27th Annual Princeton Forum

Saturday, May 4, 2024

Virtual Workshop 10:00 AM – 3:00 PM EDT

Registration: Register now! Registration will close at 5:00 pm EDT on Friday, May 3, 2024
Costs: AMWA members $20, non-members $25, students/postdocs FREE.
Format: Virtual Meeting on Zoom
Questions? Contact princetonforum@amwa-dvc.org with the subject line *"Question about AMWA-DVC Princeton Forum"*

10:00 AM – 10:05 AM	**Welcome** – Dan Benau, PhD, and Kent Steinriede, MS
10:05 AM – 10:55 AM	***So You Want to be a Regulatory Writer? Identifying Your Skills and Gaining Confidence*** — Lydia Morris, PhD, Senior Regulatory Writer, Novartis
11:00 AM – 11:50 AM	***Strategies for Leading Successful Diversity Plans*** — Mia Nagarajan PhD, Director, Medical Writing, and Snow Zhao, PhD, Principal Medical Writer, Merck
12:00 PM – 12:50 PM	***Medical Writing Technology Update*** — Dan Benau, PhD, Retired Professor of Biomedical Writing
1:00 PM – 1:50 PM	***Developing Efficient Regulatory Submissions: The Critical Role of the Submission Lead*** — Mark Bowlby, PhD, Director Global Submissions, Certara
2:00 PM – 2:50 PM	***Uses and Abuses of ChatGPT and Other AI*** — Erik Benau, PhD, Assistant Professor, Psychology, SUNY at Old Westbury

1. So You Want to be a Regulatory Writer? Identifying Your Skills and Gaining Confidence

Description:

Regulatory writers help compile the documents that must be submitted to regulatory authorities for drug development and approval. This type of writing is highly specialized and requires an exacting approach to the work. Given these features, this seminar will discuss what a regulatory writer does and the potential paths to becoming a regulatory writer. We will also explore the careful assessment of one's professional background and skills as an important first step in preparing for an entry-level regulatory writer role.

During this seminar, attendees will learn

- The typical responsibilities of regulatory writers during regulatory document development;
- The specific skills needed to carry out the daily tasks of regulatory writers; and
- Ways to identify experiences in their background that align with skills sought by regulatory writing hiring managers.

2. Strategies for Leading Successful Diversity Plans

Description:

Diversity in clinical trials is critical to ensuring proper representation of underrepresented populations, reducing disparities in health outcomes along demographic groups (eg, race, ethnicity, age, sex, gender, etc.), and improving health equity. Since 2016, the United States Food and Drug Administration (FDA) has issued guidances for improving diversity in clinical trials and, in 2022, published a draft guidance on elements of a diversity plan to be submitted to the investigational new drug (IND) application. The diversity plan would improve enrollment of participants from underrepresented racial and ethnic subgroups to allow accurate evaluation of safety, efficacy, and dosing regimen and outline a strategy to assess the impact of race and ethnicity on patient outcomes.

Medical writers have the requisite knowledge, leadership skills, and expertise to drive the development of high-quality diversity plans in cross functional teams. This seminar will provide background information on the status of diversity in clinical trials, discuss the FDA regulatory requirements for clinical trials and diversity plans, highlight the role of the medical writer in leading the development process for diversity plans, and present some potential challenges that they may encounter and proposed solutions.

During this seminar, attendees will learn

- FDA recommended diversity plan elements;
- The medical writer's role in developing diversity plans;
- The use of inclusive language in diversity plans; and
- Potential challenges and proposed solutions.

3. Medical Writing Technology Update

Description:

If you have a subscription to Microsoft 365 and use the online version or have updated your software, you may have noted some changes. Unless you work from a highly modified MS Word template, the default font used to be Calibri; now it's Aptos. If you wanted to see the codes that may be embedded in your document, you used to click the pilcrow symbol. That has disappeared from the default settings. How do you get it back? Did you know that Grammerly ™ can set off some AI detectors? These and other technical updates will be part of this presentation.

During this seminar, attendees will learn

- Some changes in a few key functions in MS Word and PowerPoint;
- Some probable direction that artificial intelligence will take that affect medical writers; and
- Some changes in submission technology affecting regulatory writing.

4. Developing Efficient Regulatory Submissions: The Critical Role of the Submission Lead

Description:

Modern regulatory submissions are often very complex; therefore, having a knowledgeable person with regulatory writing expertise is needed to lead a cross-functional team through the regulatory submission process. In conjunction with the Regulatory Affairs Lead, a Regulatory Writing Submission Lead

- Guides the team in development of a comprehensive eCTD content plan;
- Develops the strategy to align document authoring, reviewing, and publishing activities to meet the targeted submission date;
- Enables early planning to develop a submission strategy for multiple health authority submissions;
- Ensures consistency in messaging and adherence to regulatory requirements; and
- Leads best practices discussions as key tools for success.

This session will explain the Submission Lead role, benefits the role brings to a team, and the developmental pathway to becoming a Submission Lead.

