Pre-Conference Day: Wednesday, October 25

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

**Introduction to Statistics for Medical Communicators**
This workshop is designed for participants who have little or no background in statistics. Elementary statistical concepts needed to understand medical and scientific articles will be covered, including types of variables, levels of measurement, summary statistics, estimation and confidence intervals, and Student’s test. Emphasis will be placed on understanding statistical presentations and on reporting statistical information, not on calculations or mathematical explanations.

*Focus Area:* Core Knowledge/Skills

**Writing a Protocol in Compliance with ICH Guidelines**
This workshop is appropriate for medical communicators who are interested in writing or understanding the process for writing clinical study protocols. The teaching style will be primarily lecture with an exercise and opportunity for discussion. The workshop leader will focus on what regulatory/medical communicators need to know to write effectively a clinical study design that is compliant with the International Council for Harmonisation (ICH) guidance. The workshop leader will present the regulatory requirements and introduce how the use of templates can shorten the protocol development duration. Participants will learn how to gather information, manage the review process, and understand who will be using the protocol. Associated regulations and guidelines will be discussed, as well as the source documents and other tools needed for generating these documents.

*Focus Area:* Regulatory

**Clinical Study Report Writing: From Tables, Listings, and Graphs to Text**
This workshop is intended for writers and editors in clinical research with basic to moderate experience in developing clinical study reports (CSRs). With a focus on practical guidelines and examples, the workshop will give you a sense of how best to summarize information from statistical tables, listings, and graphs (TLGs) for a CSR. Examples will include selected passages from the demographics, and the efficacy and safety sections of a CSR, along with the related TLGs to clearly demonstrate the link between text and
TLGs. Emphasis will be on presenting data in a clear and concise manner. Many participants may benefit from first taking the Writing the Final Report of a Clinical Trial workshop.

**Focus Area: Core Knowledge/Skills**

**Principles and Practice of Visual Data Presentation**
This workshop is intended for medical writers and editors who have at least a moderate degree of experience working with graphical displays of data. The leader will emphasize group participation in exploring the solutions to graphic problems submitted by participants. Other means of portraying information, such as flow charts and box and whisker plots, will be discussed. For background knowledge, it is highly recommended that registrants have previously attended "Tables and Graphs and Statistics for Medical Writers and Editors" and either "Basics of Epidemiology" or "Interventional and Observational Research Design."

**Focus Area: Regulatory**

**Public Speaking for Private People: The Intensive**
We spend our lives communicating with other people. Yet as professionals, we not only communicate, we often need to win people over. For shy people, speaking in public can seem super intimidating and can often negatively impact their career success. This interactive workshop combines unique classroom learning with speaking practice exercises. Throughout the intensive, all participants are encouraged to give short talks to the group to facilitate group learning and dynamics. However, participants may choose to "pass" on some exercises, depending on the content and their level of comfort. The group will break into dyads and small groups to more intimately engage all participants, which provides another level of learning.

**Focus Area: Leadership/Management**

**11:00 AM to 5:00 PM | Executive Forum (by invitation only)**

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

**Health Economics for Medical Writers and Editors**
This workshop will introduce the principles of health economics to medical writers and editors who have little or no familiarity with this field. The presentation will address trial design, cost determination, sensitivity analysis, discounting, and analytic perspective—all in a simple, nonmathematical manner. Group discussion will emphasize application of these principles to examples taken from the published literature.

**Focus Area: Core Knowledge/Skills**

**Medical Editing Clinic**
Through a discussion of numerous editing and writing examples, you will learn strategies to improve the editing of your own and others’ medical documents, including some finer points of grammar and style. You will apply what you learn through small-group work on editing exercises. The knowledge and skills gained in the workshop should make an immediate difference in your ability to prepare a medical document that is clearer and more concise.

