

AMWA NEWS

AMWA’s Third Annual Meeting of Medical Writing Executives Tackles Value, Leadership, Change, Recruitment, and Retention

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ABSTRACT

The American Medical Writers Association (AMWA) Third Annual Medical Writing Executives Forum brought together executives of medical writing departments at some of the world’s top biopharmaceutical companies to discuss topics of urgent relevance to the companies that employ regulatory medical writers, those who manage regulatory medical writing teams, and regulatory medical writers themselves. Participants identified and discussed many of the challenges and opportunities facing the industry today.

In 2018, the American Medical Writers Association (AMWA) launched the AMWA Medical Writing Executives Advisory Council for the purpose of maintaining a connection between pharmaceutical and biotechnology department heads and the AMWA Board of Directors. The council comprises senior-level professionals whose responsibility it is to recruit, train, and manage medical communicators. Members of the council represent some of the world’s top health-science, pharmaceutical, and biotechnology companies as well as several companies that provide regulatory medical writing and consulting services. The council acts as a sounding board on issues such as workforce trends, training programs, and technologies that have an impact on the medical writing field. Council members also provide guidance on and participate in the annual AMWA Medical Writing Executives Forum.

The third annual invitational Medical Writing Executives Forum was held virtually on October 25, 2021. Joan Affleck, MBA, ELS, Associate Vice President and Head of Medical Writing at Merck & Co., chaired the forum. A list of forum attendee companies is provided in the table. The theme of the forum was *Igniting Leadership, Innovation, and Resilience in Medical Writing*. Participants divided into 5 breakout groups, each addressing a specific topic pertaining to the value of medical writing, next-generation leadership, the changing medical writing environment, recruiting and retaining

medical writers, or leading in times of change. This article reports the key opportunities, challenges, insights, observations, and recommendations of the forum participants.

Table. 2021 Medical Writing Executives Forum Attendee Company List

- Alnylam Pharmaceuticals
- American Medical Writers Association
- Astellas Pharma Global Development, Inc.
- Bass Global, Inc.
- Bioforum Group
- Boehringer Ingelheim Pharma GmbH & Co. KG
- Bristol Myers Squibb
- Certara Synchrogenix
- Eli Lilly and Company
- Encore Biomedical Communications LLC
- Endo Pharmaceuticals
- Genmab
- Gilead Sciences, Inc.
- Greenwich Biosciences, Inc.
- Harpoon Therapeutics
- ICON plc
- Janssen R&D, Johnson & Johnson
- Karen L. Fink Medical and Regulatory Writing
- Merck & Co., Inc.
- Moderna, Inc.
- Novartis Pharmaceuticals
- PAREXEL
- Pfizer Inc.
- Praxis Precision Medicines
- Regeneron Pharmaceuticals, Inc.
- Roche Diagnostics
- RRD International, LLC
- Sarepta Therapeutics, Inc.
- Seqirus
- Syneos Health
- Synterex, Inc.
- Takeda Pharmaceutical Company Limited
- Trilogy Writing & Consulting
- Ultragenyx Pharmaceutical Inc.
- Whitsell Innovations, Inc.

REVIEWING DATA/INSIGHTS FROM THE VALUE OF MEDICAL WRITING SURVEYS

AMWA formed a working group in 2021 to work toward defining and quantifying the value of regulatory medical writers. The Value of Medical Writing Working Group includes 3 subgroups: Engagement with Regulatory Health Authorities, Survey Development, and Literature Search and Assessment of the AMWA Training Outline and the DIA Competency Model. The efforts of the working group are ongoing, and initial findings have been reported.¹⁻³

During the 2021 AMWA Medical Writing Executives Forum, the participants in this breakout group discussed several topics based on the working group's efforts to date.

Using The Data

A key finding of the working group's efforts that participants in this breakout group discussed is the need to educate others about the value of medical writers in the regulatory field. Their recommendations included

- Leveraging the working group's findings to start conversations with company managers and encourage investment in the medical writing team.
- Emphasizing to all stakeholders involved in the medical writing process that regulators prefer brevity; larger documents are not necessarily better.
- Educating subject matter experts, who are stakeholders and contributors to the medical communication process (eg, biostatisticians, clinicians, pharmacovigilance physicians), that medical writers are an important part of the regulatory communication process.

