2023 AMWA

Medical Writing & Communication Conference

OCTOBER 25-28, 2023

BALTIMORE, MD

Trends and Opportunities for Medical Communicators

CONFERENCE PROGRAM



AMWA 2023

Your home for continuous learning and connection.

Welcome from the President



Welcome to the 2023 AMWA Medical Writing & Communication Conference

LEARN ● CONNECT ● EXPLORE

Welcome to Baltimore and AWMA's 83rd annual conference! We are on Baltimore's beautiful waterfront, and the Annual Conference Program Committee has prepared a wealth of programming.

Please see the conference app for all the educational and networking opportunities at the conference.

Here are some highlights:

- The general sessions on Thursday and Saturday: Our McGovern Award recipients, Dr. Jessica Steier and Dr. Andrea Love, and our Alvarez Award recipient, Dr. Katelyn Jetelina, will present their award talks. Our 2023 Fellows, Golden Apple recipient, Swanberg Award recipient, and President's Award recipient will also be acknowledged at the general sessions.
- Education sessions on a variety of topics, including soft skills and wellness. I have my eye on The Value of Medical Writing: A Toolkit for Defining, Achieving, and Communicating Success; Pursuing Excellence in Medical Writing for Continuing Education in the Health Professions: A Competency Model; and Medical Writing and Editing Internships: Preparing the Next Generation of Medical Communication Professionals.
- Jam Sessions, roundtables, MedWrite talks, and—new!—Learning Circles.
- Product showcases of artificial intelligence tools.
- Networking opportunities: New to AMWA and Conference Session, Meet and Greet, chapter dinners and Dine Arounds, speed networking, and Thursday morning's walk around the inner harbor.

Don't forget to check out sites around Baltimore, including the National Aquarium, the USS Constellation, Fort McHenry, and Fell's Point. Note that the National Aquarium, which is next door to the conference venue, has half-price tickets on Friday evenings. Tickets can be purchased through the National Aquarium.

Thank you for joining us, and I hope you enjoy Baltimore and the conference.

—Elise Eller, PhD / 2022-2023 AMWA President

Award Recipients

2023 AMWA Award Recipients



McGovern Award
Dr. Andrea Love &
Dr. Jessica Steier
Thursday, 12:30 - 1:45 PM



Alvarez Award
Dr. Katelyn Jetelina
Saturday, 12:15 - 1:30 PM



Swanberg Award
Joan Affleck
Saturday, 12:15 - 1:30 PM

Meet the Recipients of Our AMWA Member Awards



President's Award
Don Harting, MA, MS
President
Harting Communications, LLC



Golden Apple
Hope Lafferty, MA, MS
Coach, Writer, Speaker, Performer
Hope Lafferty Communications & Coaching



Fellow
Barbara O. Lightfoot, BS
Manager, Sci Com Regulatory
Eli Lilly and Company



Fellow
Anita Misra-Press, PhD
Independent Medical Writer
Freelance



Fellow
Shawn Watson,
PharmD, PhD, BCPS
Senior Director, Clinical Development
Program Lead
Bicycle Therapeutics

Schedule at a Glance

All times shown are EDT.

Pre-Conference Day: Wednesday, October 26

8:00 AM - 5:30 PM	Registration Desk Open
9:00 AM - 12:00 PM	AMWA Workshops *(additional fee)*
11:00 AM - 5:45 PM	Executive Forum *(by invitation only)*
2:00 - 5:00 PM	AMWA Workshops *(additional fee)*
2:00 - 5:00 PM	Exhibitor Setup
2:30 - 3:30 PM	New to AMWA and Conference Session
4:00 - 5:00 PM	Speed Networking
5:00 - 7:00 PM	Meet and Greet at Lobby Lounge *(cash bar)*

Conference Day 1: Thursday, October 26

7:15 - 8:00 AM	Walk Around the Inner Harbor *(optional)*
8:00 AM - 5:00 PM	Registration Desk Open
8:00 - 9:30 AM	Poster Setup
8:30 - 9:30 AM	Continental Breakfast with the Exhibitors
9:30 - 11:00 AM	Education Sessions
11:15 AM - 12:15 PM	Education Sessions
12:30 - 1:45 PM	Opening General Session with Award Address and Lunch
2:00 - 3:00 PM	Education Sessions and Product Showcase
2:00 - 5:00 PM	AMWA Workshops *(additional fee)*
3:00 - 4:00 PM	Beverage Break with Exhibitors and Product Showcase
4:00 - 5:00 PM	Education Sessions and Product Showcase
4:00 - 5:00 PM	Speed Networking
5:30 - 5:45 PM	Meet in Hotel Lobby for Chapter and Regional Networking Dinners

Conference Day 2: Friday, October 27

7:30 AM - 4:00 PM	Registration Desk Open
7:30 - 8:45 AM	AMWA Workshops *(additional fee)*
8:00 - 9:00 AM	Exhibit Hall Open with Coffee and Tea
9:00 AM - 12:00 PM	AMWA Workshops *(additional fee)*
9:00 - 10:30 AM	Education Sessions
10:30 -11:00 AM	Beverage Break with the Exhibitors and Product Showcase
11:00 AM - 12:00 PM	Education Session and Product Showcase
12:00 - 1:30 PM	Networking Lunch, Exhibit Hall Open, and Product Showcase
1:30 - 2:30 PM	Education Sessions and Product Showcase
2:30 - 3:00 PM	Beverage Break with the Exhibitors
3:00 - 4:30 PM	Jam Sessions and MedWrite Talks
3:00 - 5:00 PM	Exhibitor Takedown
5:00 PM	Meet in the Lobby for Optional Dine Arounds and National Aquarium Visit*

**tickets must be purchased through National Aquarium; 1/2 priced tickets on Friday*

Conference Day 3: Saturday, October 28

7:30 AM - 2:00 PM	Registration Desk Open
8:00 - 9:15 AM	Continental Breakfast with Poster Presenters
8:00 - 9:15 AM	Chapter Leaders Networking Event with Continental Breakfast *(invitation only)*
8:15 - 9:15 AM	Learning Circles
9:00 AM - 12:00 PM	AMWA Workshops *(additional fee)*
9:30 - 10:30 AM	Education Sessions
10:30 - 11:00 AM	Beverage Break with the Poster Presenters
11:00 AM - 12:00 PM	Education Sessions
12:15 -1:30 PM	Closing General Session with Lunch, Award Address & Annual Business Meeting

Sponsors

Thank you to our 2023 sponsors!

AMWA thanks the following sponsors for their support of the 2023 AMWA Medical Writing & Communication Conference.

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AMWA 2023



Conference Information

POLICIES

CONSENT TO USE OF PHOTOGRAPHIC IMAGES

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

HEALTH & SAFETY

While there are currently no Health & Safety protocols in place, in the event protocols are needed, all attendees will be asked to participate in and abide by all safety protocols implemented on-site for the event. We will continue to closely monitor all conditions related to COVID-19 between now and the start of the event and reserve the right to modify health screening protocols in our sole discretion. We will inform you of any such changes and as a condition of participation you agree you will follow these protocols.

You also should not attend the meeting if:

- You believe that you may have been exposed to a confirmed or suspected case of COVID-19 or
- Have been diagnosed with COVID-19 and are not yet cleared as non-contagious by state or local public health authorities or the health care team responsible for your treatment.

GUESTS

Non-registered individuals, including spouses, friends, or children under the age of 18, are not permitted in AMWA meeting rooms, receptions, or the Exhibit Hall. No one under 21 years of age is permitted at events where alcohol is served.

NAME BADGES

All conference attendees must be registered to attend the conference. All registered attendees will receive a name badge, which must be worn at all times during the conference and within the conference space. Name badges are nontransferable. If a name badge is lost or misplaced, a replacement can be made for $25. Identification will be required. Conference registrations for designated representatives include access to all open sessions and group events. (Workshops and ticketed events incur additional fees).

REFUNDS & CANCELLATIONS

Refund requests must be received in writing no less than 21 days prior to the first day of the conference to be eligible for a partial refund. No refunds will be distributed for cancellations made less than 21 days prior to the first day of the conference. No refunds or credit will be given for failure to attend, late arrival, no shows, or early departure. Conference registrations are non-transferable. Applies to conference, workshop and roundtable registrations.

SEATING

AMWA encourages attendees to arrive early at education sessions, as seating is on a first-come, first-serve basis. If no seating is available in your first-choice session, consider attending another session in the same time period.

SUBSTITUTIONS

AMWA does not allow substitutions for conference registrations. Registration fees cannot be transferred to another person.

AMWA 2023



Conference Information

TRAVEL

HOTEL
Baltimore Marriott Waterfront Hotel
700 Aliceanna St., Balitmore, MD 21202

PARKING
The hotel does not own or operate a self-parking garage and is not able to validate. Valet parking is $46/night. Other parking options can be found here.

CHECK IN/OUT
Check in: 4:00 PM
Check out: 12:00 PM

LUGGAGE
If you need luggage storage upon your arrival or ahead of your departure, please use the hotel's bell stand

CONTACT US

conference@amwa.org

30 West Gude Drive, Suite 525,
Rockville, MD 20850

https://www.amwa.org/page/Conference

AMWA BOOTH
The AMWA Booth will be located in the foyer of the Convention Registration A/B on the hotel's third floor. The booth will have information on AMWA membership, programs, and how to volunteer.

APP
The app provides the conference schedule, sessions, presenters, slides and handouts, exhibitor and sponsor information, and ways to connect with other attendees. ***There will be no print program provided onsite.***

MWC RECERTIFICATION POINTS
Most AMWA education sessions, roundtables, and workshops are eligible for points toward Medical Writer Certified (MWC) recertification. Fifty recertification points are needed to recertify at 5 years after the MWC credential was granted. Keep track of your professional development on the recertification spreadsheet, available at https://www.amwa.org/page/MWC_Recertify.

