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AMWA NEWS

The Fifth Annual AMWA Executives Forum: Advances in Technology and the Future of Medical Writing

Shiri Diskin, PhD[1]; Lisa Chamberlain James, PhD[2]; Aubri Charboneau, MSCR, PharmD, PhD[3]; and Daniel Wood, PhD[4] / [1]Bioforum Group Ness, Ziona, Israel; [2]Trilogy Writing and Consulting, Cambridge, UK; [3]Jazz Pharmaceuticals, Inc, Chesterfield, VA; [4]CSL Behring, King of Prussia, PA

The Fifth Annual Executives Forum of the American Medical Writing Association (AMWA) was held on October 25, 2023, in Baltimore, Maryland, as part of the AMWA Annual Conference. The forum brought together leaders in medical writing departments from companies across the industry to enhance communication, share information and views, and formulate goals for the medical writing profession. Representatives from pharmaceutical companies, clinical research organizations, and specialized medical writing companies were present (Table 1). The forum was facilitated by Jenni Pickett, PhD, and headed by Julia Cooper, PhD, the head of the AMWA Executives Forum Committee. Breakout discussions were organized by Karen Rutkowski, PhD.

Table 1. List of Companies Represented at the Fifth Annual Executives Forum of the American Medical Writing Association

ALK	Merck & Co, Inc
Amgen	Organon
Avidity Biosciences	Otsuka
BeiGene	PAREXEL
Bioforum	Pfizer
Bristol Myers Squibb	ProPharma Group
Certara	Regeneron Pharmaceuticals, Inc
CSL Behring	RRD International, LLC, Inc
Genmab	Synterex, Inc
Gilead Sciences, Inc	Syros Pharmaceuticals
GSK	Takeda
ICONplc	TFS Healthcare
Incyte	Trilogy Writing & Consulting
Johnson & Johnson	Whitsell Innovations, Inc
Jazz Pharmaceuticals	Zentalis Pharmaceuticals

The forum's discussion topic was advances in technology and the future of medical writing. The forum aimed to identify ways to enhance the value of medical writers (MWs) and position them as innovative leaders using technology to develop medical and regulatory communication. The forum began with a presentation of the results of a survey conducted in 2023 that gathered information on the use of technology in medical writing departments. The survey results were reported by Rutkowski et al.[1] The core activity of the forum was small group discussions, each focusing on 1 of 5 key topics, including how AMWA could support the use of technology for MWs, what tools and training MWs and MW leaders may need, and whether rules need to be established to protect writer roles. The forum also addressed concerns about companies taking risks in content reproducibility or in verifying the accuracy of outputs when utilizing assistive authoring to generate content. Finally, the forum discussed the possibility of future meetings to discuss specific aspects of technology. In this article, we present the main points raised by forum attendees.

CORE TOPICS

Topic 1: How do medical writers retain their value in the face of advancing technology that may appear to make at least some aspects of their job unnecessary?

Because change is inevitable, it is important to try to embrace the changes that are coming and for MWs and MW leaders to try to set a positive tone. Advances in technology will not make the role of the MW redundant; a good analogy can be taken from the world of aviation—autopilot technology is standard but has not removed the need for a human pilot. In the same way, advanced technology could help with the more mundane medical writing aspects and tasks, such as pulling together information for a first draft of a document.

Advanced technology has inherent limitations; for example, the current tools cannot understand nuances across documents. A human-in-the-loop (eg, a content strategist) is still very much needed in the process to ensure that data sources and tools are consistently monitored/controlled. This will create specific educational needs for MWs, as discussed below.

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There is no doubt that the role of MWs is evolving, and each process will need to be refined by individual working teams, with an assessment of the implications of choosing different paths and ways of working.

Topic 2: How do we want technology to enhance the role of the medical writer? Is there an opportunity to use technology to enhance document content quality?

Although there are already some tools that can support the role of the MW (eg, PerfectIt can help to produce a document that is compliant with a style guide), advanced technologies under development are expected to be able to go much further. However, the human-in-the-loop necessity (discussed above) means that advanced technologies should focus on providing a good first draft, with the required content drawn from various sources of 100% verified data and company-specific formatting requirements. MWs who start their work from a well-crafted initial draft will be more efficient and able to concentrate on the document's content rather than allocating time for data verification, formatting, and style guide adjustments. Advanced technology will not eliminate the writer but rather enhance the role of the writer as the content strategist.