Data That Were Unexpected/Surprising

The survey of regulatory medical writers conducted by the working group found that many regulatory medical writers feel undervalued. The working group provided insight into how companies that employ regulatory medical writers can promote professional growth and job satisfaction. Participants in this breakout group recommended increasing opportunities for medical writers to gain soft skills training, providing more opportunities for medical writers to grow into leadership roles, and exploring mentorship programs to promote collaboration and leadership.

The breakout group participants noted that today's medical writers seem to be more willing to take the lead, which is an asset to help improve collaboration with other stakeholders in the communication process. Participants noted the ability to collaborate is as important as the ability to lead.

Although not surprising, participants in this breakout group acknowledged that in the United States and some (but

not all) other countries, women form the majority in the field of medical writing. The group proposed an effort to explore what may be holding men back from pursuing a career in medical writing and how they might be encouraged to do so.

Communicating The Data

Initial findings of the working group have been published in the *AMWA Journal*¹⁻³ and presented at the AMWA 2021 Medical Writing & Communication Conference. Efforts are underway to also present findings of the working group at upcoming meetings of the European Medical Writers Association and the DIA, as well as at the AMWA 2022 Medical Writing & Communication Conference

Acknowledging the growing need for qualified, professional medical writers, participants in this breakout group proposed reaching out to high schools, colleges, and universities to increase awareness about the medical writing profession and encourage students to consider a career in medical writing.

Currently Missing From The Value Story

Participants in the breakout group expressed that a granular definition of quality is needed to provide a uniform and consistent target for all stakeholders to expect, measure against, and achieve. The breakout group thought it would be especially helpful for managers to know how quality affects the return on investment in medical writing in terms of the time, money, and resources invested. Understanding the dynamics of employing staff compared with contract or freelance medical writers would also be helpful for decision makers.

DEVELOPING THE NEXT GENERATION OF LEADERS FOR MEDICAL WRITING TEAMS

The dynamics of leadership and the characteristics of an effective leader are continually evolving. This breakout group considered the skills, tools, and opportunities that will likely be needed by tomorrow's leaders of medical writing teams.

Key Skills for Tomorrow's Aspiring Leaders

The breakout participants acknowledged that not all medical writers want to become leaders in the traditional sense of managing others, yet they agreed that all medical writers, regardless of their aspirations, will benefit from mastering the soft skills required to lead as an individual expert contributor. These soft skills include

- Flexibility
- Problem solving
- Collaboration

- Diplomacy
- Curiosity
- Agility
- Resilience
- Project management

An ideal way for someone to learn effective leadership skills is by observing an effective leader. Seeing firsthand what an effective leader does to inspire and guide their team and how they respond to challenges, provides aspiring leaders with the opportunity to see the key skills they need in action. The next step is to give aspiring leaders the opportunity to practice and internalize these newly learned skills in a safe environment in which they can challenge themselves, make mistakes, and build confidence.

Tools for Tomorrow's Aspiring Leaders

For medical writers who aspire to someday lead others, participants in this breakout identified several tools they will need to lead their regulatory medical writing teams. At the top of the list, leaders must have the trust of their team members, the ability to communicate with them clearly and directly, and leadership consistency. Leaders of medical writing teams must be able to provide positive feedback and reinforcement, ideally in the moment when such feedback is appropriate, and constructive feedback discretely when warranted.

Making sure everyone on the team has a voice and uses their voice to express their ideas, needs, and opinions is another important tool for team leaders. Being flexible with how people work can empower medical writers on the team to optimize their productivity while reducing work- and/or life-related stressors.

Autonomy is another important tool identified by the breakout participants. Team members should be given control of their own work when possible. Ownership—even of just a small piece of a larger project—fosters engagement.

Opportunities for Tomorrow's Aspiring Leaders

Today's leaders must make clear where opportunities for leadership training can be found within the organization, and reward those who are curious and aspire to become leaders by facilitating such training. Those who are training aspiring leaders should get to know the individuals they are training and their desired career paths so they can be guided appropriately. Mentorship is a powerful teaching tool, enabling aspiring leaders to learn by example.