QUIET ROOM
A quiet room will be located in **Bristol** on the hotel's third floor and will be open

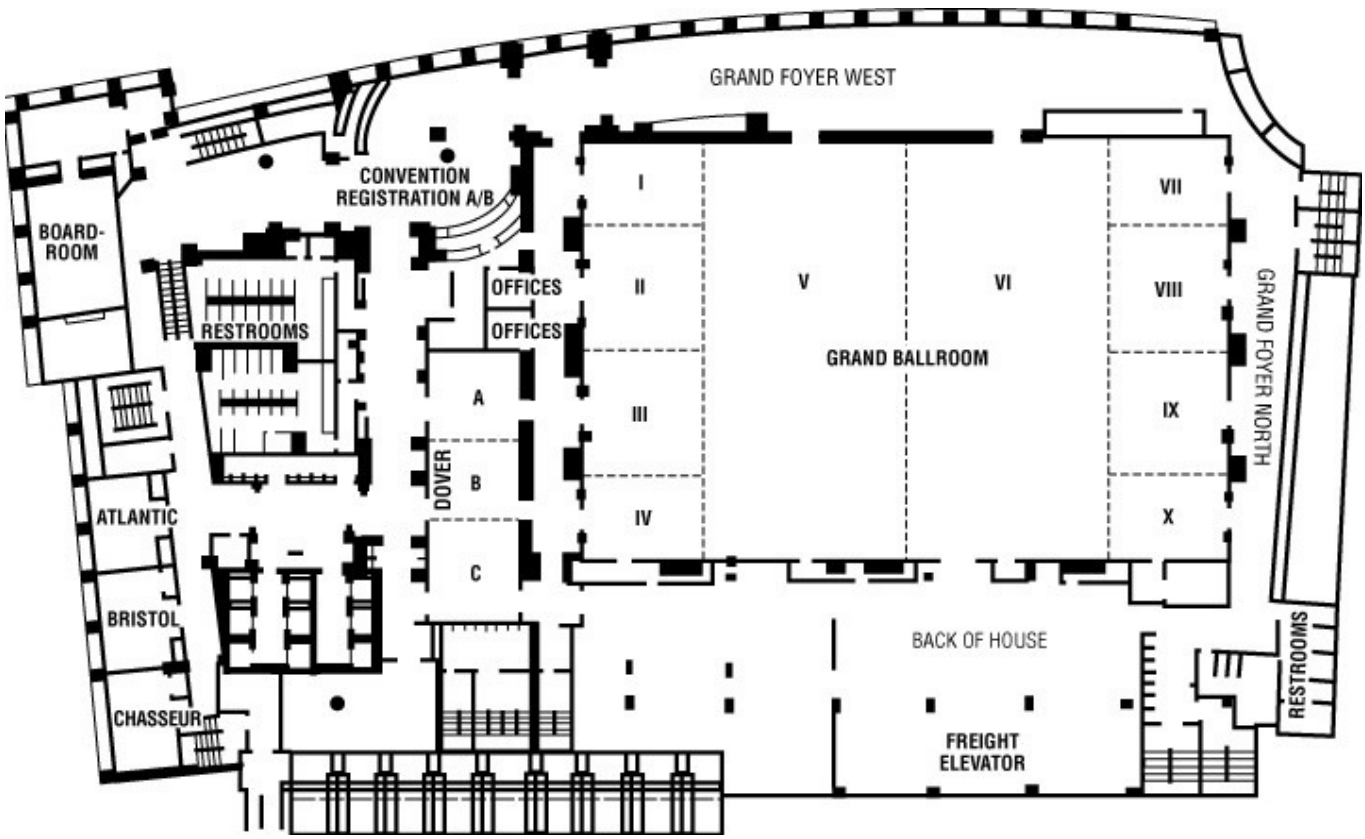
- Thursday 8:00 AM - 5:00 PM
- Friday 7:30 AM - 4:00 PM
- Saturday 7:30 AM - 2:00 PM

Please respect other attendees and refrain from taking personal meetings or phone calls.

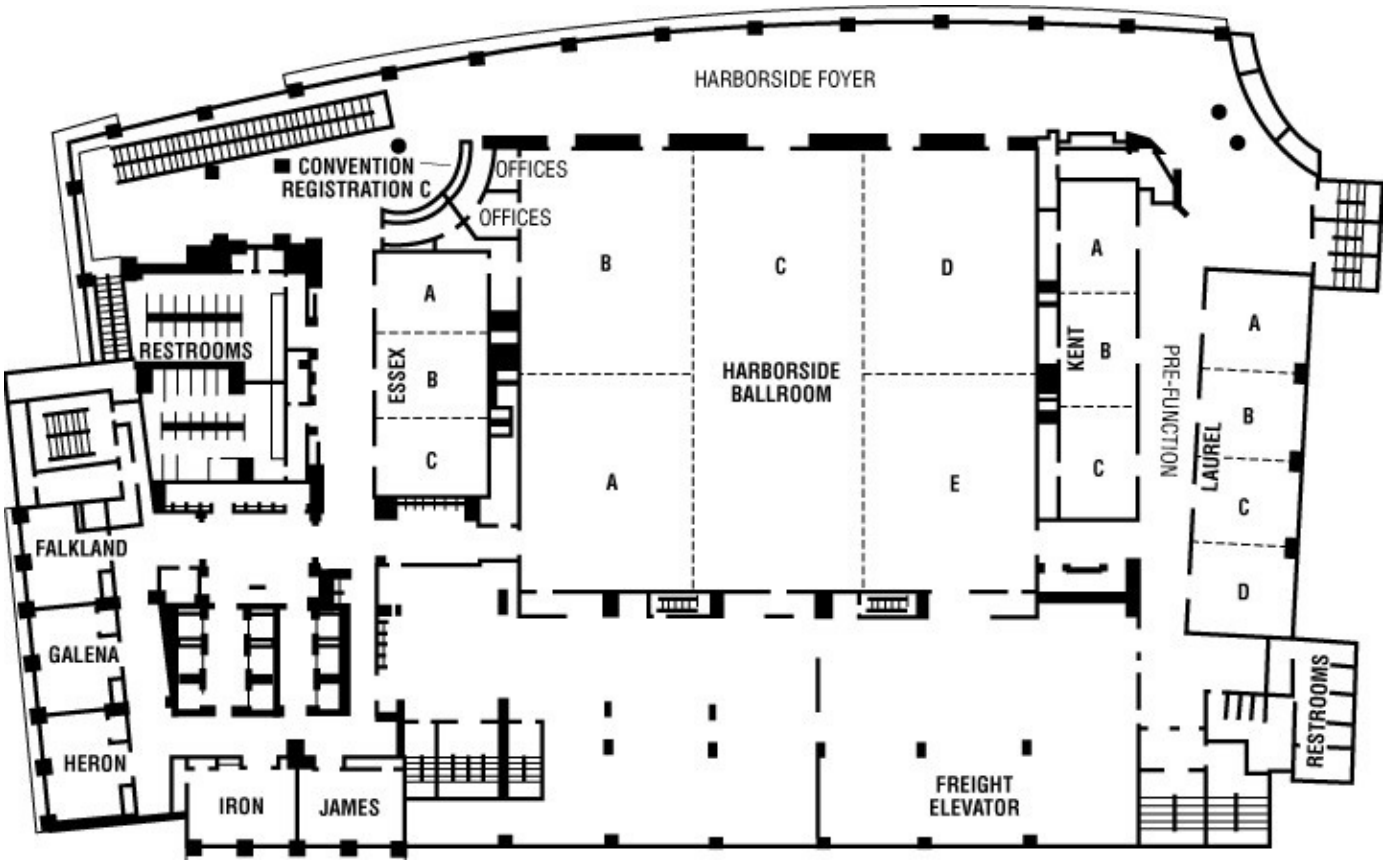
WIFI
AMWA attendees have complimentary WiFi service throughout the conference space. To connect, join the MarriottBonvoy_Conference network and enter the password Synterex.

Maps

3rd Floor - Grand Ballroom



4th Floor - Harborside



AMWA Leadership & Staff

Annual Conference Committee

Chair: Michele Sequeira, MS, MBA, MWC
UNM Comprehensive Cancer Center

Dana Blue, M.Sc.
Facet Life Sciences

J. Kelly Byram, MS, MBA
Duke City Consulting, LLC

Katrina Burton, BS
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Heather Gorby, PhD
Gorby Consulting LLC

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Mary Alice Keller, PhD
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Aurore Lebrun, PhD
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The Society for Maternal-Fetal Medicine

Mary Ellen Shepard, PhD
Shepard Medical Communications, Inc.

Eva Stabenow, MA
Wordplay Translations

Jennifer Strickler
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Emily Viles-Monari, CAE
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Exhibitors

Thank you to our 2023 exhibitors!

ACUMEN MEDICAL COMMUNICATIONS Bringing Data to Life	AROGA BIOSCIENCES	BioForum THE DATA MASTERS
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AMWA 2023

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Medical Writing & Communication Conference

OCTOBER 25-28, 2023
BALTIMORE, MD

Trends and Opportunities for Medical Communicators

Pre-Conference Day: Wednesday, October 25

8:00 AM to 5:30 PM | Registration Desk Open.....Registration A/B

9:00 AM to 12:00 PM | Workshops *(pre-registration & additional fee)*

WS #01: Introduction to Statistics for Medical Communicators.....Dover A
Bart Harvey, MD, PhD, MEd, Adjunct Professor, School of Public Health, University of Toronto, Ontario, Canada

WS #02: Writing a Protocol in Compliance with ICH Guidelines.....Grand Ballroom II
Jennifer Bridgers, MS, MWC, Director, Medical Writing, Merck & Co., Inc., Raleigh, NC

WS #03: Clinical Study Report Writing: From Tables, Listings, and Graphs to Text.....Grand Ballroom I
Kathy Spiegel, PhD, Writer, Editor, Instructor, Freelance, Grass Lake, MI

WS #04: Principles and Practice of Visual Data Presentation.....Dover B
Janet Novak, PhD, ELS(D), Scientific Research Manager, Memorial Sloan Kettering Cancer Center, New York, NY

WS #05: Public Speaking for Private People: The Intensive.....Dover C
Hope Lafferty, AM, Instructor, University of California San Diego, San Diego, CA

11:00 AM to 5:00 PM | Executive Forum with Lunch *(by invitation only)*
Sponsored by Certara.....Harborside A

2:00 PM to 5:00 PM | Workshops *(pre-registration & additional fee)*

WS #06: Health Economics for Medical Writers and Editors.....Dover A
Bart Harvey, MD, PhD, MEd, Adjunct Professor, School of Public Health, University of Toronto, Ontario, Canada

WS #07: Medical Editing Clinic.....Grand Ballroom I
Marianne Mallia, ELS, MWC, Senior Scientific/Medical Editor, Mayo Clinic, Paradise Valley, AZ
Stephen Palmer, PhD, Manager and Senior Scientific Medical Writer, Texas Heart Institute, Houston, TX

WS #10: Visual Communication.....**Dover C**
Cyndy Kryder, MS, MWC, Medical Communicator, Freelance, Phoenixville, PA

WS #11: Project Management.....**Grand Ballroom III**
Elizabeth Brown, MS, Director, Merck & Co., Inc., North Wales, PA

2:00 PM to 5:00 PM | Exhibitor Setup.....Grand Ballroom Foyer

2:30 PM to 3:30 PM | New to AMWA and Conference Session.....Harborside B

Join us to learn how to get the most out of your conference experience, including must-do events, educational opportunities, and networking tips. Also discover how AMWA education, resources, and membership benefits can enhance your professional skills and expand your professional network.

3:30 PM to 5:00 PM | Intensive *(pre-registration & additional fee)*

INT #01: How to Think Like a Leader.....**Grand Ballroom III**
Hope Lafferty, AM, Instructor, University of California San Diego, San Diego, CA

4:00 PM to 5:00 PM | Speed Networking.....Harborside C

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

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

5:00 PM to 7:00 PM | Meet & Greet.....Lobby Lounge

Conference Day 1: Thursday, October 26

7:15 AM to 8:00 AM | Walk Around the Inner Harbor *(optional)*

Joanne McAndrews, PhD, Freelance Medical Writer, St. Louis, MO

Jennifer Nepo, Principal, Medparency LLC, Armonk, NY

Start your day by meeting new friends and getting some exercise! Get to know other conference attendees on a sunrise networking walk around Baltimore's beautiful Inner Harbor area, adjacent to the conference hotel. We will meet promptly at 7:15 AM in the Baltimore Marriott Waterfront Hotel lobby on Thursday, October 26th, returning to the hotel at 8:00 AM. Sunrise will occur around 7:30 AM that morning, and the trail is well lit.