**Focus Area: Writing/Editing**
Fundamentals of Ethics and Practical Applications in Clinical Research
Ethical considerations associated with conducting clinical research will be explored in this workshop intended for medical writers, editors, and researchers with some experience/familiarity with regulated therapeutic development activities. The workshop will consist of short presentations on relevant ethical issues, with respect to therapeutic (drug, device, vaccine) clinical trials and group discussions on major ethical considerations raised in some real-world case studies. Topics include the importance of ethics in good clinical practice (GCP), as well as various protections provided to participants in clinical studies. Throughout, the workshop will focus on the central ethical issue in clinical study conduct: to ensure subject safety and well-being.
**Focus Area:** Regulatory

Visual Communication
The use of images to convey information continues to grow exponentially, and with good reason. Visual communication offers important advantages over text: delivery of a clear, unified message, ability to relay a message quickly, and better audience retention of content. Medical communicators tend to think of their expertise as writers, but to stay current and meet their employers’ and clients’ needs, they must learn to think—and communicate—more visually. In this workshop, you’ll learn about the science behind visual communication—why we need to present information visually and the benefits; trends in visual communication, such as infographics and visual abstracts; tools for content visualization; and best practices for creating effective visualizations that are appropriate for the audience and message. Throughout this workshop, you’ll have opportunities to stretch your creative muscles and work in small groups to practice communicating visually.
**Focus Area:** Core Knowledge/Skills

Project Management
With the ever-evolving role of the medical writer shifting from “document writer” to “document leader,” knowing how to successfully lead a team-based deliverable is just as critical as the writing itself. In this workshop, attendees will discover a practical approach to medical writing projects by applying project management skills and methodologies. Through a combination of presentation, demonstration, and hands-on activities, attendees will build their Project Management Tool-Kit with essential tips and effective tools that can be immediately implemented to successfully lead writing projects even when challenged with difficult stakeholders and accelerated timelines.
**Focus Area:** Regulatory

**2:30 PM to 3:30 PM | New to AMWA and Conference Session**

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)**

**How to Think Like a Leader**
You might have heard, “Some are born leaders...others have leadership thrust upon them.” But what makes
a leader? Being extroverted? Not necessarily. People skills? Not always. Impeccable timing? It might seem like that. Beyond personality, behavior, and plain luck, leadership is a way of thinking. During this intensive, discover the essence of leadership, explore the most prevalent thinking patterns among AMWA members, and how unexpected thinking habits affect the ability to lead. Attendees will take a free EEOC-validated online assessment to identify common habits of thinking across the group. Based on these results, Hope will examine whether these habits support or sabotage our work as leaders. By understanding how we think about ourselves and the world around us, we can all learn to think like—and become—effective and authentic leaders.

Focus Area: Leadership/Management

4:00 PM to 5:00 PM | Speed Networking

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.

Conference Day 1: Thursday, October 26

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

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.

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

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

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**
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?**
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**
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**
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.
Take the Leap! Steps to Integrate AI into Your Work
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
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)
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
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?
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
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 to 1:45 PM | Opening General Session with Award Address

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

Do More With Less Faster: Project Management for Medical Communicators
Medical Writers, by virtue of their role throughout a project, with particular focus on the deliverable near the end, often inherit project management responsibilities. Whether formal or not, the medical writer is often the de facto project manager, responsible for ensuring the timely delivery of source documents and input from their colleagues. This workshop will cover project planning, monitoring, and execution, and will highlight the required communication skills and the challenges faced during the project lifecycle. Discussion will include project management theory and practical applications, both within the context of a matrix organisation and as an independent providing services to clients. A medical writing group may also adopt these practices to better control their own destiny. This workshop will be a combination of lecture and in-class exercise, and will include discussions based on analysis of the scenarios presented in the homework. While the majority of the presentation will be didactic, there will be opportunity for attendees to share their experiences and ask questions throughout the presentation.