In the new era of writing with advanced technologies, quality control (QC) becomes imperative to ensure accuracy, coherence, relevance, and appropriateness. This involves not only standard grammar and syntax checks but also verification that advanced technology-generated content is free of inaccuracies and false perceptions (referred to as "hallucinations"), ensuring a fusion of human and automated writing to maintain the highest standards of quality and reliability in written communication. Advanced technologies should include an option that discloses the source of extracted information. This enhancement would increase the tool's reliability and provide reassurance for stakeholders. Such transparency may reduce the need for extensive QC measures and minimize minor routine project management tasks, such as emailing preidentified reviewers for section-specific reviews.

In considering any positive aspects of an advanced technology, it is prudent to consider current concerns and aspects that MWs would not find helpful. Assigning mathematical tasks to automated systems might be straightforward, but for MWs, it is not advantageous to have advanced technology recalculate or conduct additional analyses. It is unacceptable for any tool to be "creative"—to add fictitious references/citations or generate output that is inconsistent with the input data, or any other information, such as "hallucinations." This emphasizes the need for review cycles and humans-in-the-loop, and the importance of leaving any conclusions and nuances of regulatory interactions or contextualization to the MW. However, given the caveats described, there is an opportunity to use technology to enhance document content quality. Advanced technologies are excellent at summarizing and condensing both data and information. Manual errors become nonexistent in parts/sections not written by a human, minimizing human error. Therefore, the need for data verification in QC can be reduced by using validated tables, leading to QC evolving in the direction of greater content- and context-related responsibility.

This shift would allow MWs to focus on key aspects of content contextualization, critical thinking, and document strategy. In the not-too-distant future, QC reviewers may assume responsibility for evaluating context and meaning, using more advanced tools and techniques to assess the accuracy, consistency, and relevance of the content.

Topic 3: What types/specialties within medical writing will be most affected by technological advancements in the next 1 to 5 years?

All existing medical writing–related roles, including writers, managers, leaders, document formatting specialists, and quality function roles, will be expected to adapt to new technological innovations. To facilitate the implementation, use, and maintenance of new technologies, new roles will need to be created and roles that are typically not associated with medical writing will find increased connectivity. Change will take time, but the uptake of new technology is rapid and ongoing, particularly within larger organizations. In contrast, smaller companies may experience more challenges in immediate adoption due to budget constraints or other resource limitations. Managing multiple iterations of technologies and processes could pose difficulties for smaller companies and clinical research organizations. Consequently, smaller companies may have to resort to working on client-provided platforms, using tools acquired by clients.

It will be incumbent upon medical writing leaders to manage expectations associated with the financial and time requirements needed to appropriately configure and maintain new tools. In some cases, these commitments may be significant. As elaborated below, upcoming innovations will demand enhanced soft skills such as project management, communication, and problem-solving. Effective communication with corporate leadership regarding return on investment, risk management, and alignment with organizational objectives will be critical. In addition to "managing up," medical writing leaders will also need to be mindful of the needs of their writing and document formatting teams. Managing potential pitfalls of implementation and uptake of new technologies will be key to fully capitalizing on the advantages they will bring. Implementing change

management strategies will contribute to ensuring a smoother transition to the new normal. This resonates with the insights shared below, emphasizing the importance of understanding document content structure, organization, and cross-document content strategy.

New roles with a technical focus will be needed to oversee the set-up of emerging tools and systems, ensuring compatibility with each other as well as with existing platforms such as clinical/safety databases and clinical trial management systems. Maximizing the value of new technologies will be facilitated by the seamless integration and compatibility of systems. Postimplementation troubleshooting will also need to be a key aspect of technical support. Success in these roles will require a balance between understanding medical writing requirements and the ability to liaise with the information technology department to effectively address inevitable technical challenges.

Content strategists and content architect roles could take responsibility for the creation/management of content that can be easily adapted and updated for different platforms, formats, and audiences. These roles will be needed to monitor and evaluate the system performance and quality of the content that is generated and to work with technical leads to make the appropriate adjustments and improvements. To ensure reproducibility and consistency of content across documents, there will be a need to establish and adhere to clear and consistent rules and guidelines for content creation, as discussed above.

Regardless of role, all medical writing professionals will need to be aware of the legal and ethical implications arising from the utilization of output created by advanced technologies. It will be important for everyone to have a broad understanding of how to protect the intellectual property rights of the content owners and how to comply with the regulations and standards of the relevant authorities and organizations.