8:00 AM to 5:30 PM | Registration Desk Open.....Registration A/B

8:00 AM to 9:30 AM | Poster Setup.....Harborside Foyer

8:30 AM to 9:30 AM | Continental Breakfast (Sponsored by Regeneron Pharmaceuticals, Inc.) with Exhibitors.....Grand Ballroom

9:30 AM to 11:00 AM | Education Sessions

Educating the Next Generation of Medical Communicators: Strategies for Development of a University Level Course.....Harborside B

Elizabeth Kukielka, PharmD, MWC, Senior Medical Writer, Oxford PharmaGenesis, Newtown, PA

New medical communicators often share frustrations about gaining the experience needed to transition into the field, which is unsurprising given the lack of university courses and the training to teach them. In this session, a medical writing teacher will share her experience developing a graduate level introductory medical communications course for pharmacy students. Attendees will leave knowing how to approach other stakeholders to propose such courses and how to most effectively teach writers the conventions of medical communications.

Focus Area: Core Knowledge/Skills

Hidden Inclusion: Basics of Web Accessibility.....Harborside D

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

Expanding diversity, equity, and inclusion isn't always an obvious process. Assistive technology users are often left out of virtual discussions because research reports and other products aren't compatible with their tools. Yet society needs their expertise, and their taxes support work they can't always access. Federal law requires that any material posted on a website that is wholly or partially government supported must be accessible to everyone (or "comply with Section 508"). Got an NIH grant? Work for a public university? Your work products should be accessible. Why wouldn't you want the broadest audience possible to appreciate your hard work? You can create stunning, effective materials and include everyone in the conversation. Join me to think through what's involved, plan ahead, and ensure success.

Focus Area: Core Knowledge/Skills

How Do Medical Writers Impact the Recruitment and Participation of Underrepresented Populations in Clinical Trials?.....Harborside A

Shirley Dorval, MS, Principal Medical Writer, Merck & Co., Inc., Myrtle Beach, SC

Karla Haack, PhD, Medical Writer, Merck & Co., Inc., Canton, GA

Recent legislation has underscored the need for increasing diversity in clinical trials as a way to address systemic inequities in healthcare. Medical writers are uniquely positioned to contribute to this goal through the adoption of inclusive language as part of authoring key regulatory documents like protocols and informed consent forms. Protocol authoring should include inclusive language reflective of the diverse participant populations in clinical trials. Similarly, informed consent forms should be authored in plain language that is understandable to potential participants with different levels of health literacy and backgrounds. This interactive educational session will review the tenets of adopting inclusive and health-literate language in these two document types and allow participants to take part in mock authoring sessions that apply these principles.

Focus Area: Regulatory

Navigating the Evolving Transparency and Disclosure Landscape in 2023 and Beyond.....Harborside E

Moderator: Dan Bilodeau, Plain Language Summaries CTT Manager, ICON, plc, Wilmington, DE
Lisa Chamberlain James, Senior Partner, Trilogy Writing & Consulting Ltd., Cambridge, England
Simin Takidar, Senior Principal MW, SME for Transparency and Disclosure, Parexel International, Jersey City, NJ
Thomas Wicks, Head of Transparency, TrialScope, a Citeline company, New York, NY

As the global focus on transparency and disclosure widens under the lens of EMA policy 0070, Health Canada PRCI, and EU CTR requirements, Sponsors must now publish clinical documents and plain language summaries of protocols and trial results for trials conducted in the EU and Canada. Our speaker panel would like to share their experiences with these regulations, and discuss: 1) strategies to meet the deadlines for lay summary finalization and RFIs, 2) challenges in writing lay summaries, lay synopses, and redacting documents from a medical writing standpoint, 3) whether the summaries produced to date are really fit for purpose, 4) the medical writer's role in the redaction and anonymization of clinical trial documents and reports, and 5) upstream preparedness for clinical document publication.

Focus Area: Regulatory

The Art and Science of Eliminating Burnout.....Grand Ballroom III

Stephen Carlson, PhD, Senior Medical Writer and Consultant, Whitsell Innovations, Inc., Durham, NC

Stress and burnout are common factors of the modern work environment, particularly in medical writing. Decades of research have broadened our understanding of the causes of burnout and mechanisms for managing stress; however, actually implementing this science into our daily lives can prove challenging. Much of the common wisdom may be impractical or irrelevant to one's specific situation. The goal of this session is for attendees to understand the objective factors that underlie every cycle of burnout (the science) and to walk away with practical tips that writers of all experience levels and work environments can implement to their specific situation, including strategies at both the personal and institutional level (the art).

Focus Area: Wellness

Take the Leap! Steps to Integrate AI into Your Work.....Essex

Jenni Pickett, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc., Apex, NC

The capability and adoption of Artificial Intelligence (AI) is rapidly increasing and is now sitting on the threshold of the medical writing field. So, what do you think when you hear the words Artificial Intelligence? Do you think of machines taking over your job (or the world)? Do you get nervous? Do you want to run and hide? This session for AI beginners will help you understand what generative AI brings to the role of medical writing, prepare yourself both emotionally and technically for AI, anticipate how AI will change the way we work, recognize caveats and cautions of working with AI, and stay informed of how AI is changing the face of medical writing.

Focus Area: Core Knowledge/Skills

11:15 AM to 12:15 PM | Education Sessions

Communicating About & With Artificial Intelligence Applications.....Harborside A

J. Kelly Byram, MS, MBA, ELS, CEO | Medical & Scientific Communications Lead, Duke City Consulting, LLC,

Albuquerque, NM

Artificial intelligence (AI) technology applications have mushroomed in biomedical research, health care, and medical communications, but questions about the reliability and security of AI have proliferated just as quickly. Whether tasked with writing or editing an AI-based project or using AI to develop content, understanding how AI tools are developed, applied, and maintained can be critical to the practice of a medical communications professional. With the goal of providing attendees with the understanding of AI and a framework for critically assessing AI algorithms and their secure, ethical application, we will discuss the fundamentals of AI, the roles of AI in the translational science context, AI applications for content development, and emerging best practices and professional ethics governing AI development and use.

Focus Area: Core Knowledge/Skills

Communication Culture Club (Navigating Corporate Perceptions Imbedded in Language).....Harborside B

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

Often, the "language" of a company telegraphs the values and culture. It informs the employees how to interact with their coworkers, reports, and supervisors. For example, in a "PIE" workplace, performance, image, and exposure drive how an employee is viewed and valued. Demonstrating a hard-working and capable persona positions an individual employee for success. In an "Art of War" culture, being perceived as smart, shrewd, and controlled is highly valued; communicating the most intelligent and strategic idea is critical. Learning to observe and mirror the language culture of the company helps employees be more effective. In fact, in some organizations, success may depend on fluency. For leaders, this session will discuss supporting teams in observing/learning the lingo as well as the possibility of creating your own dialect.

Focus Area: Leadership/Management

Developing Plain Language Informed Consent Forms for Multinational Clinical Trials.....Harborside D

Haroon Mohammad, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc., New Orleans, LA

The informed consent form (ICF) helps investigators explain important aspects of clinical trials to potential participants prior to obtaining their consent. However, the use of complex medical terminology to explain clinical trial design, assessments, and potential risks can hinder inclusion of participants with limited health literacy skills. The challenge to developing an ICF is compounded by the fact that more than 5% of all clinical trials are multinational and include sites both in the United States and other countries. Developing ICFs that are easy to understand and can be used for multinational clinical trials is a challenging endeavor. Learn common key elements required by major global regulatory agencies and tips to explain complex medical terminology to develop plain language ICFs for multinational clinical trials.

Focus Area: Regulatory

Shackleton's Ghost Writer — Are Authorship Standards Always Important?.....Harborside E

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

Many of us have read and enjoyed popular literature, without giving a second thought to issues of authorship. As professional medical writers, we are acutely aware of the guidelines and standards that govern authorship of medical and scientific documents and manuscripts. Using the historical drama of Sir Ernest Shackleton's Endurance voyage, Art will juxtapose authorship criteria between popular and

scientific/medical literature. Upon returning from his epic voyages to Antarctica, Shackleton tried to recoup investors' contributions by going on the lecture circuit and publishing the stories of his adventures. These books proved quite popular and profitable and endure as both historical and popular accounts. By recounting the harrowing challenges of the Endurance expedition, Art will set the scene for a discussion of how authorship is treated, depending on the type of publication, the audience, and the potential impact on public discourse. Please join him on this journey, and come away with a taste for adventure!
Focus Area: Scientific Publications

Subcontracting 101.....Essex
Brian Bass, MWC, President, Bass Global, Inc., Fort Myers, FL
You've been freelancing for years. You charge as much as you can, you work as hard as you want to, and you earn more than you ever thought possible. Is that all there is? If retirement isn't on your horizon, perhaps it's time for you to consider subcontracting. In this session, a freelancer for more than 30 years who has been subcontracting for more than 20 years will explain why you should (and shouldn't) subcontract, how to incorporate subcontracting into your business model, and how to make subcontracting work for you.
Focus Area: Career Development

12:30 PM to 1:45 PM | Opening General Session with Award Address and Lunch (Sponsored by Merck & Co., Inc.).....Grand Ballroom V&VI

2:00 PM to 5:00 PM | Workshops *(pre-registration & additional fee)*

WS #12: Mentoring Other Writers—How to Begin.....Dover A
Amelia Young, BS, Senior Manager, Medical Writing, Parexel International, Reiles Acres, ND

WS #13: Lean Authoring.....Grand Ballroom III
Kim Jochman, PhD, RAC, Senior Director, Medical Writing, Merck & Co., Inc., Apex, NC
Elizabeth Brown, MS, Director, Merck & Co., Inc., North Wales, PA

WS #14: Do More With Less Faster: Project Management for Medical Communicators.....Grand Ballroom II
Art Gertel, PhD, Principal, MedSciCom, LLC, Lebanon, NJ

2:00 PM to 3:00 PM | Education Sessions

Entering, Navigating, and Thriving in the Field of Medical Communications.....Harborside A
Moderator: J. Kelly Byram, MS, MBA, ELS, CEO | Medical & Scientific Communications Lead, Duke City Consulting, LLC, Albuquerque, NM
Theresa Singleton, PhD, Owner and Principal Scientific Writer, Singleton Science, LLC, Beverly, MA
Damiana Chiavolini, MS, PhD, Freelance Writer, Editor, and Instructor, Dallas, TX
Medical communications can seem daunting to those wishing to enter the field. Once in the field, many find that expanding or pivoting to new or specialized areas of medical communications can be almost as challenging. Join 3 active medical communications professionals to discuss how they entered and navigated the field to find and evolve their niches and the actionable steps early and mid-career

professionals can take to thrive and build a dynamic and fulfilling career.
Focus Area: Career Development

Is the Hype Real? Real-Life User Experience of an AI Tool for CSR Production.....Harborside B
Julia Forjanic Klapproth, PhD, Senior Partner, Trilogy Writing & Consulting, Durham, NC
Looking back on almost one year of using an AI tool in day-to-day CSR production at a medical writing company, this session will report on how using the tool changes the medical writer and authoring-team experience. Using feedback from writers, the presentation will explore what we are learning about using technology to support the writing activity, including how it is changing the traditional set of activities associated with CSR planning and the interaction with the teams. The goal of this session is to inform the community about how this technology is changing the process of planning, writing, and thinking about documents and to give some ideas about new ways of thinking that medical writers need to be open to as these technologies become commonplace.
Focus Area: Regulatory