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

Mentoring Other Writers—How to Begin
Teaching our peers provides opportunities for sharing valuable knowledge, often gained through hands-on experience, but where do you start in sharing this knowledge? This workshop focuses on the skills needed to serve as a mentor, the mentee and mentor relationship, tools that can be used to assess the needs of the mentee, and how to develop a mentorship plan. Workshop participants will have the opportunity to immediately apply the information shared in this workshop to identify mentor opportunities within their current role and develop an individualized mentorship plan.
Focus Area: Career Development

Writing the Clinical Study Abstract
Abstracts are often the first piece scientific/medical literature we analyze to determine the value of a manuscript or a scientific presentation. A clear, concise, and self-contained abstract is vital, but restrictions on the structure and/or word count may make it challenging to convey all critical information. The objectives of this workshop are to evaluate the elements of the clinical study abstract (both journal and conference) and to discuss methods to write concisely and with the greatest impact. Both conference and journal article abstracts will be covered. The pre-workshop assignment provides exercises in writing an abstract and will be used for discussion in the workshop.
Focus Area: Scientific Publications

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

Entering, Navigating, and Thriving in the Field of Medical Communications
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
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

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

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

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 from Synterex, Inc.

AGILEWriter.ai: Your Automated Plain Language Document Solution
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.

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
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)
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
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.
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

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

The Right Tools for the Right Job: Cutting Through the Aland Automation Hype in Medical Writing

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 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 | Speed Networking

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.

Conference Day 2: Friday, October 27

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

See listings at the end of this document.

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

Writing the Investigator’s Brochure

This workshop is intended for beginner to moderately experienced writers in the pharmaceutical industry who want to improve their understanding of the investigator brochure (IB). The workshop leader will focus on the regulatory and informational needs of the audience and how to use best practices to communicate
information on the drug. Relevant regulations will be reviewed, and required topics discussed. The evolution of the IB from phase 1 to phase 4 will be elucidated. A discussion will focus on how to prepare an IB using subject matter experts.

**Focus Area:** Regulatory

**Proofreading: Strategy for Document Quality Control**

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

**Focus Area:** Writing/Editing

**How to Interpret and Write About Clinical Trial Data**

When writing about clinical trial data, the days of simply repeating numbers from a table have passed. Whether you are writing about data for regulatory reviewers, journal readers, patients, or other groups, your audience wants and deserves to read interpretations about what the data mean. But how does one write content that accurately and effectively interprets the data? In this workshop, the science (and art!) of interpreting data from clinical trials will be discussed and practiced, with a focus on understanding different statistical approaches to gain confidence in what can (and cannot) be said about the data. Techniques for getting stakeholder input and alignment on key interpretations and messages will also be presented. Embrace your role as a data interpreter with the knowledge and ability to lead your team through the creation of clear, accurate documents that go beyond the numbers in a table.

**Focus Area:** Regulatory

**Writing Clinical Study Report Lay Summaries—A Survivor’s Guide**

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

**Focus Area:** Regulatory

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

**CTD Structure: From IND to NDA**

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
Immunology Essentials for Medical Writers
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.

Roads Leading to Approval: The Right Level of Detail for CMC Submissions
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.

The Value of Medical Writing: A Toolkit for Defining, Achieving, and Communicating Success
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.

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

Yseop Copilot: Automate Medical Writing with AI
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
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
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
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

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

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 (e.g., to allow a first-in-human study), both nonclinical and clinical (e.g., 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 from ZYLiQ

ZYLiQ is going to give medical writers what they need, time.

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.

1:30 PM to 2:30 PM | Education Sessions
**Editing Grant Applications: Top Tips for Success**

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

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**How to Prevent Medical Writer Burnout**

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 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

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**Medical Writing and Editing Internships: Preparing the Next Generation of Medical Communication Professionals**

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

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**Offer Accepted, Now What? Keys to Successful Onboarding and Career Development From Both Perspectives**

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
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 to 2:30 PM | Product Showcase from Ideagen

Reimagine document reviews with Ideagen PleaseReview: Accelerate timelines, ensure audit-readiness and deliver better quality documents.

Ideagen help 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, Ideagen Quality 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.

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

Jam Session for Medical Writers and Editors Who Work on Research Manuscripts (90 minutes)
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)
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)
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 1
Advisory Boards: A Deep Dive
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
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?
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
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
Applying Clinical Experience to Medical Writing – Write for Your Audience
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)?
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
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**
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

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**Conference Day 3: Saturday, October 28**

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**
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**
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

**Inclusive Language for Scientific Writers and Editors**
Join us for updated guidance on inclusive language from members of the AMA Manual of Style committee, including what's new since last year's conference. Instead of a didactic presentation, this year, we encourage attendees to bring questions, suggestions, and real-world examples to work through together, from patient-first language to terms used to talk about sex and gender, study participants' age, and related
topics. Examples from the literature will also be used to talk about approaches to use of inclusive language and where to look for guidance.

