, PAREXEL International Corporation

*Tips for Studying for the MWC Exam
Valerie Sjoberg, MAc, MWC, Medical Writer and Content Manager, DaVita, Inc.; Owner, BioWrite LLC

Working Remotely – I Mean Really Remotely: Tales from Nomadic Living in an RV
Rasa G. Hamilton, ELS, MWC, Medical and Science Editor, HELPS: Hamilton Editing and Language Publishing Services

Writing a Business Plan
Mark D. Weiss, President, Apothaceutics International, Inc.

*Writing while Female: A Discussion of Gender Disparity/Bias in the Medical Writing Industry
Christine Flees, MD, Senior Medical Writer, Syneos Health

1:45 – 2:15 PM
ANNUAL BUSINESS MEETING
(all members welcome)

2:00 – 5:00 PM
AMWA WORKSHOPS (additional fee)

WS-60 Composing Narratives for Safety and Adverse Event Reporting
Jennifer Bridgers, MS, MWC, Managing Medical Writer, Merck & Co., Inc.

Well-written narratives are cohesive, concise, and clear. This workshop is designed to enhance the skills needed to compose high-quality narratives. Key elements in safety reporting, correct use of medical language, and organization of data for a well-written narrative are addressed. In addition, best practices and realistic constraints are discussed. In-workshop activities: participants will engage in exercises to build their skills in composing narratives.

Target Audience: Regulatory writers with moderate experience
Saturday, 2:00 – 5:00 PM continued

**WS-61 Clinical Study Report Writing: From Tables, Listings, and Graphs to Text**
*Kathy Spiegel, PhD, Regulatory Writing Senior Manager, Amgen, Inc.*

With a focus on practical guidelines and examples, this workshop provides an overview of the best approach to summarize information from statistical tables, listings, and graphs (TLGs) for a clinical study report (CSR). The emphasis is on presenting data in a clear and concise manner. Examples include selected passages from the demographics, efficacy, and safety sections of a CSR, along with the related TLGs, to clearly demonstrate the link between text and TLGs. In-workshop activities: participants will write and revise relevant sections of a CSR. 
*Note: previous participation in the Writing the Final Report of a Clinical Trial workshop is helpful.*

Target Audience: Writers with some experience developing clinical study reports or clinical study report shells

**WS-62 Effective Paragraphing**
*Helen Hodgson, PhD, Emeritus Professor of Communication, Westminster College*

Effective construction of paragraphs is fundamental to successful writing. This workshop provides an overview of basic paragraphing techniques for achieving clarity, readability, and desired emphasis. Topics include development of a systematic approach to improve writing by clearly analyzing text and pinpointing key findings, options for arranging paragraphs, and use of transitions. In-workshop activities: participants will engage in exercises to organize text and paragraphs effectively.

Target Audience: All writers and editors

**WS-63 Understanding Sample Size and Study Power**
*Bart Harvey, MD, PhD, Associate Professor, Dalla Lana School of Public Health, University of Toronto*

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. The workshop provides an overview of sample size and study power, as well as a discussion of the role that precision and confidence intervals play in the interpretation and reporting of a study’s power. These concepts are addressed from the vantage points of planning studies and of interpreting and assessing the results of completed studies, with an emphasis on how to effectively communicate the related concepts to lay and professional audiences. In-workshop activities: throughout the workshop, participants will identify and discuss issues applicable to sample size and study power for an example biomedical study. 
*Note: previous participation in the Statistics for Medical Writers workshop is recommended.*

Target Audience: Writers and editors with familiarity of basic biostatistics and research methods

**WS-64 Effectively Searching Online Databases**
*Thomas P. Gegeny, MS, Team Lead & Senior Medical Writer, Envision Pharma Group*

Medical communicators in all settings need to know how to search for information efficiently and effectively. This workshop focuses on the use of online databases, with a demonstration of the effective use of PubMed and several databases from the National Library of Medicine and other sources. Topics include use of advanced functions and features of databases rather than simply entering terms, as typically done on most search engines. For example, PubMed’s MeSH database, search builder, topic-specific queries are demonstrated, as well as the LinkOut connections to other databases or full-text resources when available. Creating and using personalized settings and search filters for these resources are also covered. In-workshop activities: participants will engage in discussion and application of online search strategies.

Target Audience: All writers and editors
Saturday, continued

2:00 – 3:30 PM
EDUCATION SESSIONS

Jam Session for Early-Career Freelances
Andrea R. Gwosdow, PhD, President, Gwosdow Associates Science Consultants, LLC
Theresa E. Singleton, PhD, Owner and Principal Scientific Writer, Singleton Science, LLC

This session is an opportunity for new freelances to discuss their successes and toughest problems regarding the business of freelancing. Potential discussion topics are the advantages and disadvantages of various business structures, how to find and keep clients, working with contracts, collecting payments, estimating projects accurately, and whether to bring on subcontractors. Make new connections to continue the conversations once you’re back home.

Focus Area: Freelancing
Target Audience: Writers and editors with less than 10 years of freelance experience

Jam Session for Seasoned Freelances
Brian Bass, MWC, President, 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 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. 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.

Focus Area: Freelancing
Target Audience: Writers and editors with at least 10 years of freelance experience

2:30 – 4:00 PM
CHAPTER LEADER ORIENTATION
(by invitation)
Basic Writing Errors in Medical Journals  
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Implementing an Operations Manual to Improve Medical Writing Consistency and Efficiency  
Henry Li, PhD; Emerald Feng; Amanda Krzywinski, PSM; and Alex Marcheschi, PharmD; Grifols Therapeutics LLC

Increasing Efficiency and Scientific Integrity with Master Trial Charter Documents  
Kassel Fotinos-Hoyer, MA; Janina Wolf, PhD; Nicholas Enus; Sayali Karve; and Andrea Linke

The Informed Consent Document: New Federally Required Elements  
Linda Rowse, Whitsell Innovations

Mastermind Group Case Study for Mid-Career, Freelancers: Insights and Takeaways  
Mia DeFino, MS, ELS, DeFino Consulting, LLC; Kristin Harper, PhD, MPH, ELS, Harper Health and Science Communications, LLC; Karoun Bagamian, PhD, Bagamian Scientific Consulting, LLC; Donna Simcoe, Simcoe Consultants; Dana Barberio, MS, Edge Bioscience Communications; and Jessica Yen, MS, JHY Communications

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Similarities and Differences Between Nonclinical and Medical Writing  
Rachelle Baker, ELS, and Lisa Poppenberg, MPH, ELS; Takeda Pharmaceuticals, Inc.

A Survey on Including Risks in the New "Key Information" Section of an Informed Consent Form: Where Do We Go from Here?  
Katelyn Le, MS; Stacy Kopka, MS; Doreen Chaitt, RN, MPH; Jerome Pierson, RPh, PhD; Martha Nason, PhD; and Tracey Miller, RN, CCRP  
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