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THEME ARTICLE

Globalization and the Future of Medical Writing

Julia Cooper,[1] **Jeannene Butler,**[2] **Kelley Hill,**[3] **Garima Pallavi,**[4] **Grishma Kanchan,**[4] **Jonathan Mackinnon,**[5] **Renee Primus,**[6] **Matthew Renda,**[3] **Linda Yih,**[7] **and Nan Wang**[8] **/** [1]Parexel International (IRL) Limited, Dublin, Ireland; [2]Otsuka Pharmaceutical Development & Commercialization, Princeton, NJ; [3]Alexion, AstraZeneca Rare Disease, Boston, MA; [4]Parexel International India Development & Commercialization Safety Services Private Limited, Bangalore, India; [5]Parexel International S.L., Madrid, Spain; [6]Bristol Myers Squibb, Princeton, NJ; [7]Parexel International LLC; [8]Bayer Healthcare Co. Ltd., Beijing, China

ABSTRACT

Medical writers play a key role in global regulatory submissions across the pharmaceutical industry. Before the COVID pandemic, many companies were working toward development of global regulatory submissions, with their medical writers playing a key role in this process. During the pandemic, the need for greater collaboration in fully remote working conditions, inclusion and transparency, and the unprecedented demand for speed and quality of clinical development has brought global ways of working into even greater focus. A panel of medical writers, including department and regional heads and subject matter experts, were invited to consider how other influences on our industry may drive the evolution of medical writing yet further as a global profession in the coming years. This article summarizes the panel's responses to 5 questions on the future direction of the profession.

Medical writing is an increasingly global profession. During the past few years, the effects of the COVID pandemic have only served to increase the ways in which it is possible to be a medical writer on global teams regardless of one's own location. We invited a panel of medical writers to gaze into their crystal balls and consider how medical writing may yet further evolve as a global profession over the next 10, 20, or more years. Participants were invited to consider 5 questions on the future direction of the profession and to provide short responses to as many of the questions as they felt able. Our panel included department and regional heads and subject matter experts (SMEs); their biosummaries can be found at the end of this article.

How has the impact of the pandemic and increasing demands on the speed, quality, and complexity of clinical development driven globalization? What solutions initiated from medical writing have been successful to accommodate this change? Where might this lead us next?

Jonathan Mackinnon: The pandemic and increasing complexity of clinical development is driving a need for more expansive multinational or multiregional clinical trials that cover a greater geography in order to access increasingly specific participant populations. In response, medical writing associations are increasing education/training efforts in how to manage these changes as part of regulatory document preparation. Over time, this might lead us to increased specialization within the medical writer community where—once a writer has an established a base skill set via experience across regulatory documents—they start to specialize in certain areas so that they can stay up to date with the current challenges, eg, data analysis and reporting versus study design and setup.

Linda Yih: In terms of impact, more compounds seem to be moving ahead "at risk," so teams need to take this into account when it comes to planning and contingencies. Successful writers have been able to drive effective

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collaboration and communications, mediate differences, and validate actions to meet overall goals. Cultural awareness (whether country, company, or team-specific) has become key to encourage open discussion and ensure all parties are heard and understood. Future collaborations may require refined skills in managing conflict, negotiation, influence, and persuasion.

Renee Primus: During and postpandemic, we have witnessed the importance of rapid mobilization to meet new and unexpected global requirements ensuring patient safety and access to treatments. The consequences of global disruption have pointed to the need for greater collaboration, inclusion, and transparency and a call to action for a shared objective among all members of the health care system. Members of the medical writing profession have been and continue to be well-positioned as problem solvers during disruption by bringing innovative solutions and leading complex deliverables. For example, COVID-related country-level commitments and the development of processes, tracking, reporting templates, and oversight to meet compliance and quality were key leadership contributions from medical writers—and during a time of urgency and under some extreme conditions. In addition, structural, content, and harmonized updates to existing regulatory documentation (eg, Periodic Aggregate Safety Report and the Clinical Study Report) provide another example of leadership from medical writing to drive well-communicated, transparent, and consistent reporting for global digestion. The call to action includes greater data-sharing using secured technologies and harmonized ways of working including more integrated and collaborative health authority (HA) shared accountabilities.

Nan Wang: COVID has had a negative impact on a global basis in certain industries, but other professions that can be relatively easily adapted into remote forms will experience heightened demand, such as medical writing. The unprecedented demand for the speed and quality of clinical development has driven us to pursue even higher levels of globalization. Ever-increasing global standardization and automation should be the key drivers for a successful medical writing organization.