Focus Area: Scientific Publications

**Strategically Writing and Reviewing Regulatory Documentation: How to Implement for Success**

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)*

**The Foundations of Medical Writing**

All medical writers and editors need a solid understanding of the building blocks of writing, such as grammar, punctuation, and sentence structure. Also needed are the skills to use these building blocks to write clear and concise documents that meet readers’ expectations. This workshop focuses on techniques to communicate information clearly and efficiently in all genres of medical writing. Participants will learn how to use rhetorical principles to help them through the stages of the writing process, how to convey the main message in a document, and how to search for and cite credible references to support content appropriately.

Focus Area: Writing/Editing

**Grant Editing**

The workshop leader will provide participants with an understanding of the editing concepts inherent in "grantsmanship," the strategic elements behind preparation of a successful grant application. To register for this workshop, it is recommended that you have already taken Grant Writing: NIH and Non-NIH Options and Strategies for Writing and Editing NIH Grants, or have 3 years of experience in editing grant applications.

Focus Area: Grantsmanship

**Leadership Development for Medical Writers**

In our current global, remote working environment, the value of medical writing depends on excellent interpersonal, active listening, and influencing skills in addition to strong technical writing ability. Much of our existing training programs focus on technical/knowledge-based competencies. But developing medical writers to be leaders (of a project, of other writers) should be an essential focus. As for any role, good leaders do not emerge fully formed from the seed of a medical writer. There is a specific skill set needed to make a great leader/people manager capable of successful collaborations with cross-functional, global teams and influential development of other medical writers. This workshop will summarize the characteristics of the training environment that promote development of these skills and provide
behavioral tips and real-world examples to illustrate the skill set and characteristics desired in a medical writing leader.

**Focus Area:** Leadership/Management

**Public Speaking for Private People: The Intensive**
We spend our lives communicating with other people. Yet as professionals, we not only communicate, we often need to win people over. For shy people, speaking in public can seem super intimidating and can often negatively impact their career success. This interactive workshop combines unique classroom learning with speaking practice exercises. Throughout the intensive, all participants are encouraged to give short talks to the group to facilitate group learning and dynamics. However, participants may choose to "pass" on some exercises, depending on the content and their level of comfort. The group will break into dyads and small groups to more intimately engage all participants, which provides another level of learning.

**Focus Area:** Leadership/Management

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

**Building the Next Generation of Regulatory Writers from the Ground Up**
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**
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**
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
Protection of Commercially Confidential Information: Key Strategies for Preparing Submissions to CTIS

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

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


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

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

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
12:15 PM to 1:30 PM | Closing General Session with Award Address & Annual Business Meeting *(Lunch Provided)*

**Roundtable Discussions**

*Roundtables will take place on Friday, October 27, from 7:30 to 8:45 AM. Pre-registration & an additional fee apply.*