During this seminar, attendees will learn

- To describe the roles and responsibilities for which a Submission Lead may be responsible on a submission;
- Identify the key components for a proposed career developmental pathway to become a Submission Lead; and
- Apply leadership principles to strengthen submission team members' constructive engagement.

5. Uses and Abuses of ChatGPT and Other AI

Description

The thought that we could have a machine one day generate language imperceptibly similar to human language predates Noam Chomsky's dissertation. The early days of that era have arrived with great

promise, amazement, terror, disappointment, risk, pitfalls, successes, failures, and above all, ways to save time and help you write more effectively and efficiently. This talk will present a brief overview of what generative AI is (including ChatGPT), how it is being (mis)used and monitored in academia, and how to use it relatively safely and effectively. Examples include beefing up letters of recommendation, finding that word that's on the tip of your tongue, checking your grammar, running your statistics for you, and breaking up a mental log-jam so you can finish that project and continue on your day.

Faculty

Lydia Morris, PhD, Senior Regulatory Writer, Novartis

Lydia received her PhD in Genetics and Molecular Biology from Emory University in 2012. After completing a post-doctoral position at the University of North Carolina at Chapel Hill, she landed her first role as a medical writer in educational and training writing in 2016. Lydia also has several years' experience in medical communications writing abstracts, manuscripts, and slide decks in the CRO space. In addition, she briefly returned to UNC in Fall 2017 to teach a semester of Science Writing for graduate students in the Biological & Biomedical Sciences PhD program.

Lydia has been active in the AMWA Carolinas Chapter, serving as the treasurer from 2017 to 2019 and the chapter president from 2020 to 2021. She enjoys talking about her medical writing journey and is passionate about informing and inspiring people who are interested in medical writing as a career. Lydia is currently a Senior Regulatory Writer at Novartis and also sits on the regulatory subcommittee of the 2023-2024 AMWA Education Committee.

Mia Nagarajan PhD, Director, Medical Writing, Merck

Mia received her PhD in Molecular Biology and Microbial Genetics and has worked in various organizations with over 15 years of industry experience in medical, clinical, and regulatory writing in different therapeutic areas. She has written a broad range of regulatory documents and led programs and regulatory submissions for worldwide markets. She has contributed to important department initiatives, is a focused authoring and clinical study report subject matter expert for medical writing, and a mentor, coach, and trainer for junior writers. As a manager, Mia actively engages with and guides cross-functional teams, shares knowledge, and fosters a positive, collaborative culture for continuous learning and career development.

Snow Zhao, Principal Medical Writer, Merck

Snow holds a PhD in Cell Biology and has 8 years of industrial experience in preparing regulatory documents across various therapeutic areas. Snow has led regulatory submissions for worldwide markets and serves as a subject matter expert for diversity plans. Additionally, she is a mentor, coach, and trainer for junior writers.

Dan Benau, PhD, Retired Professor of Biomedical Writing

Dan, Co-Chair of the Princeton Meeting this year, was an active regulatory writer from 1990 to 2006. He went from industry to academia and was appointed Director of Biomedical Writing Programs at the University of the Sciences and Professor of Biomedical Writing. Dan retired from USciences in 2021. He has been active in medical writing professional organizations including AMWA, DIA, and RAPS. Dan is currently teaching as an adjunct professor in the University of California San Diego Extension Studies Certificate Program in Medical Writing and Editing.

Mark Bowlby, PhD, Director Global Submissions, Certara

Mark has over 28 years of experience in the clinical research and drug development industry. During the last 13 years, he has led numerous small molecule and biologics marketing applications and investigational product applications to the US Food and Drug Administration and European Medicines Agency. Mark has led the authoring of study level (eg, Investigator's Brochures, clinical study reports) and submission level (eg, clinical summaries, overviews, and briefing packages) regulatory documents. Earlier in his career, Mark planned and wrote numerous biomedical manuscripts, posters, and slides regarding his scientific research. His therapeutic areas of expertise include ophthalmology, cardiovascular, neurology, psychiatry, chronic pain and nephrology. Mark has an expert understanding of drug discovery and development approaches used in the current biopharmaceutic environment.

Erik Benau, PhD, Assistant Professor, Psychology, SUNY at Old Westbury

Erik is a licensed clinical psychologist and an assistant professor of cognitive psychology at SUNY at Old Westbury. He graduated with a PhD in Clinical Psychology from The University of Kansas and completed a T32 Postdoctoral Fellowship in Adolescent Psychiatry at Columbia University Irving Medical Center. Prior to this, he completed a Masters in Health Psychology at the University of the Sciences in Philadelphia, and a Bachelor's in Cognitive Science from Hampshire College. He researches the intersection of stigma, cognition, emotion, and psychopathology using multimodal methods ranging from psychophysiology to meta-science. Erik's present interests include the effects of stigma of mental illness, identifying suicide risk (especially in minoritized populations), and figuring out where emotions come from.