Leadership desires may vary, and it is important for today's leaders to keep this in mind. Whereas, some medi-

cal writers aspire to a management track, others may aspire to leadership in a technical track. Likewise, a career path is different from a development path, and it is important for today's leaders to know the difference when providing guidance to tomorrow's aspiring leaders.

CHANGES IN THE MEDICAL WRITING ENVIRONMENT

In this breakout group, participants identified changes that are currently taking place in the medical writing environment and discussed what medical writers can do address them.

They grouped the changes taking place into 3 categories:

- Financial demands
- Technological innovations
- Team challenges

Financial Demands

Breakout group participants noted the current demand for cost savings in their medical writing departments, which affects internal and external resource utilization. There is an added burden of internal resource management and oversight.

Increasing demands on the costs associated with managing outsourced medical writers includes demanding that outsourced medical writers self-manage their associated costs. On the staff side, there is currently a salary competition taking place in which managers are challenged to keep costs down while paying appropriately for qualified staff resources.

Technological Innovations

Technology enables medical writing teams to eliminate some of the more mundane tasks and increase efficiency, especially in regulatory writing with the use of standardized templates. Technology has changed the way teams interact with medical writers and not all of it is positive or useful. Overly customized software can be well intentioned but overly burdensome for medical writers to use. It is incumbent upon managers to determine the level of technology that best meets the needs of the team and the work environment without overcomplicating processes.

Although it may seem that standardized technologies cannot be applied to the unique requirements of rare disease indications, a similarly unique or specialized use of technology may not be required.

The breakout group participants also discussed the differences between logic-based and artificial intelligence-based technologies and agreed that more information is needed to choose the appropriately technology for a particular application or team.

Team Challenges

Challenges experienced by medical writing teams add expense and time to a project. Templates can help streamline these processes, provided they are not too individualized. Regulatory medical writers must keep in mind that they are writing for a health authority audience, not for subject matter experts.

Two major challenges faced by regulatory medical writers concern document brevity and timelines. Regulatory reviewers have said they want documents to be clearer and more concise, but medical writers typically lack the authority to impress this upon other stakeholders in the document development process. Verbose documents also take more time to produce, which contributes somewhat, but not solely, to the second challenge of timelines. Medical writers rarely have influence over the timelines that drive their work, and when pushed to meet timelines that may be unrealistic to the task, can experience burnout and possibly even stress-related injuries.

What Medical Writers Can Do

The breakout group participants identified ways in which medical writers can address these changes taking place in the regulatory environment. These include

- Clarifying the role of medical writers to stakeholders, some of whom who simply want scribes.
- Elevating the visibility of the medical writer as a vital member of the team.
- Engaging medical writers in setting timelines and giving them confidence and authority to push back against unrealistic deadlines.
- Conducting after-action reviews with the team to identify what went right and discuss opportunities for improvement.
- Highlighting transparency initiatives to help with standardization, use of templates, and leaner authoring.

RECRUITING AND RETAINING MEDICAL WRITERS

Participants in this breakout group discussed turnover rates, the key attributes to look for when recruiting medical writers beyond writing skill, interacting with recruiters, training programs, and methods for recognizing, remunerating, and retaining top talent.

Turnover

Some companies have experienced attrition exceeding the rate of onboarding new employees, with turnover rates among medical writers reportedly as high as 30%. Burnout is a large contributor to turnover, with some medical

writers moving to freelance work to achieve a better work-life balance while others fear moving out of the company environment due to stability. Another contributor to turnover is the disparity in position leveling across companies, which may make it enticing for staff medical writers to move from a larger pharmaceutical company to a smaller biotechnology company that may be recruiting at higher positions and offering higher salaries.

Key Attributes to Look for When Hiring Medical Writers

Beyond writing skill, the breakout group participants identified a range of key attributes for hiring managers to look for when recruiting medical writers:

- Ability to work remotely
- Well-rounded document experience
- Contribution to a diverse team
- Innovative thinking, particularly concerning adoption of automation
- Emotional intelligence

During the hiring process, some companies engage panels to interview candidates, which can be intimidating and time consuming. Other companies have considerably more expedited interviewing processes. The interview is especially important because it provides candidates an opportunity to talk the talk and show what they truly know.

