2024 Spring Conference

Friday, May 3, 2024
8:00 am to 5:00 pm
The Friday Center, Chapel Hill, NC

Navigating Changes in Medical Writing
2024 Conference Schedule

Morning Educational Sessions
Attendees can attend either Track A or Track B at any time.

Track A: How to Think Like a Leader

Our ability to lead affects every aspect of our lives. Leadership is a mindset—a collection of habits of thinking. This session examines the 3 most common ways participants think and how these habits support or sabotage our work as leaders. In advance of the workshop, participants will take a free validated assessment that measures mindset. By understanding the pitfalls and benefits of our habits of thinking, we can all learn to think like—and become—effective and authentic leaders.

_Hope Lafferty, AM, ELS, Writer, Trainer, and Coach, Hope Lafferty Communications & Coaching_

Track B: PIPs - Initial Submission and Modifications

A Paediatric Investigation Plan (PIP) is an early opportunity and EU requirement to outline the investigation of a new drug in adolescents and children. The initial PIP is a comprehensive set of documents that defines the disease to be studied and plan for investigating the new drug in the applicable pediatric population. This presentation will lay out the components and process for the PIP life cycle, including initial PIP applications and modifying adopted PIPs.

_Sam Suarez, PhD, Senior Principal Medical Writer, AbbVie_

Sponsor breakout session with refreshments

Track A: Understanding The Promotional Review Process for Beginning Medical Writers

Tailored for new promotional medical writers or those seeking insights into the Promotional Review Committee (PRC) process, this session explores the vital role of PRC in reviewing and approving pharmaceutical promotional materials. The session equips participants with essential background knowledge for effective collaboration in the industry, providing a foundational understanding of promotional review intricacies and its pivotal role in crafting impactful medical writings.

_Sendra Yang, PharmD, MBA, Medical Information Professional_

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2024 Conference Schedule

Track B: Navigating Regulatory Medical Writing in an Evolving Clinical Landscape

This presentation aims to highlight recent changes to the ICH E6 Good Clinical Practice guideline and how regulatory medical writers can leverage this information, manage the rapidly evolving drug development landscape, effectively engage stakeholders, maintain data integrity, and drive efficient and patient-centric programs.

Andrea Clark, PhD, Senior Regulatory Medical Writer, Aroga Biosciences

Lunch roundtables (see page 5)

Networking Session

Afternoon Educational Sessions

Track A: Lean Writing Implementation: A Success Story

This session will define lean writing and its importance when writing clinical regulatory documents. The impact of transparency requirements on clinical regulatory documents will be described. Details will be provided on how a lean writing initiative was created and implemented at a mid-size pharmaceutical company, which included an overhaul of protocol, IB, and CSR templates and process, as well as creation of "drop-in" in-text tables. Lessons learned and metrics for success will be shared.

Sarah Wilson, MS, Director, Head of Medical Writing, Alkermes

Track B: Plain Language Double Feature

Pulling It All Together – Plain Language Summary Regulations and Best Practices

Authoring plain language summaries (PLS) to meet regulatory requirements requires multiple skill sets. These include an understanding of the ten required elements for European Union PLS. Another skill is the ability to locate relevant information in large source documents, such as clinical study reports and protocols, to author accurate results and safety sections. Finally, authors must have a knowledge of health literacy best practices to meet PLS reading level requirements. In this presentation, we will discuss how to integrate these skills to successfully author PLS.

Lee Holland, PharmD, MPH, Associate Director, RSM, Plain Language Summaries, Certara

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Lost in Translation: The Importance of Plain Language Summaries of Publications (PLSPs)

This session will discuss what a PLSP is, why it is important, and what tools and guidelines are available when creating a PLSP. Attendees will get hands-on practice in creating a PLSP. Chantelle Rein-Smith, PhD, CMPP, Principal Medical Writer and Consultant, Whitsell Innovations, Inc.

Sponsor breakout session with refreshments

Track A: Building Atomic Habits to Achieve Audacious Goals

Do you feel pressure to work quickly and efficiently with limited resources? "Atomic Habits" and "The Oz Principle" offer practical solutions. These books teach us to make small, consistent improvements to achieve long-lasting results and take ownership of our actions to achieve ambitious goals. Let's discuss how to apply these principles to your career. Demetrius Carter, MBA, PMP, RAC-US, SVP, Regulatory Sciences & Medical Affairs, Certara

Track B: Resume review
2024 Roundtable Sessions

Due to limited seats, switching roundtables is not possible.

1) Write Like a Pharmaceutical Boss: Drug Info Pearls Writers Need to Know
Get ready to master the art of writing about medications! Join our roundtable, "Write Like a Pharmaceutical Boss," for beginning medical writers. Whether you write for consumers or professionals, grasp the essentials. Explore common medication queries, reliable information sources, and key terminology. Craft precise, reader-friendly content that excels. Join us!
Mechelle Renee Akers, PharmD, RPh, CPh, Freelance Medical Writer, Lucente Medical Communications

2) Helpful Tools for Editing in Medical Writing
Medical Editors use different types of resources to ensure accuracy, readability, and clarity. Share your favorite editing “helper” with the table so we can discuss the resources used for assisting medical writers and editors with tasks ranging from managing project time to fact-checking, invoicing, security, etc. We will explore commonly used reference materials such as style manuals, medical dictionaries, AI resources, and software options that help editors with specific projects.
Leslie DeCraene, Certified Medical Writer and Editor, Owner Precise Med Prose

3) Redefining Traditional: Off the Bench and into the Medical Writing Field
This session will be a candid conversation about my decision to return to medical writing after spending a decade at home with family. Adjusting to the transition and becoming educated on regulatory writing has offered many learning opportunities. I will talk about my experiences, describe my personal exploration of the medical writing field, and share perspectives of colleagues. I also will facilitate discussion around the challenges and successes in the constant pursuit of work/life balance.
Kate Pedone, PhD, Medical Writer, Whitsell Innovations, Inc.