Pursuing Excellence in Medical Writing for Continuing Education in the Health Professions: A Competency Model.....Harborside D
Donald Harting, MA, MS, ELS, CHCP, President, Harting Communications LLC, Downingtown, PA
Haifa Kassis, MD, President, Crisp Writing, Boston, MA
Continuing medical education (CME) writing, which includes developing needs assessments as well as instructional content and test questions, has become more difficult in recent years. Pressure to demonstrate measurable learning outcomes, competition among medical education companies, and technological innovations all challenge CME writers to become—and remain—competent. Demand for such writers is strong: commercial support grew by 32% in the past decade, and medical education company executives report they cannot find the skilled writers they need. While a competency model for regulatory writers exists, until now there has been no roadmap to guide CME writers. In this session, you will learn about the first competency model developed specifically for medical writers who wish to excel in the field of accredited continuing education in the health professions.
Focus Area: Continuing Education for Health Professionals

Putting Your Plain Language Writing to the Test: Getting the Most out of User Testing.....Harborside E
Samuel Entwisle, PhD, Medical Writer, Center for Information and Study on Clinical Research Participation (CISCRP), Boston, MA
User testing is the ultimate way to ensure that plain language deliverables are clear and accessible. Panels of patients, patient advocates, healthcare professionals, and members of the public can provide crucial insights that improve the quality of these documents. User testing every project is the gold standard, and it provides a treasure trove of potentially useful data. How can we best use these data to establish new best practices? During this session, we will discuss lessons learned from implementing user feedback on Plain Language Summaries.
Focus Area: Health Communication

You've Got to Be Kidding! A Guide to Handling Ethical Dilemmas Without Losing Your Mind.....Essex

Michelle Sauer Gehring, PhD, ELS, Senior Project Manager, UTHealth, Houston, TX
Larry Lynam, DSc, President Emeritus, The Lynam Group, LLC, Tucson, AZ
Whether we are new to the medical communication field or have already built a collection of war stories, sooner or later, we all find ourselves facing ethical dilemmas. How we address them can have long-term consequences. Join us for this interactive session where we will be presenting actual dilemmas we have faced. We will of course share what we did, but we want to give you a chance to answer that question, "what would you do?" Our medical communication ethics skills are best honed when we share multiple perspectives, so this session seeks to engage fellow professionals who have also endured sticky situations. Together, we will identify best practices, determine creative strategies to handle the trickiest of situations, and practice de-escalation (and escalation) techniques.
Focus Area: Core Knowledge/Skills

2:00 to 3:00 PM | Product Showcase: Synterex, Inc.

AGILEWriter.ai: Your Automated Plain Language Document Solution.....Grand Ballroom I
Reduce the frustrations that are part of your informed consent forms (ICFs) and other plain language documents! Developing ICFs is time-intensive and often results in a deliverable that may be inconsistent with your protocol or may be too complicated for trial participants or their representatives to comprehend. Additionally, ICFs may appear in many different formats, including master ICFs, additional study-specific component ICFs (eg, pregnant partner ICFs, biologic sampling ICFs), country-specific ICFs, and site-specific ICFs, each introducing additional challenges to the ICF development process.

AGILEWriter.ai reduces the time to create ICFs, simplifies the ICF to a level appropriate for your intended trial participants, and minimizes errors between the source document and the ICF.
AGILEWriter.ai integrates cutting edge AI technology, laylanguage dictionaries, and standard readability tools in a single, efficient ICF authoring tool suitable for Sponsor companies of all sizes as well as hospitals and academic institutions. We will demonstrate how to set up the initial master ICF and will walk through how AGILEWriter.ai detects key elements in your protocol to populate your ICF template. AGILEWriter.ai can be programmed to support in-house and commercially available ICF and protocol templates.

3:00 PM to 4:00 PM | Beverage Break (Sponsored by JAMA Network/Oxford University Press) with Exhibitors.....Grand Ballroom Foyer

3:00 PM to 4:00 PM | Product Showcase: PerfectIt

The Right Tools for the Right Job: Cutting Through the AI and Automation Hype in Medical Writing.....Grand Ballroom I
In a tech-saturated landscape, how do you separate the useful from the distracting? Does a tool speed up document creation, or does it add another layer of complexity? What's distinguishes AI from automation? And how do you navigate the tricky terrain of security and confidentiality? Achieving efficiency in medical writing is more than just slotting in AI or automation. It hinges on understanding your workflow, defining clear goals, and selecting tools that align with these objectives. In this session, we'll untangle these queries, showcasing how Draftsmith and PerfectIt can amplify the quality and speed of your work.

We demonstrate how using tools in the right ways can help to achieve a more efficient process that results in high-quality and engaging content.

4:00 PM to 5:00 PM | Education Sessions

A Regulatory Writer's Guide to Leading an Efficient Comment Resolution Meeting in a Virtual World.....Harborside A

Megan Pearson, MS, Senior Scientific Writer, Bristol Myers Squibb, Lawrenceville, NJ

Leading an efficient and effective comment resolution meeting (CRM) is a critical role of the regulatory writer. The writer must present key discussion topics in an organized and impactful way, effectively engage team members in a focused discussion, resolve comments within a given timeframe to adhere to timelines, and navigate difficult team dynamics. A poorly run CRM can lead to confused and unproductive discussions, lack of participation and feedback from the team, inability to resolve comments, and overall poor team dynamics. Writers face many challenges while navigating the comment resolution process in a virtual world and will learn strategies and skills to overcome these challenges to effectively lead teams through this process.

Focus Area: Regulatory

Editing Your Own Work (After You've Read it 1,000 Times).....Harborside E

Hope Lafferty, AM, Instructor, University of California San Diego, San Diego, CA

Medical writers don't only write. We're researchers, content developers, project managers, multilevel editors, proofreaders, and publishers. Each role requires a different way of thinking. Writers and managers view projects strategically; editors and proofreaders approach projects tactically. Switching between these different ways of thinking can prove challenging—especially when we're exhausted, fed up, and under deadline. Attendees will gain both strategies and tactics to catch embarrassing or compromising mistakes without glazing over so that they may produce impeccable documents that are error-free, wince-free, and easier to read.

Focus Area: Career Development

Plain Language With a Page Limit: Strategies for Writing 2-Page Protocol Synopses and Other Deliverables.....Harborside B

Zack Fey, Medical Writer, Center for Information and Study on Clinical Research Participation (CISCRP), Boston, MA

Plain language best practices include using plenty of white space, larger font sizes, and adding visual aids. However, following these best practices is a challenge when trying to meet a page limit. A recent example is the 2-page limit set by the European Union Clinical Trial Regulation (EU CTR) for a clinical trial protocol synopsis that should be understandable to a lay person. This is no small task, but it can be done. This session will include a discussion about the strategies employed by a team that has written over 40 plain language protocol synopses to date. Attendees will learn how to adapt their plain language writing to provide clear and concise protocol synopses, trial result summaries, and ICFs for clients and the public.

Focus Area: Health Communication

4:00 PM to 5:00 PM | Speed Networking.....Harborside C

Joanne McAndrews, PhD, Freelance Medical Writer, St. Louis, MO

Jennifer Nepo, Principal, Medparency LLC, Armonk, NY

Networking is one of the biggest benefits of AMWA's Medical Writing and Communication conference. Get to know other conference attendees in a speed dating–like format. Attendees will be randomly paired up, and each pair will have 5 minutes for introductions/discussion. New rotations will occur every 5 minutes, giving you an opportunity for interaction with at least 10 other attendees. Who knows what connections you will make? The co-leaders of this session met at an AMWA Annual Conference Speed Networking Session in 2012 and became close friends. Practice your elevator pitch and remember to bring lots of business cards and/or have your LinkedIn App at the ready! This session will begin and end promptly and is open to all conference attendees.

5:30 PM to 5:45 PM | Meet in Hotel Lobby for Chapter Networking Dinners

Conference Day 2: Friday, October 27

7:30 AM to 4:00 PM | Registration Desk Open.....Registration A/B

7:30 AM to 8:45 AM | Roundtable Topic Discussions with Breakfast *(pre-registration & additional fee)*.....Grand Ballroom

RT #01: Attracting and Retaining Medical Writers Through Mentoring Programs
Heidi Chapman, MS, Associate Principal Medical Writer, Trilogy Medical Writing and Consulting, Durham, NC

RT #02: Attracting New Talent Through Regulatory Medical Writing Internship and Shadowing Opportunities
Mary Malley, MS, Associate Director, Janssen Pharmaceuticals, Spring House, PA

RT #03: Authoring the Informed Consent Form (ICF): Current Challenges and Opportunities
Helen Sonner, PhD, Director, Informed Consent Medical Writing, Merck & Co., Inc., Rahway, N

RT #04: Being Our Own Worst Critic: Using Critical Thinking Skills to Strengthen Science Communication
Andrea Clark, PhD, Regulatory Medical Writer, Aroga Biosciences, San Diego, CA

RT #05: Best Practices for Developing Patient-Centered Online Health Information
Christina Norwood, MS, ELS, PDQ Patient Cancer Information Manager, National Cancer Institute, Rockville, MD

RT #06: Best Practices for Effective Kick-Off Meetings for Abstracts, Posters, Presentations, and Manuscripts
Holly Capasso-Harris, PhD, ISMPP CMPP, Associate Principal Medical Writer, Certara Synchrogenix, Wilmington, DE

RT #07: Beyond the Data: Strategies for Managing Teams Through Critical Writing Projects
Michelle Megnin, MPH, Associate Director, Regulatory Medical Writing, Janssen (Johnson & Johnson),

Titusville, NJ

RT #08: Bringing Science to Life: Creating Compelling Videos and Documentaries to Showcase Scientific Research
Ariadna Pomada Villalbi, Comunication Specialist, University Health Network, Toronto, NY

RT #09: Building a Scalable Recruiting Model and Other Innovative Approaches to Attracting Talent
Sharon Hartman, MS, PMP®, Business Operations Head, Regulatory Medical Writing, Janssen R&D, Spring House, PA

RT #10: Certification of Editors in the Life Sciences
Leslie Neistadt, ELS, Managing Editor, St. Louis University, St. Louis, MS

RT #11: ChatGPT and the Future of Medical Writing
Jenny Minigh, PhD, Exec Dir MW, inSeption Group, Catlettsburg, KY

RT #12: Collaborative Authoring
Anjana Bose, PhD, Director, Global Submissions, Certara/Synchrogenix, Wilmington, DE

RT #13: Conducting Original Research on Medical Writing: How to Get Started?
Donald Harting, MA, MS, ELS, CHCP, President, Harting Communications LLC, Downingtown, PA

R #14: Discover Your Calling: Mastering Your Medical Writing Niche
Sophie Ash, BSc (Hons), DipION, Business & Medical Writing Coach, Prospology, San Diego, CA

RT #15: DMPs All Around: How Do We Help Researchers Fulfill Data Management and Sharing Requirements?
Matthew Sandbulte, PhD, Grant/Scientific Writer, University of Nebraska Medical Center, Omaha, NE

RT #16: Driving Teams Towards Optimized Submissions. How Can Medical Writing Help Build the Case For Change?
Neil Garrett, PhD, Head, Regulatory Medical Writing, Janssen, Spring House, PA

RT #17: Fact Checking and Annotating for Medical-Legal Review (MLR)
Melissa Bogen, ELS, Medical Editor, Owner, Bogen Editorial Services, Greenwood Lake, NY