Topic 4: What new technologies or tech tools are medical writing leaders considering for their medical writing groups, and are there differences across specialties within medical writing?

In line with survey results,[1] forum attendees reported that medical writing groups are considering several new technologies and tools to enhance their work. All acknowledged the need to implement technological tools, but several concerns were raised. These were mainly with respect to the use of generative tools, whose outputs need verification and can be subject to hallucinations in writing regulatory documents in the heavily regulated industry. Medical writing leaders are interested in tools that are tested and validated for content reuse and structured content management (SCM). The US Food and Drug Administration is considering rule-based systems as well as generative systems. Currently, medical writing groups are using SCM/structured content authoring systems, automated patient narratives, automated tools to support quality checking (eg, PerfectIt), plagiarism checker software, platforms such as PleaseReview to facilitate and manage review cycles, regulatory information management systems (such as Veeva Vault) to facilitate and manage collaborative authoring and large project workflows (eg, regulatory submissions), and Synchrowrite, a web-based tool that imitates Word but is not impacted by Microsoft technology upgrade pushes. Medical writing groups are considering the adoption of artificial intelligence (AI)–assisted authoring, utilization of advanced technologies for writing narratives, protocols, and clinical study reports, as well as internal authoring through generative pretrained transformers (GPT). These tools are anticipated to generate preliminary drafts, which can then be adapted and revised by MWs, as discussed above.

During the discussion on "wishful thinking," participants contemplated the idea of an advanced technology that harmonizes text across document sections, entire documents in a submission, or even across multiple submissions. Yet, the feasibility of such synchronization remains uncertain. Far from merely ensuring the identity of phrasing (ie, accurate copying), the notion is that harmonization of messaging across document sections or documents with different structures and contexts requires a human-level understanding that large language models are unlikely to attain.

Medical writing groups mostly use the same tools across specialties, with the main differences being the use of literature search-and-summary tools, which have mostly been adopted by MWs in the medical communication sphere, rather than in regulatory writing.

Looking forward, the large differences in the rate and extent of adoption of advanced technology were assumed by attendees to derive from company size.

Topic 5: Which new skills will medical writers need to acquire to be effective in this technology-enhanced environment?

MWs are crucial strategic partners in this evolving landscape, requiring new skills for effective collaboration and integration of new technologies in document development.

Strong leadership and communication skills will be critical as medical writing teams evaluate and integrate new technologies into document development workstreams. Medical writing leaders will need to be well acquainted with the concepts of return on investment and risk management (as described above) to share with key stakeholders and manage expectations. Senior-level writers may be required

to take on responsibilities such as developing and implementing advanced technologies, serving as superusers, and providing training to both junior MWs and cross-functional users (ie, good neighbors).

MWs will need to be adept at change management and actively foster continuous learning and improvement as new systems are implemented and iteratively updated over time. As digital champions, MWs will need a keen understanding of the evolving technologies, such as AI generative systems, content reuse, SCM, and internal GPT bots. Digital literacy will be crucial for MW leaders, enabling them to assess the most suitable technology for their company's stage and size, and effectively implement and collaboratively use new authoring technologies. For instance, an MW may need to write prompts for AI systems or bots, providing clear instructions to achieve the best results from the tool.

Strong critical thinking and content logic skills will be necessary for optimal use of new technologies, allowing MWs to holistically plan for standardization and reuse of content across documents as needed for a drug development program and across submissions. This planning extends from the study protocol to the statistical analysis plan, clinical study report, and summary-level documents, leveraging advanced technologies and/or SCM technologies. Collaboration with content owners (subject matter experts) in developing and managing standard content libraries within the new systems will be vital for enhancing document development efficiency.

Topic 6: How will technological evolution affect the training of medical writers?

Senior-level writers may need to serve as superusers/digital champions and be responsible for training junior MWs on how to use new technology for authoring documents. As technologies evolve quickly, MWs may require regular refresher training and guidance materials (eg, quick reference cards). Technologically savvy writers may carve out a new role to help develop and implement new systems, support change management, and provide ongoing training for MWs and cross-functional users.

How can AMWA help?