Jeannene Butler: One "silver lining" for the pandemic was that it necessitated organizations to think differently about the conduct of their clinical trials, and we saw innovative solutions designed to keep clinical development programs moving forward, despite the limitations to person-to-person contact. In medical writing, there was also no pause in our work, and globalization of our regulatory submission documents continued to be a focus for our team. We often preplan for global submissions by starting our documents much earlier, even before the completion of the final clinical trial, with region-specific background text and assumed successful outcomes. Adding in more automation and technology to this early-writing process can help to reduce the time and effort for the medical writers and may also reduce the impact for rework by the medical writers in the later stages of document development.

Kelley Hill & Matthew Renda: Medical writers have always been able to work remotely. During the pandemic, they exemplified efficient and effective communication, high productivity, and high quality, helping the world adjust to remote work. Increased demands leading to increased collaboration across time zones have necessitated the use of shared document platforms and highlighted the importance of careful document handoffs to "follow the sun." However, the expectation that one is always available increased propensity for "burnout," which many experienced as time went on. Multitasking was taken to an extreme in some cases, which may have led to a decreased ability to focus and affected critical thinking. It will be increasingly important to leverage technology and prospective planning wherever possible and have priority established by management to keep focus and quality from all contributors at its peak.

Julia Cooper: Medical writing lends itself to remote working, and this has been a common model in North America and parts of Europe for many years. During the pandemic, virtual teams were a necessity (and still are) but also brought benefits such as being able to hire diverse talent in geographical locations where office-based working was previously the norm. Employee satisfaction has increased through flexible working hours, autonomy, and the ability to work from different locations. Zoom, Microsoft Teams, and similar platforms help maintain employee engagement; however, building team cohesion can still be a challenge. In the future, we need the technology to evolve yet further (think Star Trek holodeck!) to provide an environment as close as possible to a face-to-face meeting when opportunities for in-person meetings are limited or nonexistent.

Grishma Kanchan: With increased demands on the speed, quality, and complexity of clinical development,

globalization via social integration has been one of the biggest outcomes of the pandemic. Medical writing has predominantly been a geographically diverse team; however, the pandemic pushed us to focus on sustainable and inclusive growth, which required changing our work culture to maximize contributions of people globally. Medical writing was quick to implement platforms for global collaborative work. With technologies continuing to improve, we must be open to new ways of working, such as collaboration in the Metaverse. The Metaverse could aid meaningful interactions between colleagues by replicating an office environment. Communication in the Metaverse may also be more authentic and build trust when compared with face-to-face conversations which may, at times, be affected by social anxiety or lack of confidence. Coming together in the Metaverse can be empowering by creating a space where people at work can feel present, connected, and productive. The Metaverse could also give medical writers the chance to observe, learn from, and work alongside the best in the industry, without physical or geographical barriers. In clinical development, medical writers could immerse themselves in real-life scenarios and gain insights into a patient's or physician's journey to devise solutions for existing challenges. The Metaverse may also allow medical writers to understand the "larger picture" by helping to visualize the clinical development process from drug discovery and development to approval and postmarketing surveillance. This could provide writers with key knowledge to understand the target audience and write better and effective clinical documents.

How might the medical writing profession be defined in the future, eg, common certification or development programs, shared job descriptions, intergalactic medical writers association, sharing ideas across companies, different relationships between clinical research organizations (CROs)/contractors and sponsors, other?

Linda Yih: We can make great strides together by sharing ideas and solutions to common challenges across companies. AMWA is already spearheading this effort with industry leads on several important topics. On a more granular level, this can be achieved by building mutually trusting relationships between CROs/contractors and sponsors. All involved need to be transparent with their needs and concerns and open to others' perspectives.

Jeannene Butler: Regulatory medical writing is quite different from other types of medical writing and would benefit from having its own global standards and development programs. A global regulatory medical writing organization would allow for a more focused view of our specific writing profession but expanded to include perspectives and ideas from across the world. An increased focus on education for newer medical writers at the undergraduate level is needed. This could be in the form of 1 or 2 courses for regulatory medical writing to be added to the curricula for related health science degrees or expanded to develop an overall medical writing major program at colleges and universities, where common elements of scientific writing are taught, and the regulatory medical writing courses could be a concentration for that major.