- Attracting and Retaining Medical Writers Through Mentoring Programs
- Attracting New Talent Through Regulatory Medical Writing Internship and Shadowing Opportunities
- Authoring the Informed Consent Form (ICF): Current Challenges and Opportunities
- Being Our Own Worst Critic: Using Critical Thinking Skills to Strengthen Science Communication
- Best Practices for Developing Patient-Centered Online Health Information
- Best Practices for Effective Kick-Off Meetings for Abstracts, Posters, Presentations, and Manuscripts
- Beyond the Data: Strategies for Managing Teams Through Critical Writing Projects
- Bringing Science to Life: Creating Compelling Videos and Documentaries to Showcase Scientific Research
- Building a Scalable Recruiting Model and Other Innovative Approaches to Attracting Talent
- Certification of Editors in the Life Sciences
- ChatGPT and the Future of Medical Writing
- Collaborative Authoring
- Conducting Original Research on Medical Writing: How to Get Started?
- Discover Your Calling: Mastering Your Medical Writing Niche
- DMPs All Around: How Do We Help Researchers Fulfill Data Management and Sharing Requirements?
- Document Complexity Tool to Assist With Resourcing Decisions
- Driving Teams Towards Optimized Submissions. How Can Medical Writing Help Build the Case For Change?
- Fact Checking and Annotating for Medical-Legal Review (MLR)
- I Have My Abstract: Now What? Tips and Shortcuts for Creating an Effective Poster
- Impact of Medical Writing on Streamlining Clinic Tasks: Best Practice Instructions
- Inclusive Language for Scientific Writers and Editors
- Objective Method for Selecting Resource Management Tool - Comprehensive Assessment with Quantitative and Qualitative Measures
- Optimizing the Value of QC: What do Medical Writers Want? What can QC Provide?
- Patient-Focused Drug Development: How Can I Be a Patient Advocate as a Medical Writer?
- Quick Onboarding and Preparation for Medical Writers to Support Regulatory Submissions
- Quick Tips for Using Online Reference Management Software (Mendeley) for Manuscript Preparation
- Resilience: Burnout Prevention and Management for Medical Communicators
- Risk Management Plans: A Discussion on Best Practices and Lessons Learned
- Roles and Responsibilities of the Medical Copywriter in Promotional Medical Writing
- Scientific Writing in Academia: Building Resources and Support
- Statistically Speaking: How to Avoid Confusing or Misleading Your Audience
- Staying Curious: Understanding Motivations in Building and Managing Medical Writing Teams
- Strategically Writing and Reviewing Regulatory Documentation: How to Implement for Success
- Strategies for Driving Successful Reviews
- Strategies for Resolving Workplace Conflict
- Study Smarter: Creating an MWC® Exam Study Plan That Works for You
- The Art of Saying "No"
- The Role of Medical Writers in Authoring the Integrated Summary of Immunogenicity Report for Biotherapeutics
- The Well-Rounded Medical Writer: It Goes Beyond Good Writing
- Transitioning from Clinical Research to Medical Writing
- Understanding Early Clinical Writing
- Using Theoretical Scenarios to Guide Decision-Making
- Value of Medical Writing Toolkit Discussion: Interacting with and Influencing Key Stakeholders
- Value of Medical Writing: Writers’ Toolkit
- What is Career Satisfaction to a Medical Writer?
- When Should Medical Writers Be Publication Coauthors?
- Writing Strategies for Expediting Initial Investigational New Drug (IND) Applications
- Your CV Speaks First – Tips on Presenting Yourself Well for the Medical Writing Opportunity

**Posters**

- A Mixed-Methods Study of Online Drug Information Needs Among Caregivers and People with Cancer
- Authorship: Begin with the End in Mind
- Collaborative Writing in the Publication Process Among Authors in Health Sciences
- Deductive Writing: A Top-Down Approach to Authoring Top-Quality Regulatory Documents
- Developing Undergraduate Curriculum for Medical Writing in Higher Education
- Diversity, Equity, and Inclusion – How Can Medical Writers Make a Difference?
- Ensuring Consistent Terminology in CTD Module 3 (Quality)
- Faculty Physician Perspectives and Experiences Regarding Scholarly Clinical Writing: A Qualitative Interview Study
- How to Set Up Your Document for a Successful Quality Control Review
- Impact of Medical Writing on Streamlining Clinic Tasks: Best Practice Instructions
- In Rare Form: Considerations for Medical Writers in the Rare Disease Space
- In Vitro, In Vivo, and Everything in Between: A Standardized Template for Nonclinical Study Reports
- Maximizing Quality Control Review of Regulatory Documents
- My Path to Becoming a Regulatory Medical Writer: Investing in the Next Generation of Talent
- Overcoming Impostor Syndrome as a New Medical Writer
- People Manager Coaching Framework Utilizing Multifaceted Learning Approaches
- Robotic Process Automation for Regulatory Medical Writing Now and in the Near Future
- Say the Right Thing: Developing a Program Lexicon for Cross-functional Teams
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