RT #18: I Have My Abstract: Now What? Tips and Shortcuts for Creating an Effective Poster
Michelle Stofa, MS, Manager, Editorial Services, Nemours Children's Health, Wilmington, DE

RT #19: Inclusive Language for Scientific Writers and Editors
Stacy Christiansen, MA, Managing Editor, JAMA, Chicago, IL

RT #20: Optimizing the Value of QC: What do Medical Writers Want? What can QC Provide?
Pamela Fioritto, MSJ, Senior Quality Reviewer & Medical Editor, Whitsell Innovations, Inc., Cleveland, OH

RT #21: Patient-Focused Drug Development: How Can I Be a Patient Advocate as a Medical Writer?
Alysia Drummond, MPH, CHES, Medical Writer, inSeption Group, Overland Park, KS

RT #22: Quick Onboarding and Preparation for Medical Writers to Support Regulatory Submissions
Henry Li, PhD, Director, Medical Writing, Merck & Co., Inc., Rahway, NJ

RT #23: Quick Tips for Using Online Reference Management Software (Mendeley) for Manuscript Preparation
Diane Morton, MS, MWC, Senior Technical Writer, Research, SSM Health, St. Louis, MO

RT #24: Resilience: Burnout Prevention and Management for Medical Communicators
Reggie Wilson, Guilt-free Health Coach, Fit for Freelance, Naples, FL

RT #25: Risk Management Plans: A Discussion on Best Practices and Lessons Learned
Lauren Peters, MS, Manager, Medical Writing, Janssen Research & Development, Spring House, PA

RT #26: Roles and Responsibilities of the Medical Copywriter in Promotional Medical Writing
Holly Hagan, MSc, Medical Writer, Holly Hagan Consulting Inc., Collingwood, Ontario, Canada

RT #27: Scientific Writing in Academia: Building Resources and Support
Rebecca Ward, PhD, Medical Writer, Massachusetts General Hospital, Boston, MA

RT #28: Statistically Speaking: How to Avoid Confusing or Misleading Your Audience
Jennifer Pickett, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc., Apex, NC

RT #29: Staying Curious: Understanding Motivations in Building and Managing Medical Writing Teams
Jason Casavant, JD, Executive Director, Medical Writing, Synterex, Inc., Dedham, MA

RT #30: Strategically Writing and Reviewing Regulatory Documentation: How to Implement for Success
Amanda Tricarico, Director, Strategy and Scientific Writing, Bristol Myers Squibb, Princeton, NJ

RT #31: Strategies for Driving Successful Reviews
Laura Bisogno, PhD, Medical Writer and Consultant, Whitsell Innovations, Chapel Hill, NC

RT #32: Strategies for Resolving Workplace Conflict
Gretchen Griffin, MS, MBA, Executive Director, Head of Global Medical Writing, BeiGene, Frederick , MD

RT #33: Study Smarter: Creating an MWC® Exam Study Plan That Works for You
Pamela Stebbins, MWC, President, Spark Strategic Communications Inc, Denver, CO

RT #34: Study Smarter: Creating an MWC® Exam Study Plan That Works for You
Rachel E. Hile, PhD, MWC, Medical Writer, Cook Research, Inc., West Lafayette, IN

RT #35: The Art of Saying "No"
Abigail Agoglia, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc., Chapel Hill, NC

RT #36: The Role of Medical Writers in Authoring the Integrated Summary of Immunogenicity Report for Biotherapeutics
Keri Hamilton, PhD, Principal Medical Writer, Merck & Co., Inc., Raleigh, NC

RT #37: The Well-Rounded Medical Writer: It Goes Beyond Good Writing
Andrew Park, PharmD, Senior Medical Writer, PROMETRIKA, LLC, Cambridge, MA

RT #38: Transitioning from Clinical Research to Medical Writing
Robert Dann, BS, MA, Strategic Medical Writer, Synterex, Inc., Phoenix, AZ

RT #39: Understanding Early Clinical Writing
Rob Panek, PhD, Early Clinical Medical Writing - Principal Medical Writer, ICON plc , Lancaster, NY

RT #40: Using Theoretical Scenarios to Guide Decision-Making
Kleopatra Kouroupaki, Dr. phil. nat., Principal Medical Writer, Trilogy Writing & Consulting Inc., San Diego, CA

RT #42: Value of Medical Writing: Writers' Toolkit
Catherine Tyrrell, BSc, Head of Medical Writing and Disclosure, CSL Seqirus, Summit, NJ

RT #43: What is Career Satisfaction to a Medical Writer?
Gregory Morehouse, MS, MWC, Principal Medical Writer, ICON plc, Deerfield, IL

RT #45: Writing Strategies for Expediting Initial Investigational New Drug (IND) Applications
Brenda Taylor, MS, CAPM, Director, Global Submissions, Certara-Synchrogenix, Wilmington, DE

8:00 AM to 9:00 AM | Exhibit Hall Open with Coffee & Tea.....Grand Ballroom Foyer

9:00 AM to 12:00 PM | Workshops *(pre-registration & additional fee)*

WS #16: Writing the Investigator's Brochure.....Grand Ballroom II
Kathy Spiegel, PhD, Writer, Editor, Instructor, Freelance, Grass Lake, MI

WS #17: Proofreading: Strategy for Document Quality Control.....Dover A
Damiana Chiavolini, MS, PhD, Writer, Editor, Instructor, Freelance, Richardson, TX

WS #19: How to Interpret and Write About Clinical Trial Data.....Grand Ballroom III
Kim Jochman, PhD, RAC, Senior Director, Medical Writing, Merck & Co., Inc., Apex, NC

WS #20: Writing Clinical Study Report Lay Summaries—A Survivor's Guide.....Dover B
Lisa Chamberlain, PhD, Senior Partner, Trilogy Writing & Consulting Limited, Cambridge, MA

9:00 AM to 10:30 AM | Education Sessions

CTD Structure: From IND to NDA.....Harborside A
Michael G. Baker, PhD, President & Principal, Haselwood Biosciences, LLC, San Francisco, CA
This session summarizes the modular structure of the Common Technical Document (CTD), identifies the elements that apply to an IND, and explains how the CTD evolves and is built through New Drug Application (NDA)/Biologics License Application (BLA) submission and beyond. While the focus is on drug development considerations in the United States (US), rest of world (ROW) regulatory considerations also

are discussed.
Focus Area: Regulatory

Immunology Essentials for Medical Writers.....Harborside B
Moderator: Beth Knight, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc., Raleigh, NC
Hannah Dewald, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc., Raleigh, NC
Irene Papanayotou, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc., Raleigh, NC
Many medical writers have backgrounds in biology; however, the field of immunology remains complex and ever-evolving while impacting numerous areas of clinical research. Medical writers often encounter immune diseases and immune-related endpoints in clinical documents. This panel presentation provides an overview of the immunology therapeutic area to prepare the medical writer with the background needed to proficiently understand and navigate these topics. The basics of the immune system are outlined, including the innate and adaptive branches, cell types, and homeostasis. Various ways that the system can be dysregulated are described, along with the resulting diseases. Finally, immunological topics, endpoints, and evaluations pertinent to regulatory documents are identified, with additional focus on immunogenicity and cancer immunotherapy.
Focus Area: Core Knowledge/Skills

Roads Leading to Approval: The Right Level of Detail for CMC Submissions.....Harborside E
Helen (Nellie) Forwood, MA, RAC, CQE, Associate Director Regulatory Writing, Synchrogenix, Rockland, DE
Carlos Rousselin, BS, Associate Principal Regulatory Writer, Synchrogenix, Nashville, TN
In CMC regulatory writing, there is a difference in the level of detail required for NDA and BLA products. The expectations tend to diminish as time elapses and the regulatory authority becomes more familiar with a specific type of medicinal product. Small molecule oral solid products have been submitted to, approved more frequently, and represent a different set of expectations than biologics, vaccines, and gene therapy (GT) products. Biologics, vaccines, and GT products tend to be comparable to each other, yet they contain significant differences in requirements for certain modules. This seminar will provide a high-level overview of the expectations required for Module 3 submissions for a small molecule oral solid product NDA, a biologic BLA, a vaccine BLA, and a GT BLA.
Focus Area: Regulatory

The Value of Medical Writing: A Toolkit for Defining, Achieving, and Communicating Success.....Harborside D
Catherine Tyrrell, BSc, Head of Medical Writing and Disclosure, CSL Seqirus, Summit, NJ
Katie Kelm, Associate Director Medical Writing, PPD part of Thermo Fisher Scientific, Chapel Hill, NC
The value of a medical writer (MW) exceeds drafting documents and ensuring submission readiness; the additional contributions of MWs often go unrecognized. An AMWA working group was formed to address measures of success for deliverable development and its drivers. We aimed to empower MWs to manage expectations with respect to timelines, quality, and best practices. We leveraged our knowledge, experience, and expertise to identify the best practices for addressing barriers that MWs encounter when communicating success to key stakeholders, including achieving timelines, team collaboration, and defining key quality metrics. The outcome is a toolkit that writers and managers can reference to create and implement their own processes to successfully develop medical writing deliverables. This presentation

will demonstrate the toolkit and provide examples for its use.
Focus Area: Leadership/Management

10:00 AM to 11:00 AM | Beverage Break (Sponsored by Bioforum) with the Exhibitors.....Grand Ballroom Foyer

10:00 AM to 11:00 AM | Product Showcase: Yseop

Yseop Copilot: Automate Medical Writing with AI.....Grand Ballroom I
With the extraordinary capacity of Generative AI and the emergence of LLMs, what is the impact of this technology on more regulated industries like BioPharma? Currently, medical writers across hundreds of clinical trials are slashing writing times and improving the consistency and reliability of reports using AI. Yseop Copilot is the most powerful content automation tool available to medical writers today, using LLM in a secure, easy, and pre-configured way for biopharmaceuticals.
In this session, we will analyze how some of the top life sciences firms have leveraged content automation to supercharge productivity, reducing writing times from 4 hours to just 4 seconds. The demonstration will review how medical writers can accelerate regulatory report submissions and writing processes using Yseop Copilot while eliminating thousands of hours of writing and review time.