Renee Primus: The regulatory writing profession requires recognition as a defined role in driving speed to patient. A common pain point by writers is that they are not always used for their skills in strategic writing and leadership but instead misunderstood as formatters and scribes. The writer brings value as an expert on regulatory requirements supporting regulatory review and approval and accordingly shapes documents to strategically address these requirements. Sponsorship across pharmaceutical companies and CROs to form well-defined, harmonized, and consistent position profiles capturing core capabilities and responsibilities would promote the profession and effectively pave the way to a degree-facing curriculum integrated with regulatory affairs. A curriculum design recognizing the multiple and overlapping responsibilities between regulatory writers and regulatory strategists would meet the needs of future changes to the regulatory landscape promoting speed to patient.

Nan Wang: Medical writing has a long history in Europe and North America and is well defined and recognized in the pharmaceutical industry.

- In the future, the medical writer's role and responsibility will be better recognized and accepted in other developing regions, eg, Asia-Pacific. The trend has already been observed in China.
- An industry community facilitating knowledge and experience sharing across companies and the understanding between CROs, sponsors and investigators will play a more important role.

Kelley Hill & Matthew Renda: Assuming that "medical writing" in this instance refers to regulatory writing, building a framework for developing writers within secondary education/universities would provide a pipeline of future

writers. This would include a broad framework that begins with superb writing skills as well as expanded skill sets required for data interpretation and detailed knowledge of regulatory governance. To further career development, management training would include strategic planning, project management, resource planning, technology skills, contract negotiation, and the ability to coach for career development. The business of medical writing also requires the need to assess what skill sets are needed for specific projects. In addition, the expanding requirements for transparency and plain language writing offer separate but related paths for development. Core competencies could be identified and job levels that are aligned across companies would also help define specific job titles, making them more uniform across the industry. This would help control "title inflation," which is often the reason writers will leave one company to move to another, which erodes institutional knowledge and experience, the bedrock that medical writers contribute to drug/device development.

Garima Pallavi: Clinical trials are becoming increasingly complex; adoption of advanced technology is slowly becoming the norm. The pharma industry is moving toward personalized medicine/precision medicine. This shifting landscape requires medical writers to be adequately equipped to develop expertise in these areas, understand and expertly design studies, and communicate results to regulators. Complex study designs call for medical writers to develop the right amount of subject matter expertise. The rapidly changing regulatory terrain also requires medical writers to continually learn and develop their core competencies. The COVID pandemic has underscored that the magnitude of globalization in the health care industry is going to see a steep rise. Companies that already had medical writing operations spread out globally experienced minimal disruption in their business. To keep up with the rapidly evolving demand in the industry, companies must focus on building a globally diverse talent pool. Global capability centers (GCC) are swiftly becoming the new normal, and companies are giving up their traditional beliefs about having a concentrated talent pool to adapt to a GCC model. The advantages of a global talent pool are multifold: from ensuring round-the-clock business continuity to leveraging on a world-class talent pool and building resilient and agile capabilities. Building and nurturing a global talent pool will require using shared job descriptions, employing standard hiring methodologies, a common approach to training, upskilling of staff, and applying uniform performance and conduct standards. Professional medical writing associations offering certification programs such as AMWA and EMWA provide vast opportunities for writers to learn and expand their network; however, these associations have mostly had a strong regional presence. To meet the fast-paced demands of the industry, it will be imperative to shift the mindset to have a global community of medical writers, which allows the whole fellowship to develop common skills. COVID has taught us that we can successfully organize virtual conferences and training programs and make SMEs more accessible to colleagues globally. The future of medical writing will be about breaking down silos and unlocking a diverse talent pool that transcends geographical boundaries.

Jonathan Mackinnon: As complexity increases, it's likely that certification or training programs will become more commonplace to demonstrate a base skill set. Within regulatory medical writing, my view is that study design and transparency will be significant drivers of lasting change.

- Study design: complexity and simplicity are at opposing ends of the pendulum but are increasingly being woven together as more specific interventions (more targeted action and more complex endpoints) are being included in studies looking to simplify participation and minimize burden. Medical writers will need to be able to navigate the increased design and analysis complexity as well as participate in risk assessments, derisking (eg, applying passive data collection from digital health technologies to replace on-site clinical assessments), and subsequently simplification.
- Transparency: regulatory documents used to be considered highly prized proprietary information with restricted access, whereas now, publicly available redacted regulatory documents substantially increase medical writer access to precedent content. Consequently, how medical writers engage with precedent and standardized content and how that content facilitates downstream process will form part of a medical writer's training.

