a clear as could it be. Additionally, he suggested adding a plain language abstract to the study synopsis, especially when the sponsor does not plan to provide a separate plain language summary. Other handy tools include developing a plain language glossary and templates.

Prepare for Redaction and Anonymization
For participant information, AVOID the following:
- using pronouns in patient narratives; consider using "the patient" instead,
- using "verbatims" with quotes by the investigator, as these may include unique circumstances that could describe a patient, or
- including patient IDs in images of tables. If patient IDs are required, then either include tables with selectable text (instead of copied as an image) or keep table formatting consistent across all images to ease redaction.

For study or sponsor staff information and other identifiers, AVOID the following:
- adding names of the study staff with their organizational titles; instead, use only their study role,
- including contact information such as fax, phone, or email,
- incorporating CVs or certificates or adding them to an appendix,
- adding personal identifiers to bookmarks (such as patient IDs, names, study admin), or
- providing treatment allocation and group information throughout the document.

Other final considerations:
- Limit duplication that requires duplicate redactions, for example, providing a table with patient narrative information followed by text with some of the same information.
- In the sample Case Study Report Case Report Form (CRF), use a clearly fake patient ID like XXXX or 0000 (not even "1234").
- Aim to keep page numbering consistent between the CSR and the PDF copy to help remove out-of-scope information.
- Because foreign language pages are out of scope, you may keep these in an appendix or remove them.

These are some best practices for medical writing with a disclosure mindset. It is part of your job as a regulatory medical writer to have a basic knowledge of disclosure regulations and support trial transparency.

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Author declaration and disclosures: *The author notes no commercial associations that may pose a conflict of interest in relation to this article.*

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BRIDGING THE GAP: TRANSITIONING INTO REGULATORY MEDICAL WRITING

Speakers
Amber Carr, PhD, *Medical Writer, Merck, Rahway, NJ*
Savannah Mageau, PharmD, *Medical Writer, Merck, Rahway, NJ*
Shengjie Xu, PhD, *Medical Writer, Merck, Rahway, NJ*

By Stephany Panlilio, MS

The role of a medical writer is everchanging and requires a range of technical knowledge and soft skills to create cohesive documents in preparation for submission to regulatory health authorities. Medical writers come from a variety of different backgrounds with varying levels of experience. For those looking to enter the field, there are a number of transferable skills from previous experiences, training opportunities, and techniques to bridge knowledge gaps in preparation for transitioning into a regulatory medical writing role. This article summarizes the experiences of Dr Carr, Dr Mageau, and Dr Xu as they each transitioned into regulatory medical writing.

Skills Leveraged from Previous Experiences
In their presentation, Dr Carr, Dr Mageau, and Dr Xu shared their previous roles in experimental research, pharmacy practice, computational research, and teaching and medical communication and the skills they gained from each that were transferable to their role as medical writers. The skills they found most applicable to medical writing are summarized into the following 3 categories: soft skills, technical skills, and core knowledge.

Soft Skills
The soft skills of self-management and project management that Dr Xu gained from her time in experimental research have helped in her medical writing role. Managing time, setting priorities, and working independently are critical as a medical writer, and developing these skills can increase productivity. Medical writers must be able to manage multiple project timelines and have the flexibility to adjust when something unexpected arises (eg, shifting research

direction, delays at clinical sites, etc.). In addition to managing timelines, managing resources is important for a successful submission, as is continuously reassessing those resources as the project develops.

Dr Mageau was able to apply the leadership skills she developed from her previous experience in pharmacy practice. In medical writing, leadership is important because writers coordinate with several functional areas to produce documents, which includes coordinating meetings and leading presentations.

Technical Skills

Dr Carr found that her experiences in computational research and teaching and medical communication developed her technical skills for process proficiency and scientific communication, which in turn proved to be applicable to her role in medical writing. As a medical writer, the ability to manage and organize multiple projects concurrently and keep a process-driven approach saves time and can lead to streamlining processes in the future. As medical writing becomes more dependent on technology, it is important to have medical writers who are proficient in different software and who are willing to troubleshoot or test software as needed.

Scientific communication is another soft skill Dr Carr was able to bring from her previous experience to medical writing. Having a background in scientific communication taught her how to write for her audience by ensuring that the appropriate level of detail is included for the intended audience as well as modelling scientific thinking while keeping the audience engaged. Lastly, being able to communicate scientific information includes using evidence to craft a coherent story and to support the conclusions, as is done when writing clinical study reports and other regulatory documents.

Core Knowledge

In her pharmacy practice experience, Dr Mageau was able to gain real-world experience in several therapeutic areas, which helped to develop her core knowledge of different disease states, which is especially helpful when writing clinical regulatory documents. She was also able to utilize her experience collaborating with multidisciplinary teams as well as leading discussion and presentations, as medical writers build documents with several cross-functional teams.

Training Opportunities

Numerous opportunities to further develop knowledge and understanding of the drug development process, clinical research, and medical writing are available to those looking to enter the field. Training courses recommended by Dr Carr, Dr Mageau, and Dr Xu included the Introduction to the Principles and Practice of Clinical Research offered by the National Institutes of Health (NIH), the Regulatory Affairs Certification Preparation Program offered by the North Carolina Regulatory Affairs Forum, and Making Medicines: The Process of Drug Development certificate program offered by Eli Lilly.