11:00 AM to 12:00 PM | Education Sessions

An Unexpected Perk of a Career in Medical Communication: Educating Scientific Publication Authors.....Harborside A
Anne Murray, PhD, MWC, Lead Medical Writer, Clinical Research Institute at Methodist Health System, Dallas, TX
Many potential authors have little experience preparing scientific publications, including knowing the importance of dissemination, format of a manuscript, peer review process and/or potential ethical pitfalls. All members of a research team are responsible for ensuring that scientific publications are clear, accurate and ethical. Although medical communicators may not make the author list, our contributions could be publicly apparent in the acknowledgements. Ensuring that that the publication is high quality helps preserve not only the reputations of the authors, but also those "guilty by association" in the acknowledgments. For most medical communicators, educating authors may seem like an obscure potential job duty. However, many of us will have to educate authors about how to prepare a publication during informal conversations, publication planning meetings, and seminars.
Focus Area: Scientific Publications

Demystifying Business Plans for Freelance Medical Writers.....Harborside B
Abigale Miller, MSc, Medical Writer, The Anthill, Fergus, OH
How do you decide whether to take on a new project? Or what additional skills you need? Or how to focus your marketing efforts? The business plan is a great tool to help make those decisions. If you have intended to write a business plan for years, you're not alone. Many freelancers resolve to write a business plan, but either never start or don't fully implement it. It can be difficult to know where to start, where to find relevant tools and advice, and how to implement the plan effectively. This session will outline the importance of a business plan for all freelance writers, provide components of a business plan that are

relevant to freelance medical writing, and describe steps for effective implementation.
Focus Area: Career Development

Medical Communication Education: A Panel on Challenges and Opportunities.....Harborside D
Moderator: Michelle Sauer Gehring, PhD, ELS, Instructor, University of California-San Diego Extension, San Diego, CA
Donna Simcoe, MS, MS, MBA, CMPP, Medical Publications Consultant, Simcoe Consultants, Inc., San Diego, CA
Laura Happe, PharmD, MPH, Director Of Online MS in Pharmaceutical Outcomes and Policy and Clinical Associate Professor/Editor-in-Chief, University of Florida/Journal of Managed Care and Specialty Pharmacy, Charlotte, NC
Barbara Gastel, MD, MPH, ELS(H), Professor; Director, MS Program in Science and Technology Journalism, Texas A & M University, College Station, TX
We want to establish that this session is for mid- to advanced-level communicators who are actively teaching in the field. The medical communication industry continues to grow, and with it, the demand for trained personnel is increasing. Just like the field itself, educational programs for medical communicators vary widely and continue to evolve. This panel brings together expertise from degree and university certificate programs that focus on scientific communication and related areas. Panelists will describe their specific programs and identify key trends, opportunities, and challenges. Aspects to be addressed include core competencies, delivery and design of specialty tracks, remote and adult learning strategies, and the importance of real-world experience. Those who teach in the medical communication field are encouraged to attend this interactive discussion.
Focus Area: Continuing Education for Health Professionals

Plain Language Summary of Publication: Maximizing Value by Maximizing Patient Engagement.....Harborside E
Kimbra Edwards, PhD, Senior Director, Health Communication Services, CISCRP, Boston, MA
A Plain Language Summary of a Publication (PLSP) is a translation of an original scientific publication into easy-to-understand language and graphics. PLSPs can serve as a valuable resource for patients and the public, patient advocacy groups, and non-specialist clinicians. A new and evolving form of health communication, PLSPs can come in many formats and be distributed in many ways. A patient-centered approach is key to creating an effective PLSP. Patients not only provide valuable feedback when reviewing PLSPs, but patients can also contribute as authors by providing written testimonials and contributing to the selection and presentation of content. Using specific PLSPs as case studies, in this session we will highlight how to maximize patient engagement to maximize value.
Focus Area: Health Communication

Variations in Investigational New Drug (IND) Applications Presented via Case Studies.....Essex
Moderator: Mark Bowlby, PhD, Senior Director, Global Submissions, Certara - Synchrogenix, Wilmington, DE
Anjana Bose, PhD, Director, Global Submissions, Certara - Synchrogenix, Wilmington, DE
Brenda Taylor, MS, CAPM, Director, Global Submissions, Certara - Synchrogenix, Wilmington, DE
Investigational New Drug (IND) applications are diverse and encompass a broad range of programs: first-time application for a new drug to a new indication for a previously studied or approved product. Data

summarized in INDs range from nonclinical only (eg, to allow a first-in-human study), both nonclinical and clinical (eg, for an early/mid-stage program with ex-US clinical data), or a mature program (new indication of an approved or abandoned product). Regulatory submission leads work closely with all stakeholders to weave in the various pieces in conformance with existing regulatory guidelines and provide guidance to a multifunctional team. This session aims to use various case studies as examples to share lessons learned and potential ways to navigate the challenges for a successful application.
Focus Area: Regulatory

11:00 AM to 12:00 PM | Product Showcase: ZYLiQ

ZYLiQ is going to give medical writers what they need, time.....Grand Ballroom I
The premise is simple… Using AI and Machine Learning, the tool eliminates the drudgery of copy/paste, allowing for completion of CSR's 60% faster than manual effort alone.
The tool consumes source documents and then places text in the appropriate CSR sections (formatted according to ICH E3 guidelines). ZYLiQ also uses NLP and NLG to generate appropriate text for sections in the CSR as well as auto-creating the results of in-text tables. Meaning, that after a writer configures the sponsor template, they are minutes away from the tool automatically creating an effective first-draft. Beyond using AI to automate the creation of an amazing first-draft, ZYLiQ offers a workflow module to help writing teams review, comment, edit and approve the final draft. Leveraging this workflow platform allows for the ML adjustment of the AI models so that the tool is more effective the next time it is used. As a software tool, ZYLiQ is deployed behind a customer's firewall or in their private cloud, eliminating any data security issues. The tool is also priced per/study, removing budget concerns around annual licenses or number of user limitations.

12:00 PM to 1:30 PM | Networking Lunch.....Grand Ballroom

12:00 PM to 1:30 PM | Exhibit Hall Open.....Grand Ballroom Foyer

1:30 PM to 2:30 PM | Education Sessions

Editing Grant Applications: Top Tips for Success.....Harborside A
Kimberly Mankiewicz, PhD, ELS, Scientific Editor, The University of Texas Health Science Center at Houston, Houston, TX
Scientific research would not be possible without grant funding, making grant applications an inherent part of the job for many scientific researchers. As a medical writer/editor, your skills can be helpful in assisting scientists with their grant applications and securing funding for their work. In this session, we will be discussing fundamentals of successful grant applications and how medical writers and editors can play an important role in the grants process. We will discuss how to use your expertise to help scientists with their grant application and why you should consider adding grant proposal editing to your portfolio. We will also provide you with a new library of resources to help you learn more about grant proposal mechanics and funding agencies.
Focus Area: Grantsmanship

How to Prevent Medical Writer Burnout.....Harborside B
Nidhi Johal, Director of Medical Writing, North America, Trilogy Writing & Consulting, Durham, NC

In today's world, the demand for medical writers is higher than ever before, and medical writers face intense pressure in their work environments. Regulatory documents have become increasingly complex, yet we see an increased demand from clinical study teams and management to deliver documents with shortened timelines and faster turnaround times. Review teams are getting larger and more involved in the document authoring process, adding another layer of complexity. As a medical writer, how do you manage to deliver high-quality documents amidst such challenges, yet keep your own sanity? Learn about tips and various techniques medical writers can use to manage the factors that affect the document authoring process, work with teams more effectively, and improve overall efficiency and productivity to prevent burnout.
Focus Area: Wellness

Medical Writing and Editing Internships: Preparing the Next Generation of Medical Communication Professionals.....Harborside D
Moderator: Erica Goodoff, ELS(D), Senior Scientific Editor, The University of Texas MD Anderson Cancer Center, Pearland, TX
Barbara Gastel, MD, MPH, ELS(H), Professor, Texas A&M University, College Station, TX
Joan Affleck, MA, MBA, Associate Vice President, Head of Medical Writing, Merck & Co., Inc., Pahway, NJ
Internships can greatly benefit both interns and hosts. Interns gain hands-on experience and professional contacts, and hosts can develop a pipeline of highly qualified new employees while obtaining short-term assistance. However, medical communication internships are of limited availability, and many organizations may feel that they lack the resources or expertise to offer these opportunities. If your organization does not yet have an internship program, learn about the benefits of such a program, ways to make a business case for it, and ways to help ensure that the program serves all concerned. If you already have a program, learn how you might increase its success.
Focus Area: Leadership/Management

Offer Accepted, Now What? Keys to Successful Onboarding and Career Development From Both Perspectives.....Harborside E
Amelia Young, Senior Manager, Medical Writing, Parexel International, Reiles Acres, ND
Bersabeh Boroumand, Medical Writer I, Parexel International, Toronto, ON
Medical writing job opportunities for experienced candidates today are promising; however, for those that are new to the profession or may lack prior writing experience, attaining these roles and the essential writing skills can be challenging. Breaking down these barriers and developing staff from within can improve career stability and increase retention. From the perspective of both a new Medical Writer and their Manager, we will discuss each party's needs during recruitment, onboarding, and career development. Techniques to measure and build on the new Medical Writer's existing skills and ways to foster open communication and construct strong relationships will also be reviewed.
Focus Area: Career Development

Social Media (SoMe) CME: The Next Evolution.....Essex
Cindy van Dijk, MA, Principal, Scientific Communications, Vancouver, WA
Alison Kickel, FACEHP, CHCP, President, Bonum CE, LLC, Denver, CO
Continuing medical education (CME) provides evidence-based best practices in different therapeutic

specialties to advance the most current knowledge on disease states, guidelines, therapeutic practice, and emerging treatment options. CME programming natively hosted on social media (SoMe) channels is emerging as a powerful and widely accessible vehicle to enhance timely interactivity among individuals and organizations. The benefits of SoMe CME are extensive, but few organizations and individuals are adequately prepared to develop content for these novel outlets. This session will focus on how SoME is changing the way CME is administered, including an environmental scan of existing programming, associated challenges, the value SoMe CME provides, what's on the horizon, and why developing skills in this area is a timely and prudent professional strategy.
Focus Area: Core Knowledge/Skills

1:30 PM to 2:30 PM | Product Showcase: Ideagen PleaseReview

Reimagine document reviews with Ideagen PleaseReview.....Grand Ballroom I
Accelerate timelines, ensure audit-readiness and deliver better quality documents.
Ideagen helps the quiet voices and safe hands that protect organizations to minimize risk, strengthen compliance and keep people safe. We work with 85% of the top 25 global pharmaceutical companies, 4/5 of the top global CROs and 4/5 of the top global medical device companies to deliver world-class, innovative software solutions.

Ideagen PleaseReview enables secure real-time document review, co-authoring, and redaction in order to shorten the document review process by up to 65%. It integrates with Veeva, OpenText, InteliNotion, IdeagenQuality Management and Generis CARA, making it simple to share and access key information securely.

Find out more about Ideagen PleaseReview's key features and how the software has benefited companies like uniQure and Lexicon, transforming the way they work on document reviews.