What kind of regulatory changes might impact the way medical writers work in future? Do you anticipate recent or future regulations (what kind?), or changes at the regulators themselves, driving change for medical writers? What could that look like?

Jonathan Mackinnon: Maturation of the understanding of risk and risk mitigation (International Council for Harmonisation of Technical Requirements for

Pharmaceuticals for Human Use (ICH) E6[R2]) as well as a fundamental shift toward Quality by Design (ICH E8[R1] and the likely reflection of this in ICH E6[R3]) will have a material impact on medical writer work in the future. More sophisticated risk management strategies, targeted enrollment and forecasting, and quality-focused study design will change the way studies are designed and analyzed. Designing study protocols will combine a greater understanding of risk management and mitigation verbiage with new methodology for constructing studies that focus on critical to quality factors; for clinical study reports, reporting on these strategies will become more commonplace.

Kelley Hill & Matthew Renda: Increased transparency requirements (ie, European Union Clinical Trials Regulation (EU CTR)) are already changing the way writers work, as personal protected data need to be identified early as part of an overall disclosure strategy and company confidential information adapted as more information becomes public during development. Specific examples: instead of "47 year old female from France," data output is changed so the text reads "a 40 to 50 year old person from Western Europe."

One huge change would be if regulators move from the current document-centric Common Technical Document (CTD) structure to a real-time study data flow. Advanced computation in the coming decades might permit regulators to automatically interpret trial data with marketing applications built on a rolling basis. In such a future, medical writers would leverage technical and data science skills because documentation would be reduced to introductory/contextual statements, leaving interpretation up to the agencies.

Renee Primus: The regulatory writer carries both technical and strategic expertise; current and future changes to the regulatory landscape, speeding access of new health care products to patients, will require this expertise more than ever and are already happening. Over the past 5 years, Food and Drug Administration (FDA) initiatives have been introduced with impact to the regulatory writer. For example, Real-Time Oncology Review and the Assessment Aid aim to increase the speed of information for regulatory review and require both exquisite planning and focused reporting of complex and approval-supporting data—with quality. In addition, parallel review initiatives such as FDA Project Orbis require new approaches to work concurrently with multiple participating countries—with speed. Accumulus Synergy, creating innovative solutions to reduce regulatory review times and transform global data exchange, is another good indication of reshaping the industry by removing barriers to speed of information. In all these examples, the agile regulatory writer possesses the range of technical and behavior skills to both inform needed changes as well as execute in a changing global regulatory environment.

Nan Wang: Harmonization of regulations across the globe can be expected to enhance the global simultaneous development and make drugs available to patients quickly.

- Medical writers in different countries/regions will work more closely and share knowledge and understanding, which will contribute to the establishment of the "global" document strategy and the process to support global simultaneous submission.
- Medical writers working in specific countries/regions with unique regulatory requirements should take the initiative to understand a global approach and promote local requirements with solutions. They should take the bridging role to implement global-level standardizations.

Jeannene Butler: Based on recent learnings from EU CTR, we may need to consider revising the process and/or structure of how protocols and amendments are developed. Protocols require structure to clearly define parameters for the conduct of a clinical trial; however, because many trials are now being conducted globally, we need to consider how best to accommodate region-specific changes and requests from HAs in an expedited manner. For example, EU CTR Requests For Information (RFI) can come in from various member states, and these require responses, and often protocol amendments, within a couple of weeks. Instead of creating and maintaining country-specific protocol amendments for each change, perhaps the protocol could exist in an electronic format with version control and the ability to tag country-specific elements and switch the view depending on the region where the investigator is conducting the trial.

How might the skills profile and daily work for medical writers of the future be shaped by enhanced standardization, harmonization, automation (artificial intelligence [AI]), or other factors?

Jeannene Butler: Although no AI would ever be able to completely replicate the skill and art of a human medical writer's work, technology can, and should, be enhanced and socialized to make our jobs easier. If there was an increase in standardization and enhanced technology to assist with the daily work of medical writers, we would need to adapt

by becoming more tech-savvy ourselves, for example, learning the AI systems and coding to modify those as needed for our specific documents. What would NOT change would be the ability of medical writers to analyze scientific data and craft language around those results, and the critical soft skills of leadership, communication, and collaboration with our project teams and SMEs.