In addition to training courses, Dr Xu had the opportunity to serve on an Institutional Review Board (IRB) where she gained hands-on experience. When serving on the IRB, Dr Xu learned local and international regulations, including good clinical practice, as well as ethical principles for clinical research. This experience also gave her the opportunity to review clinical study protocols and Investigator's Brochures (IBs), which is applicable to her role as a medical writer.

Dr Mageau participated in an internship at GlaxoSmithKline, where she gained experience in the Global Medical Sciences and Clinical Pharmacology groups. From this experience, she compiled data and used source documents, such as clinical study reports and IBs, to write manuscripts, abstracts, and presentations.

Another opportunity to expand knowledge and gain experience in the industry is by networking, as suggested by Dr Carr. Joining local and national chapters of organizations like AMWA provides opportunities for communicating and creating relationships with others in the field and learning from their experiences, finding training recommendations, and attending conferences to learn what is new in the industry.

Bridging Knowledge Gaps

All 3 presenters shared their experiences bridging the gaps in their knowledge in their training course at Merck, which follows the AMWA Recommended Training Outline and focuses on 3 key areas: core knowledge and skills, documents, and soft skills.

Core Knowledge and Skills

Dr Mageau recommended the AMWA Essential Skills Certificate Program, which provides a background for the core knowledge in medical communication. In addition, taking this course also shows a commitment to developing professionally, further enhancing credibility as a medical writer.

Development of technical aptitude as a medical writer is important to enhance productivity and efficiency in writing documents. As regulatory documents are now primarily digital, Microsoft Word is a helpful authoring tool. In

addition, utilizing a collaborative authoring platform, such as SharePoint, enables multiple writers to work on a document concurrently. As documents are further developed, tools such as table, listing, and figure tools are available to help format and present data clearly to reviewers. Lastly, as a large amount of data are presented in regulatory documents, it is essential to have a quality control tool in place to ensure a document is ready for submission.

Documents

In the rotational training program at Merck, Drs Carr, Mageau, and Xu were able to gain hands-on experience and participate in shadowing opportunities to develop an understanding of the types of documents that medical writers author. During that time, they learned how documents were built during the authoring process, shadowed the Quality Control group, attended consensus meetings, and eventually transitioned to being lead authors.

Soft Skills

Lastly, further developing self-management and people skills helps to strengthen a medical writer's ability to work collaboratively even while remote, build connections, and maintain high productivity. Medical writers are responsible for leading meetings and managing a team to build a cohesive document. Having strong people skills is critical to achieving this goal.

When transitioning into a regulatory medical writing role, there are several transferrable skills that can be utilized from previous experiences, including soft skills, technical skills, and core knowledge. To further prepare new writers, numerous training opportunities are offered through organizations such as NIH, local regulatory affairs forums, and more. Lastly, AMWA provides a recommended training outline focusing on core knowledge and skills, documents, and soft skills that further helps to bridge any knowledge gaps for new writers entering the everchanging field.

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Author declaration and disclosures: *The authors note no commercial associations that may pose a conflict of interest in relation to this article.*

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GROWING YOUR CAREER AS AN EDITOR

Speakers
Crystal Herron, PhD, ELS, *Redwood Ink, San Francisco Bay Area, CA*
Loretta Bohn, ELS, *RTI International, Research Triangle Park, NC*
Erica Goodoff, ELS(D), *The University of Texas MD Anderson Cancer Center, Houston, TX*

By Angela Trenkle, BS
Being a strong editor is a skill set that can open many doors in the medical writing field. In this panel session, three editors discussed some of their tips and tricks for navigating the world of editors.

How Editing and Writing Differ

Ms Goodoff began by explaining that writing is almost like a brain dump; you are just writing everything that is in your mind with regard to the topic. Editing requires more of a critical thinking piece: I have content, but how do I shape it? Dr Herron added that emotional intelligence is also an important skill to have for editing so that you can eloquently explain your proposed changes to authors. Ms Bohn also emphasized that editing is not personal and that editors are looking at the writing from a different perspective—advocating for readers. All three of these editors mentioned that it was important to explain why you're recommending the changes and to back up your suggestions with data and resources.

Key Skills for Editing Grant Proposals

Ms Goodoff began by stating that a key skill for editing grant proposals is to find ways to make it as effortless as possible to read the text and to make sure that the logic flows and ties back to the main objective. Dr Herron emphasized that the storytelling element of the research project is important, which includes how the research project is expected to end. Ms Bohn pointed out the navigation pane in Word, which is a good way to look at pieces of a grant for consistency. All three mentioned the importance of cutting down the length and wording and ensuring that the entire document is consistent in flow.

Teaching/Mentoring Editors

Ms Goodoff began by discussing how coaching new colleagues in editing differs from editing when the client is the only one who will see your edits. It can be helpful to teach new editors because it helps you to become a better editor, but you must find that balance between fixing the problems and teaching the new editor to do it themselves. With