Many companies are focused on ensuring diverse slates of candidates for open positions as well as diverse interview panels. Building diversity strengthens the quality of a good medical writing team and can take the team to new levels of innovation including being able to manage challenges from different perspectives.

Companies that require writing tests vary between in-person and automated platforms. It was noted that writing tests can be perceived as demeaning by more-experienced medical writers who may subsequently decline and be lost as potential candidates. Developing an experience grid may make it easier for hiring managers to determine and compare candidates' true experience rather than reviewing CVs.

Interacting With Recruiters

Participants agreed that personal recommendations and referrals are best for identifying qualified candidates. Companies have had varying degrees of success using internal and external recruiters and have found that recruiters themselves need training on the skillsets required to be a successful medical writer.

Training

Several breakout group participants reported that their company provides training programs in the form of apprenticeships, writing academies, and summer internships. University training programs are needed, as well as efforts to educate students about careers in medical writing.

Retaining Top Talent

Bonuses, career ladders, and work-life balance are among the tools companies can use to retain top medical writing talent. This may include monetary and gift award programs, retention bonuses, and offering clear development and leadership opportunities. It can be challenging when an employee's drive for advancement exceeds the company's established processes and timelines for promotion.

Work-life balance is an important consideration for staff medical writers and may include opportunities for part-time work and personal time off. In the European Union, it was suggested that most regulatory medical writers are part-time. As a result, companies and staff must adapt to maintain workflow and timelines, such as document sharing among team members. Having a reliable group of backup writers can also help.

LEADING TEAMS DURING A TIME OF CONSTANT STATE OF FLUX AND AMBIGUITY

Participants in this breakout group discussed the role of team leaders in managing change within their medical writing departments, and how managers can help affect change within their teams and with outside vendors.

Managing Change

Change is constant. Critical factors in managing change are transparency, community, and trust. Managers of medical writing teams can best manage change by being upfront and honest, present and calm, transparent, and realistic (ie, not superficially or unrealistically positive). Teams tend to absorb and then radiate the mood of their environment, whether that mood is calm or negative. Managers should lead by example at all times and especially when times are tough.

Team managers should be honest about what they know and do not know to avoid team members thinking that information is being kept from them. It is easier to get a team to embrace, or at least accept, change when they understand why it is needed or happening. It can be helpful to discuss the opportunities that change may bring. However, change should not necessarily be normalized, such as when a key support structure is no longer in place. The COVID-19 pandemic provides an example of this, when schools were no longer meeting in person and employees began working from home with their children learning from home.

Affecting Change

Affecting change within a medical writing team is challenging and time consuming for the team manager. Managers must address the concerns, expectations, and needs of the team members and implement the necessary changes while also maintaining the team's focus on the project tasks, goals, and timelines at hand. Providing the information medical writing teams need to understand and be a part of the change will help suppress the speculation and rumor that might otherwise persist. Engaging the assistance and support of Human Resources when relevant can also be helpful.

Managers must be cognizant of the impact changes can have on team members. For example, working from home during the COVID-19 pandemic fostered greater productivity, but it also led to higher rates of burnout as staff found themselves working longer hours. Some breakout group participants said they provide opportunities for their team members to recharge, including offering mental health days that can be branded as "Days of Reflection" or "Curiosity Days." Change is not forever, and the medical writing team may be reassured to know that a company's or a department's response to change can evolve if something does not work as well as planned.

Change can also be difficult for vendors, whom some perceive as threats rather than members of the team. It is important to match the expectations of the team and the vendor at the start of the relationship and ensure goals are aligned.

Some participants in the breakout group noted that they invite their contract medical writers to team meetings to foster a collegial atmosphere built on familiarity, trust, and cooperation. Connecting vendor members of the team with sponsor members can help build and strengthen these relationships. In dealing with vendors during times of change, once again, communication is the key to success.

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