Renee Primus: Strategy and data design to support critical messages and drive labeling claims are key writer competencies but not leveraged enough due to some siloed ways of working across teams where preplanned data templates and lack of technology restrict manipulations. Technologies that allow direct interface and strategic data design for automated data entry while maintaining integrity would enhance more direct review and interpretation by regulators. Writers working collaboratively to bring their insights will enhance team effectiveness in the production of fit-for-purpose, message-driven documentation that aids the regulatory reviewer in their decision-making roles. In general, the more we remove the unnecessary and replace with strategic information design, the greater the value that writers bring to documentation will be realized.

Jonathan Mackinnon: It is likely that future medical writers' skill sets will include elements of data science and content management as clinical research transitions from a document- to content-driven industry. Rather than developing a document in isolation, writers will be expected to work with interlinked content that is developed in parallel—as opposed to sequential document preparation.

Kelley Hill & Matthew Renda: Consideration of diversity and inclusion are missing from many types of document templates and should become part of the training for medical writers. In addition, as industry moves to adopt automation and content-reuse to aid in document development, commensurate technical proficiency will be increasingly important for future medical writers.

Nan Wang: Medical writers will need to be able to translate the dynamic regulatory environment and diverse regional regulatory requirements into standardized and harmonized document strategy in order to foster communication efficiency. They will be able to work across boundaries and codevelop automation (AI) tools, which will add value to the medical writer's daily work. With the powerful automation/AI tools in place, medical writers will concentrate more on the generation of the content flow and process management to ensure adequate communication among cross-functional expert groups.

Julia Cooper: Technology applications for medical writing are evolving at a pace that would not have been anticipated a few years ago. It may be many decades before AI can fully replace a human medical writer; however, repetitive tasks may soon be accomplished by automation and/or AI, allowing the writer to focus on the science. For example, patient narratives can already be programmed to a large extent. New AI-based tools may enable writers to generate tables and listings via an interface directly linked to the study or submission database, without requiring involvement of a programming team, or to identify trends and patterns in data for consideration when writing results sections. It will be important that we collaborate globally to understand the benefits and limitations of these new tools and what this means for the medical writer skill set going forward.

If budget and/or technology was no limit, how would you see global medical writing teams working/collaborating in the future?

Jeannene Butler: In an amazing future for medical writers, there would be standard document templates and language across companies and regions, endorsed by HAs worldwide, which would only need minor customization for each organization. With standardized templates, AI would then be developed to electronically create the data-driven sections of the documents once the trial(s) have completed database lock and data cleaning. AI would also create and manage all the technical elements of the documents, including tables of contents, abbreviation lists, reference lists, and all formatting elements. Background product/regulatory text would be created once by medical writers, reviewed by teams, and stored in a common "master" location that would then be automatically pulled into appropriate sections of the documents. If that text was changed in the master location, it would be automatically changed in every related document, and there would be regional variations tagged as well. Medical writers would continue to work with the project SMEs to draft and refine summary and conclusion text for each document as their main focus.

Renee Primus: Modernization of ICH M4 guidance on the CTD – in particular on structure/content and leveraging cloud-based templates and tools—would be one great opportunity for the field of medical writing to work together and drive innovation.

Kelley Hill & Matthew Renda: Structured content use is already being adopted across the industry. Perhaps it would be possible to develop a shared platform of common text across all pharma/science for certain topics; for example, disease descriptions that are automatically updated with info from new publications.

Nan Wang: Medical writers will work with automation tools much more often. The human medical writer will focus on message and content, and the tool will focus on repetitive and routine tasks in the background. Medical writers from different countries/regions will work on global master documents, with knowledge and technical support, and contribute to the packages submitted in different regions. Medical writers will be involved much earlier in the process and will obtain better overview of the data flow in drug development.

Julia Cooper: In the future, medical writers will be able to focus on the science, for example, through intelligent access to content libraries for authoring protocols and semiautomated generation of Clinical Study Reports and submission documents. The writer will truly be recognized as an expert in their own right, responsible for guiding the team through the limitations and advantages of an automated document generation process.

Jonathan Mackinnon: Ideally, deeper organizational collaboration on document standards, content standards, and content management processes.