2:30 PM to 3:00 PM | Beverage Break (Sponsored by Aroga Biosciences) with the Exhibitors.....Grand Ballroom Foyer

3:00 PM to 5:00 PM | Exhibitor Takedown

3:00 PM to 4:30 PM | Jam Sessions

Jam Session for Medical Writers and Editors Who Work on Research Manuscripts (90 minutes).....Laurel AB
Monica Nicosia, PhD, Principal, Nicosia Medical Writer LLC, Bryn Mawr, PA
Preparing research manuscripts for submission to peer-reviewed biomedical journals is challenging. No two projects are alike. For medical writers and medical editors, attention to detail is key. Only other people who work on these types of projects can help demystify the process and provide guidance for handling challenges. During this moderated open-discussion session, attendees will learn from each other by asking questions and sharing experiences, insights, and tips on a variety of topics. This forum will also provide a good opportunity to make new connections and network with peers who might work in different settings (eg, freelance, medcom companies, pharma/biotech companies). Potential discussion topics include

research skills, approaches to writing a first draft, supportive technology, tactics for optimizing manuscript quality, and working with difficult personalities.
Focus Area: Scientific Publications

Jam Session for Seasoned Freelancers (90 minutes).....Laurel CD
Brian Bass, MWC, President, Bass Global, Inc., Fort Myers, FL
When accomplished musicians jam, their combined talent, energy, and experience make a special kind of synergy. A similar kind of magic happens when seasoned freelancers get together to discuss their ideas, concerns, and challenges with peers who have the same or more experience. These rare gems of collegial conversation and commiseration happen spontaneously and usually unpredictably. This discussion will provide a supportive space for experienced freelancers to wrestle their demons and share their experiences. Whether you emerged bloodied and bruised, valiant, or victorious, we all have stories to tell, and we can all learn from and teach each other. This session is lightly structured to permit a free flow of discussion without getting stuck for too long on a single topic.
Focus Area: Career Development

Jam Session for New to Mid-Level Freelancers (60 minutes).....Harborside C
Abigale Miller, MSc, Medical Writer, The Anthill, Fergus, OH
Freelance medical writing can be lonely, especially when a writer is launching their freelance career. It can be difficult to know where to turn for advice, and to know whether your questions are shared with other writers. Join a supportive group of fellow medical writers to discuss challenges, concerns, and ideas related to the early phase of a freelance medical writing career. Expected topics include finding new clients, establishing and negotiating rates, developing a niche, scheduling, and project management. The session will be unstructured but lightly facilitated, giving priority to discussion topics and questions brought by participants.
Focus Area: Career Development

3:00 PM to 4:00 PM | MedWrite Talks

MedWrite Talks I.....Harborside A

Advisory Boards: A Deep Dive
Cindy van Dijk, MA, Principal, Scientific Communications, Vancouver, WA
Advisory Boards are powerful tools sponsors use to extract information and perspectives from key opinion leaders or influencers on clinical development strategies, commercial positioning, and patient responses. The scope, timing, and diversity of topics are well defined, and timelines for deliverables give the medical writer firm deadlines to meet. This session will cover the "nuts and bolts" of advisory boards, the hard and soft skills needed to succeed, the timing of what it takes for execution and delivery, and practical questions a medical writer should ask to ensure client objectives are met.
Focus Area: Career Development

Don't Be Afraid of the Machines: AI Will Transform and Enhance the Future of Medical Writing
Demetrius Carter MBA, PMP, RAC-US, SVP, Regulatory Science, Certara Synchrogenix, Durham, NC
There is a lot of buzz currently on how Artificial Intelligence (AI) and applications like ChatGPT will transform the writing industry. Like most transformative technologies, such as the phone, computers, and

robots, our natural tendency is to fear what we do not understand. However, we embraced these technologies once we established the utility of these tools and learned how they improve our lives through efficiency and quality improvements. When applied to medical writing, I foresee a similar outcome for using AI tools, such as machine learning, natural language processing, and data fabric. These automation tools will simplify the authoring process, allowing medical writers to focus on higher-order activities. As a result, the medical writer's role will evolve and become even more impactful in the future.
Focus Area: Regulatory

Is it Possible to Fully Automate QC of CSR?
Nalin Gupta, Strategic Advisor, GENINVO, Bloomington, IL
QC of Clinical Study Report (CSR) is a very tedious and manual task. Several research articles and surveys point out that QC takes up 10% to 30% of overall time in the document life cycle. If the author or senior resource is doing this task, then we can do the math on how many hours are spent on this task. This paper will discuss various checks that are a must and can be automated very easily. It will also discuss complex checks that can be automated with precision to some extent. An overview of the Artificial Intelligence (AI) techniques required will be discussed, and how this can be implemented to support checking both "within" and "across" document consistency.
Focus Area: Regulatory

Living a Legacy
Joan Affleck, MBA, Associate Vice President, Medical Writing, Merck & Co., Inc., Rahway, NJ
As writers, we often think in stories with beginnings, middles, and ends. When we consider the story of our own career, we might see it that way. But there might be another option. Whether or not there is a fully developed vision for a professional life, it is never too early to begin living that legacy. Aspects of the journey and opportunities to bring long-term goals to fruition will be explored in this presentation.
Focus Area: Career Development

MedWrite Talks II.....Harborside B
Applying Clinical Experience to Medical Writing – Write for Your Audience
Amy Porter, PhD, Associate Principal Medical Writer, Certara Synchrogenix, Tucson, AZ
The main goal of scientific medical writing is to inform the target audience objectively of a new scientific development. The target audience typically consists of researchers and healthcare professionals, but laypersons are increasingly a focus too. However, scientific writing is often focused on what authors want to convey instead of considering the target audience. Several suggestions will be provided for scientific medical writing geared towards the target audience, with a focus on considerations for plain language summaries and shorter scientific communications (eg, brief reports). Attendees will learn, amongst others, how scientific plain language writing can make use of lessons learned from writing plain language medical documents (eg, patient information), while facing some unique challenges too.
Focus Area: Scientific Publications

Are the Robots Taking Our Jobs (Again)?
Tatyana Wanderer, PhD, Executive Director and Head of Medical Writing, Syros Pharmaceuticals Inc, Nashville, MA
Technology-enabled authoring has been slowly transforming our community for over a decade. In

November 2022, the introduction of Chat GPT, a powerful and versatile natural language processing tool, sent ripples through our community yet again. We will provide examples of how new AI tools have been used to effectively edit text, accurately describe data from tables, and convert complex scientific language into plain language. We will also discuss the implications of this technology on our field, including its potential to revolutionize communication and data analysis
Focus Area: Core Knowledge/Skills

Hidden Talent in Medical Writing: Hiding in Plain Sight
Jeanette Towles, MA, RAC, President & CEO, Synterex, Inc.
Hidden talent (a.k.a. hidden workers) describes a phenomenon by which the traditional hiring process excludes the candidacy of applicants with particular attributes—those from disadvantaged backgrounds or who have a gap in their work history, as examples—who otherwise may have the requisite skills to be successful in a role and in fact whose ability to overcome adversity would make them particularly well suited for the role. In this talk, we will look at the possible causes of this phenomenon and how we can address those underlying causes in the medical writing field to create an optimally diverse, inclusive, and talented workforce.
Focus Area: Career Development

Please Don't Call Me "Elderly": Avoiding Ageism in Your Writing
Stephanie Morrison, MPH, Writer-Editor, National Institute on Aging, National Institutes of Health, Bethesda, MD
Ageism has been described as "the last form of discrimination that's widely accepted in our culture." Because ageism is so pervasive, it's easy for well-intentioned writers to inadvertently reinforce harmful stereotypes about older adults. But these stereotypes have serious implications for the health of older people: Studies have associated ageism with poorer physical and mental health, reduced quality of life, and even earlier death. With increased awareness, medical writers have an opportunity to counter common but misguided assumptions about the later part of life. This presentation will provide guidance for choosing respectful, inclusive, and accurate language and images to describe older adults. By making a few subtle but intentional changes, medical writers can help people of all ages think more positively about aging.
Focus Area: Health Communication

5:00 PM to 5:15 PM | Meet in the Hotel Lobby for Optional Dine Arounds

5:00 PM | Optional National Aquarium Visit (on own)*

**Tickets must be purchased through National Aquarium; half-priced tickets on Friday.*

Conference Day 3: Saturday, October 28

7:30 AM to 2:00 PM | Registration Desk Open.....Registration A/B

8:00 AM to 9:15 AM | Continental Breakfast with Poster Presenters.....Harborside Foyer

8:00 AM to 9:15 AM | Chapter Leaders Networking Event with Continental Breakfast (by invitation only).....Grand Ballroom III

8:15 AM to 9:15 AM | Learning Circles (NEW!)

Learning Circles are a new educational experience that offers a facilitated discussion with a larger group of participants. Discussions are meant to be interactive, and space is offered on a first-come, first-served basis. Please find our Learning Circle topics below:

Attracting and Retaining Medical Writers Through Mentoring Programs.....Laurel AB
Heidi Chapman, MS, Associate Principal Medical Writer, Trilogy Medical Writing and Consulting, Durham, NC
The demand for medical writers and the limited supply of good medical writers seems to be an industry-wide problem. How can mentoring programs help attract and retain medical writers? Participants will share their experiences with formal/informal mentoring programs and discuss how to leverage an existing program to attract and retain medical writers.
Focus Area: Leadership/Management

Breaking into Regulatory Writing.....Harborside C
Madison Hedrick, MA, Senior Medical Writer, ARTIVION, Little Rock, AR
Oftentimes, one can get pigeonholed into a focus area of medical writing. During this learning circle, we will discuss breaking into regulatory writing and share different career paths, such as grants, manuscripts, and CME.
Focus Area: Regulatory

Strategically Writing and Reviewing Regulatory Documentation: How to Implement for Success.....Laurel CD
Amanda Tricarico, Director, Strategy and Scientific Writing, Bristol Myers Squibb, Princeton, NJ
Strategic regulatory documents are the industry standard; however, making the shift to writing and reviewing documents with the Regulatory Reviewer in mind can be difficult to achieve. A well-defined framework for delivering education and training, change management, and continuous improvement is critical to success. Embedding Strategic Writing and Reviewing principles across all regulatory documents delivers focused, well-constructed documents that enable Health Authority review and approvals in the shortest time possible. This discussion will focus on implementation strategies including a learning platform, preparing for resistance, templates as guardrails, and continuous improvement techniques to drive success.
Focus Area: Regulatory

9:00 AM to 12:00 PM | Workshops *(pre-registration & additional fee)*

WS #21: The Foundations of Medical Writing.....Grand Ballroom I
Sharese Terrell Willis, PhD, ELS, CEO, Doc's Editing Shop, LLC, Memphis, TN

WS #23: Leadership Development for Medical Writers.....Grand Ballroom II
Angela Russell Winnier, PhD, Senior Director, Medical Writing Therapeutic Area Lead, Pfizer, The Woodlands, TX
Julia Forjanic Klapproth, PhD, President, Trilogy Writing & Consulting, Hessen, Germany

9:30 AM to 10:30 AM | Education Sessions

Building the Next Generation of Regulatory Writers from the Ground Up.....Harborside A
Moderator: Clare Marie Tomaselli, PhD, MD, MPH, Associate Medical Writer, Merck & Co., Inc., Satellite Beach, FL
Karla Haack, PhD, Medical Writer, General Medicine, Merck & Co., Inc., Canton, GA
Haley Guzman, Associate Medical Writer, Merck & Co., Inc., Lakewood, WA
A recent study from Research and Markets indicates that the global medical writing market will more than double in the next 8 years, yet the training opportunities to create a skilled workforce to meet this demand remain limited. Creating an entry-level medical writer training program addresses this disparity. Recruitment from talent pools with transferrable skills allows organizations to build well-rounded leaders. Panelists will share their experiences participating in such a program, how they leveraged their diverse work and educational experiences prior to becoming medical writers, how the program has positively impacted their medical writing department, and aspects of the program that were key to helping them succeed.
Focus Area: Career Development

Emerging Best Practices to Develop Master Protocols.....Harborside B
Swati Dadhich, PhD, Principal Medical Writing Scientist, Janssen Research & Development, LLC, Gaithersburg, MD
Kimberly Herman, PhD, Principal Medical Writing Scientist, Janssen Research & Development, LLC, Roxboro, NC
There is increased interest in developing adaptive trial designs that test multiple drugs and/or subpopulations in parallel under a single master protocol. Master protocols have the capability to provide Sponsors with leverage to conduct complex studies, given their inherent study design flexibility whilst maintaining the operational infrastructure for multiple substudies. This session will include an overview of the structure of master protocols, their advantages, challenges, and Janssen experience. The presentation will also discuss considerations in choosing a standard versus master protocol format.
Focus Area: Regulatory