MWs have the opportunity to be advocates or champions of change, and organizations/associations like AMWA can actively contribute to this evolving landscape. AMWA has the potential to shape the future of medical writing by defining necessary skills and training MWs, outlining new roles, developing decision trees for advanced technology selection, creating a lexicon, and producing a toolkit to assist MWs in navigating the upcoming changes more smoothly. To support these transitions, AMWA could engage in several initiatives, including collaborating with quality assurance professionals to better define and document best practices for audits of advanced technology-generated content. Additionally, expanding training offerings to cover programming and engineering skills would empower MW professionals to create, edit, and manage content using emerging technologies. Furthermore, AMWA could offer training sessions covering the development of compelling business cases for advanced technology, provide insight into measuring and demonstrating the value and impact of technology, and deliver training on effective communication and persuasion strategies with stakeholders and decision-makers, and alignment of technology with organizational visions and missions. This multifaceted approach would help prepare both individual MWs and MW-focused companies to transition effectively into the new technological advancements.

Considering the multitude of advanced technology already available, AMWA could assist MWs in navigating this landscape in several ways:

- Provide an analysis of all the tools currently available.
- Develop a standard questionnaire for vendors to complete about their tools, including vendor sandboxes to showcase MW use cases for their tools.
- Establish a section on the AMWA website with a portal for vendors to update their information as their tool improves, allowing reviews from the medical writing community.
- Create a toolkit to aid managers in selecting advanced technologies, including tool profiles and comparisons of tools.
- Conduct a benchmarking exercise to determine key regulatory considerations, providing a metric for evaluating different advanced technologies.
- Publish successful business cases in the *AMWA Journal*.

Although some suggestions may not be feasible for AMWA to undertake, there is a clear need to develop training protocols for the evolving role of MWs in the context of advanced technology. Refining soft skills, articulating the benefits of advanced technologies to stakeholders, managing their expectations, and simultaneously honing change management skills and techniques are essential for MWs to thrive in the new era of AI and other advanced technologies. With the right training and skills (Figure 1), MWs will be equipped to become even stronger strategic partners in drug development teams.

CONCLUSIONS

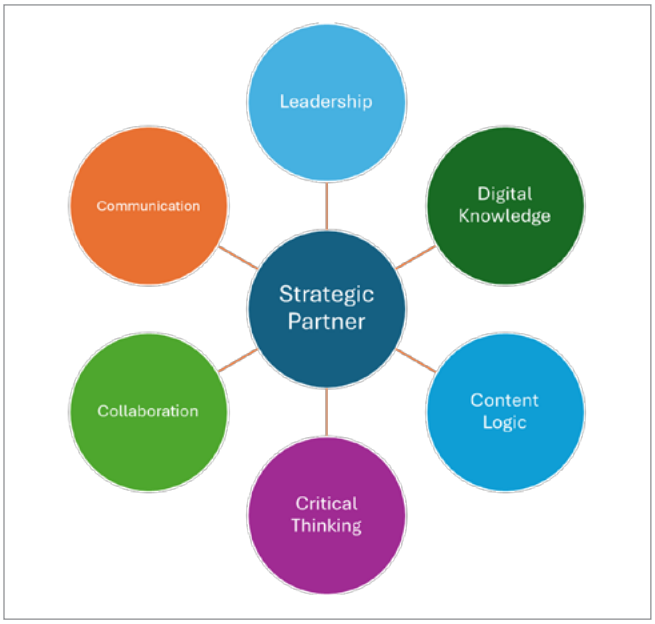

Figure 1. Key skills for a medical writer to be a successful strategic partner in a technology-enhanced environment.

Technological advancements are imminent and will undoubtedly affect the profession of medical writing. Far from being a threat, the upcoming changes should be viewed as an opportunity for the evolution of the profession. MWs—highly skilled, educated, and extensively trained professionals—are often underutilized by performing routine tasks such as accurate copying of materials from sources and document formatting. The careful adoption of appropriate tools can shift the balance, reducing the time and effort spent on tedious tasks and allowing a greater focus on document strategy and message formulation.

To allow for successful integration of such tools, leaders will have to adopt a positive approach and hone the training and capabilities of future generations of MWs. Beyond the current set of required skills (knowledge of regulations, scientific understanding, various soft skills), a senior writer will have to hone their critical thinking and appraisal skills, be an expert user, and even be a contributor to the development of sophisticated technological writing tools. AMWA can assume a facilitating role in the responsible and effective adoption of advanced technologies by MWs through advocacy and education activities.

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Author contact: *Shiri.Diskin@bioforumgroup.com*

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