Linda Yih: Medical writing teams would have a budget and time to train junior staff on live project work and allow them to shadow senior writers to learn the nuances of managing a team with confidence. Collaborative authoring tools would support training as well as urgent projects. As new technologies are introduced, writers will need to be agile in their learning while managers provide a safe environment for learning. The next generation of writers may also have ideas on how to use or create technology to work in more efficient and meaningful ways. Knowledge-sharing and lessons learned sessions may be held to encourage transparency and continuous improvement.

Grishma Kanchan: Metaverse! The Metaverse has the potential to break down physical and geographical barriers between people. Medical writing is a global team, and with the majority of writers working remotely and virtually, using the Metaverse to explore a collaborative world and to be able to connect and interact with one another is an exciting possibility.

LOOKING FORWARD

The future of medical writing will bring many opportunities to evolve as a global profession, learning to adopt new content-driven ways of working, expanding our skill set into data science, and capitalizing on new technologies that replace repetitive tasks. With a track record for agility, medical writing is well-placed to adapt to this rapidly changing environment. Considering some recent developments that could not have been anticipated a few years ago, we need to remain vigilant to anticipate emerging global industry trends and what these may mean for expansion of our skill set. As a global profession, we also need to take ownership and drive these opportunities in a direction that increases the future value of medical writing yet further.

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Author contact: *julia.cooper@parexel.com*

BIOSUMMARIES

Jeannene Butler is Senior Director, Global Head of Medical Writing at Otsuka Pharmaceutical Development & Commercialization, and she leads a team of over 30 medical writers to develop clinical and regulatory documents for the worldwide Otsuka organization. Jeannene began her medical writing career in 2006 and has been a member of AMWA since 2007. She has contributed as a medical writing leader for several major pharmaceutical, CRO, and biotech companies.

Julia Cooper, PhD, is Corporate Vice President, Head of Global Medical Writing Services at Parexel International. She leads a team of around 270 clinical and regulatory writing staff across the Americas, Asia, Europe, and South Africa. Julia has been a member of AMWA and EMWA since 1995. From 2013 to 2016, Julia was based in Parexel's Shanghai office, where she helped set up the China Medical Writers Community. She is an EMWA Nick Thompson Fellow and serves as chair of the AMWA Executives Advisory Council.

Kelley Hill is Executive Director, Medical Writing and Clinical Trial Transparency at Alexion, AstraZeneca Rare Disease. She is a scientist and professional communicator,

with experience spanning over 30 years across the pharmaceutical industry and academia. She has extensive clinical regulatory and scientific writing experience in complex therapeutic areas, with a focus on rare diseases. She has served as a contributor to and in a leadership role for global clinical regulatory submissions supporting review and approval of drugs for diseases with unmet medical needs. She is an innovator with expertise in process improvement and operational excellence, and her global teams' performance has redefined benchmarks within Alexion for collaborative achievement and efficiency.

Grishma Kanchan is a Senior Medical Writer at Parexel International and has been with the organization for close to 7 years. She has a master's in Biotechnology from the University of Salford, United Kingdom, and predominantly works in the rare diseases and disorders sector.

Jonathan Mackinnon, PhD, is an Associate Director Medical Writing Services at Parexel International and a subject matter expert on clinical study protocols. He also teaches protocol development and trial design at the London School of Hygiene and Tropical Medicine.

Garima Pallavi is a Senior Director at Parexel International. She leads the medical writing department in India and possesses around 18 years of regulatory writing and leadership experience.

Renee Primus, PhD, is Head of Global Scientific and Regulatory Documentation at Bristol Myers Squibb with 25 years of experience in nonclinical research and clinical regulatory sciences. Renee and her team drive documentation strategy and authoring of message-driven, fit-for-purpose regulatory documents in support of drug development, submissions, and approvals.

Matthew Renda, PhD, is Director of Medical Writing Operations at Alexion, AstraZeneca Rare Disease. He has 12 years of academic research experience focused on gene therapy and 15 years of pharmaceutical development experience providing regulatory submission management and medical writing leadership to optimize cross-functional processes, implement innovative technologies, and efficiently develop clinical documents.

Nan Wang, PhD, is Head of Medical Writing at Bayer Healthcare. She has more than 12 years' experience in medical writing from both pharmaceutical companies and a CRO. Nan is a founding member and chairperson of the China Medical Writers' Community.

Linda Yih, BSc, is a Senior Director in Medical Writing Services at Parexel International. As the global lead for the People Development initiative, she focuses on onboarding, professional development, recruitment, and retention of writers as well as managers.