4) The Art of Saying “No”
If you struggle to assert yourself and say "No" when you need to, this session is for you! We'll share experiences to highlight the importance of setting boundaries at work, then discuss some of the obstacles to saying "No". The discussion will end with suggestions for finding a personal approach to saying "No" that feels natural and comfortable. This interactive session is suitable for writers of all experience levels, including those seeking to enter the field.
Abigail Agoglia, PhD, Medical Writer, Whitsell Innovations, Inc.
2024 Roundtable Sessions

Due to limited seats, switching roundtables is not possible.

5) Upskilling in Preparation for AI-Enabled Writing
The world of medical writing is advancing at a rapid pace, thanks to the use of generative AI tools. In this roundtable discussion, we will explore the new skill sets that medical writers need to master to use AI technologies to their fullest potential. As AI tools revolutionize content creation, medical writers must adapt and learn new competencies to thrive in this highly competitive field. By examining the strengths and weaknesses of generative AI in medical writing, this presentation emphasizes the importance of understanding AI-generated content and its implications for scientific communication. Additionally, we will delve into the vital role that expertise, ethics, and quality control methods play in the dynamic relationship between medical writers and AI technologies. This insightful discussion will equip medical writers with the knowledge and skills they need to stay ahead of the curve in the ever-evolving medical and regulatory writing field. Join us as we cover these essential aspects and embrace the exciting possibilities of AI-powered medical writing.
Demetrius Carter, MBA, PMP, RAC-US, SVP, Regulatory Sciences & Medical Affairs, Certara

6) Let’s Talk Money: Financial Decision Making While Freelancing
In this roundtable session, Simone will share some ideas on what to consider financially when entering the freelance world and how it differs from W2 work; what to consider in working as a contractor; and how to invest in yourself and your future as a freelance worker. If you have ideas you would like to discuss or are seeking ideas on how to think about finances as a freelancer, this table provides an environment to share tips and advice whether you are thinking about entering this space or are a seasoned veteran.
Simone Otto, PhD, Manager Medical Writing, Propharma

7) The Ins and Outs of Breaking into Medical Writing I and

8) The Ins and Outs of Breaking into Medical Writing II
In these roundtable sessions, attendees will have the opportunity to engage in a discussion with an experienced medical writer about their unique path to breaking into the medical writing field. The presenters will discuss with attendees the soft and technical skills that an individual can develop to demonstrate proficiency within the medical writing field in addition to the programs and opportunities available locally and nationally to further develop these essential skills.
Stephanie M Byrd, PhD, RAC and Julia DiFiore, PhD, Senior Clinical Research Scientist and Clinical Research Scientist II, Syner-G BioPharma Group
9) Strategies for Driving Successful Reviews

Review is a critical component of the document writing process, but often the outcome does not meet our needs or expectations. As medical writers, how can we ensure that reviewers clearly understand their roles and responsibilities, focus only on the appropriate content and messaging, and provide actionable comments? Join this roundtable for a discussion of how to drive a successful review. We will share our successes, failures, and tips for effective communication during the review process.

Laura Bisogno, PhD, Medical Writer, Whitsell Innovations, Inc.

10) How to Think Like a Leader—Roundtable discussion

Our ability to lead affects every aspect of our lives. Leadership is a mindset—a collection of habits of thinking. For attendees of How To Think Like A Leader, this roundtable is a deeper Q&A for even more insight about how to optimize one’s habits of thinking to lead more effectively. This roundtable is open to all conference attendees even if they do not attend the full workshop. Participants are encouraged to take the free assessment at habitfindercoach.com/hope and bring their results.

Hope Lafferty, AM, ELS, Writer, Trainer, and Coach, Hope Lafferty Communications & Coaching
Registration Details

Click here to register online

*Get member price by joining AMWA before registering.

An automatic email will be sent from AMWA to confirm registration and provide a receipt.

When you register, choose the Roundtable Session you would like to attend (only 1). Changes to your selection will not be permitted.

Questions?
For questions related to the conference program or registration, please contact Abigail Agoglia, AMWA Carolinas Conference Chair, at conferencechair@amwacarolinas.org.

Cancellation/Refund Policy
You may cancel your registration before 8AM on April 26th by emailing conferencechair@amwacarolinas.org. A refund of 90% of your registration payment will be processed within 2 weeks of cancellation and remitted via check or Zelle. No refunds are available after the deadline, and no credits will be issued for failure to attend, late arrival, or early departure.

REGISTRATION LINK: HTTPS://TINYURL.COM/4348E878