Find Your Flow: Connect Ideas to Guide Readers Through Your Writing.....Harborside D
Crystal Herron, PhD, ELS, Managing Director, Redwood Ink, San Rafael, CA
Medical writers have the important job of reporting data and facts. But many medical writers merely string these facts together with periods, without creating clear connections between ideas. With this approach, medical writers run the risk of crafting boring writing that quickly loses readers' attention—and their interest in the message. Fortunately, medical writers can apply valuable writing principles to create a smooth flow that guides readers through the content, builds on their knowledge, and keeps them engaged

in the writing.
Focus Area: Core Knowledge/Skills

Protection of Commercially Confidential Information: Key Strategies for Preparing Submissions to CTIS.....Harborside E

Blake Schouest, PhD, Scientific Medical Writer, Aroga Biosciences, Inc., San Diego, CA

The EU Clinical Trials Regulation (EU CTR) and transition to the Clinical Trials Information System (CTIS) portal will increase the transparency of clinical trials conducted in the EU, but the regulation has also introduced new challenges for protecting privileged information from disclosure. The burden of identifying and protecting personal data and commercially confidential information (CCI) has fallen on sponsors, but there are currently few resources that provide practical approaches. This session will provide an overview and history of the EU CTR and outline key strategies/approaches for protecting CCI in documents submitted to CTIS. Additionally, participants will be guided through a case study in which CCI was redacted in a document published on CTIS.
Focus Area: Regulatory

10:30 AM to 11:00 AM | Beverage Break with the Poster Presenters.....Harborside Foyer

11:00 AM to 1:30 PM | Poster Takedown

11:00 AM to 12:00 PM | Education Sessions

Making Time for What Matters: Work-Life Fulfillment Through Prioritizing Needs.....Harborside A

Reggie Wilson, Personal Health Strategist, Fit for Freelance, Naples, FL

Often, entrepreneurs and ambitious startups assume they need strenuous pace, long days, and no work-life balance to be successful. Even the polarizing term “work-life balance” misses the point. Work and life are not a seesaw of balancing opposites; they are just two of many ways to meet your needs so you can survive and thrive in your environment. It’s time to align your day-to-day with your major values. In this session, get some clarity on what the healthy, fulfilling life of your dreams looks like, then build your lifestyle around that vision so you have the confidence to go after your business goals.
Focus Area: Wellness

Next-Level QC Review and Editing in Medical Writing.....Harborside B

April Welch, ELS, Associate Director, Quality Control and Editing, Global Regulatory Operations and Writing, PTC Therapeutics, Boston, MA

Quality control (QC) review and editing of scientific documents is more than checking numbers on a page and fixing misplaced commas. QC reviewers and editors serve a critical role as the last line of defense in catching costly errors before documents go out to their intended audience. Oftentimes, context and critical thinking are required to find easily overlooked errors and inconsistencies. These complexities are not easily taught but can be learned through experience, feedback from writers, and interaction with other QC reviewers and editors. In addition, efficient and fit-for-purpose processes and tools allow QC reviewers and editors to focus on the most important aspects of their reviews. Learn how to implement

these methods—and others—to bring your QC review and editing skills to the next level!
Focus Area: Core Knowledge/Skills

Writing About Health and Medicine for Earned, Owned, and Social Media.....Harborside D
Abbie Miller, MWC, Manager, Science and Medical Content, Nationwide Children's Hospital, Columbus, OH
Maximize your impact with writing and visualization strategies for getting your content noticed in earned, owned, and social media channels. Medical writers know that when it comes to sharing your message effectively, knowing your audience is crucial. It's also important to understand your channels. In this session, you will learn the differences among earned, owned, and social media channels. We'll cover health communication considerations for each channel and discuss the intersection between audiences and channels. You'll learn tips and tricks for writing, editing, creating visuals, and adapting content for each channel.
Focus Area: Health Communication

12:15 PM to 1:30 PM | Closing General Session with Lunch, Award Address & Annual Business Meeting (Sponsored by PerfectIt).....Grand Ballroom V&VI

Posters On Display

Posters will be displayed in the Harborside Foyer on the fourth floor starting Thursday, October 26.

A Mixed-Methods Study of Online Drug Information Needs Among Caregivers and People with Cancer
Christina Norwood, MS, ELS, Patient Cancer Information Manager, National Cancer Institute, Rockville, MD

Authorship: Begin with the End in Mind
Helene Bowen Brady, DNP, M.ED, RN, NPD-BC, NEA-BC, Nurse Scientist, Brigham and Women's Faulkner Hospital, Boston, MA and Adjunct Faculty, Regis College, Weston, MA
Kathleen Ahern Gould, PhD, RN, Nurse Scientist, Editor in Chief of Dimensions of Critical Care Nursing, Wolters Kluwer; Nurse Scientist, Brigham and Womens Faulkner Hospital, Boston, MA; Adjunct Faculty Boston College, Newton, MA

Deductive Writing: A Top-Down Approach to Authoring Top-Quality Regulatory Documents
Katie Henley, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc., Chapel Hill, NC
Linda Valsdottir, MS, Medical Writer and Consultant, Whitsell Innovations, Inc., Chapel Hill, NC

Diversity, Equity, and Inclusion – How Can Medical Writers Make a Difference?
Abigail Agoglia, Ph.D, Medical Writer and Consultant, Whitsell Innovations, Inc., Chapel Hill, NC
Dwyn DeSilver, BS, Medical Writer and Consultant, Whitsell Innovations, Inc., Chapel Hill, NC
Maureen Piotrowski, MBA, Medical Writer and Consultant, Whitsell Innovations, Inc., Chapel Hill, NC
Linda Rowse, B.S., MBA, Senior Medical Writer and Consultant, Whitsell Innovations, Inc., Chapel Hill, NC

Ensuring Consistent Terminology in CTD Module 3 (Quality)
Christian Small, MA, ELS(D), Manager, Global Regulatory CMC, BeiGene USA, Inc., Sacramento, CA

Leslie Kowitz, MA, ELS, Senior Manager, Global Regulatory CMC, BeiGene USA, Inc., Walnut Creek, CA

Faculty Physician Perspectives and Experiences Regarding Scholarly Clinical Writing: A Qualitative Interview Study
Karla D. Passalacqua, PhD, ELS, MWC, Lead-Medical Writing and Education, Henry Ford Health, Detroit, MI
Andrea L. Williams, MS, Medical Education Instructional Design Consultant, Henry Ford Health, Detroit, MI

How to Set Up Your Document for a Successful Quality Control Review
Katelyn Rivas, PhD, Medical Writer, Synterex, Arlington, VA

Impact of Medical Writing on Streamlining Clinic Tasks: Best Practice Instructions
Gloria Bunn, BSN, RN, CPN, Clinical Educator, Children's Healthcare of Atlanta, Atlanta, GA
Amanda Batlle, MSN, RN, CPNP-PC, NPD-BC, Manager Education & Quality, Children's Healthcare of Atlanta, Atlanta, GA
Brittney Frye, BSN, RN, CPN, Clinical Educator, Children's Healthcare of Atlanta, Atlanta, GA

In Rare Form: Considerations for Medical Writers in the Rare Disease Space
Elizabeth Tarasewicz, PhD, Associate Director, Principal Writer, Global Regulatory Operations and Writing, PTC Therapeutics, Inc., South Plainfield, NJ
Rosemary Barrett, MSRA, Medical Writer, Global Regulatory Operations and Writing, PTC Therapeutics, Inc., South Plainfield, NJ

In Vitro, In Vivo, and Everything in Between: A Standardized Template for Nonclinical Study Reports
Laura Hunter, PhD, Senior Medical Writer, PTC Therapeutics, South Plainfield, NJ
Sloane O'Neill, MA, Medical Writer I, PTC Therapeutics, South Plainfield, NJ

Maximizing Quality Control Review of Regulatory Documents
Kelly Danyow, Director of Editorial Services, Acumen Medical Communications, Oak Ridge, NJ
Jamie Spagnuolo, Lead Editor, Acumen Medical Communications, Somerville, MA

My Path to Becoming a Regulatory Medical Writer: Investing in the Next Generation of Talent
Rafi Naseer, MS, Medical Writing Scientist, Janssen Research and Development, Titusville, NJ

Overcoming Impostor Syndrome as a New Medical Writer
Samantha Ivey, Medical Writer and Consultant, Whitsell Innovations, Chapel Hill, NC
Claire Gianakas, Medical Writer and Consultant, Whitsell Innovations, Chapel Hill, NC

People Manager Coaching Framework Utilizing Multifaceted Learning Approaches
Carl Jameson, MS, CPC, Director, Regulatory Medical Writing, Janssen (Johnson & Johnson), Spring House, PA
Hazel Olway, MS, CPC, Principal Medical Writing Scientist, Janssen (Johnson & Johnson), High Wycombe, Buckinghamshire, UK

Robotic Process Automation for Regulatory Medical Writing Now and in the Near Future
Nika Matzke, PhD, Director, Janssen R&D, Raritan, NJ
Jennifer Seamon, PhD, Senior Manager, Janssen R&D, Raritan, NJ

Say the Right Thing: Developing a Program Lexicon for Cross-functional Teams
Mia Nagarajan, PhD, Director, Medical Writing, Infectious Disease and Vaccines, Merck and Co., Inc., Rahway, NJ
Desmond Ryan, MS, Director, Medical Writing, Infectious Disease and Vaccines, Merck and Co., Inc., Upper Gwynedd, PA

The Use of QuickBase as a Resource and Capacity Management Tool for Medical Writing
Jenna Cook, PhD, Associate Director, Regulatory Medical Writing, Janssen Pharmaceutical Research and Development, Raritan, NJ
Rey Valenzuela, PMP, Program Coordinator, Established Products, Janssen Pharmaceuticals, Established Products, Raritan, NJ

Training the Next Generation of CME/CE Writers: A Competency Model
Haifa Kassis, MD, President, Crisp Writing, Boston, MA
Donald Harting, MA, MS, ELS, CHCP, President, Harting Communications LLC, Downingtown, PA

Understanding Patients' Preferences for Receiving Health Communications and Information About Clinical Trials
Liza Selwan-Lewis, PhD, Principal Medical Writer, AbbVie, Irvine, CA
Trisha Rettig, PhD, Principal Medical Writer, AbbVie, Irvine, CA

Updating Documents - Best Practices and Strategies for Success
Sarah Wetzel-Strong, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc, Skaneateles, NY
Amanda Conway, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc, Lansdale, PA

What is Career Satisfaction to a Regulatory Medical Writer?
Robert Panek, PhD, Principal Medical Writer, ICONplc, Lancaster, NY
Sara Fernandes, PhD, Senior Principal Medical Writer, ICONplc, Raleigh, NC
Mauro Meloni, PhD, Principal Medical Writer, ICONplc, Raleigh, NC
Gregory Morehouse, MS, Principal Medical Writer, ICONplc, Deerfield, IL
Rona Grunspan, MD, Sr Director, ICONplc, Leawood, KS

Your Guide to Understanding the New European Union-Clinical Trial Regulations (EU-CTR)
Hannah Dewald, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc, East Orange, NJ
Katherine Oberdove, MS, PA-C, Medical Writer and Consultant, Whitsell Innovations, Inc, Kailua, HI