Optimizing the value of regulatory medical writers

Dylan Harris[1], **Lisa Chamberlain James**[2], **Julia Forjanic Klapproth**[3], **Brian Bass**[4], and **Angela Russell Winnier**[5], **on behalf of the AMWA Value of Medical Writing Working Group**

1 Takeda Pharmaceutical Company Limited, Lexington, MA, USA;
2 Trilogy Writing and Consulting, Cambridge, United Kingdom;
3 Trilogy Writing and Consulting, Frankfurt, Germany;
4 Bass Global Inc, Fort Myers, FL, USA;
5 Pfizer, The Woodlands, TX, USA

This article was originally published in *AMWA Journal*. 2021;36(4):138–44. amwa.org https://doi.org/10.55752/amwa.2021.82

Correspondence to
dylan.harris@takeda.com

Abstract

An expanding need for clinical documentation and regulatory health authority interactions during drug development has drawn increased attention to the role of the regulatory medical writer. This role is frequently misunderstood and poorly recognized. The American Medical Writers Association (AMWA) formed a working group in 2020 dedicated to defining the value that regulatory medical writers contribute. The purpose of this article is to demonstrate the value that regulatory medical writers bring to the drug development and approval processes and to explore the ways in which efficiencies in regulatory writing can be increased. Current models for success provide guidance on training to help medical writers achieve their full potential, but obstacles and barriers to medical writing efficiency and document quality remain. Surveys developed by the AMWA working group revealed that (1) regulators who review clinical documents believed that regulatory writers improve document quality and (2) writers are frequently recognized for leadership and collaboration. Maximizing medical writing value requires thoughtful leadership and investment in training that includesboth technical knowledge and soft-skill proficiency.

Introduction

Expansion of the biopharmaceutical industry has given rise to many jobs with very specialized skills sets supporting both the conducting and reporting of clinical trials. One of these specialized jobs is that of the medical writer. There are now several types of medical writers: those who focus on clinical data publication writing, those who support medical education and conference materials, and those who primarily prepare regulatory documentation supporting ongoing clinical trials (eg, clinical study protocols, investigator brochures, investigational new drug [IND] applications) and the reporting and submission of trial results to regulatory agencies (eg, clinical study reports and Module 2 clinical summary documents for marketing applications). Writers in this latter category have been termed "clinical writers," "regulatory writers," or "clinical–regulatory writers," and exploration of the value of their role is the focus of this article. For purposes of the current discussion, these writers will be referred to as regulatory writers.

Companies engaged in the development of new medicines have a high need for expert communicators and devote substantial budgets to ensuring that documentation supporting clinical trials and regulatory submissions is accurate and of high quality. However, because company structures and team structures vary significantly, expectations of the role of the regulatory writer may also vary. Full exploitation and harnessing of the writer's skills and value requires members of the clinical project team to have a common understanding of the writer's role. As this proposition regarding the value of the regulatory writer has become a prominent topic in the medical writing community, the American Medical Writers Association (AMWA) has formed a working group focused on understanding and communicating the value that regulatory writers bring to project teams. The remit of this working group included developing a series of surveys designed to gather information about the value that regulatory writers represent, as well as a thorough review of the literature to identify articles that address this topic. This article aims to demonstrate the value that regulatory writers bring to the drug development and approval process and to explore both common obstacles to efficiency and ways we can increase efficiencies in regulatory writing, including through improved training of medical writers industry wide.

Current models for success

A Medical Writing Competency Model was developed by an industry-wide group of medical writers to provide guidance on how to assure quality and consistency in the medical writing function.[1,2] It also serves as a tool to describe the value and contributions of medical writers to drug development and medical communications. The model defines the essential knowledge, skills, abilities, and behaviors (KSABs) necessary for medical writing competency. It is purposefully designed to include the scope and breadth of the medical writing profession, and it is applicable to both medical writers and managers of medical writers.[1] The Competency Model establishes 5 core competency domains through which the KSABs applicable to medical writing can be assessed and a medical writer's competency can thus be certified.[1,3] These 5 core competency domains are gathering, evaluating, organizing, interpreting, and presenting.[3] They are the backbone of medical writing certification and the foundation of the Medical Writer Certified (MWC) examination.[1,4] In addition to defining and facilitating assessment of the core competencies that contribute to a medical writer's value, the Medical Writing Competency Model and MWC examination inherently provide guidance on training to help medical writers achieve their full potential.

Obstacles to efficiency

Notwithstanding the training and competency models currently available, there are still substantial obstacles and barriers to efficient medical writing to be recognized, acknowledged, and overcome. These obstacles have a significant and direct impact on submission timelines, success, and ultimately the speed of delivery of new medicines to patients.

Lack of adequate writing skills and strategy

Documents prepared without using lean writing techniques take longer to write, review, approve, and therefore submit. They also slow down the regulatory review and approval by agencies. Thus, not only the sponsors but also, ultimately, the end users of new drug treatments are affected by these documents that hinder readability and comprehension.[5]

Oshiro et al surveyed registrants of 12 non compulsory workshops on scientific publishing, in which respondents were asked what they found most difficult about preparing a manuscript.[6] Two of the most common barriers to manuscript publishing included uncertainty about how to organize. Lean writing techniques and technical skill in writing help give a writer clarity in structuring thought and organizing it into a meaningful order with a good thought flow. When a document is structured to present data in a manner that builds ideas, the reader can more easily follow what the intended messages are and can more readily understand the conclusions.

Insufficient time

A key barrier to efficient medical writing is having sufficient time to craft the documents. Writing is an iterative process and writing the scientific documents that medical writers prepare is also a collaborative process involving multiple stakeholders, all of whom bring different perspectives that are relevant to the totality of the storyline. This means that timelines for the writing activities need to allow for sufficient time to pull a large amount of information together from multiple sources and weave it into a cohesive document. Timelines need to permit teams the bandwidth to strategically review the ideas and data presented. Complex documents with many interrelated topics may require multiple reads, with adequate timelines supporting this activity.

In addition, the time available for medical writers to focus on the data presentations and honing of the messaging is often reduced because they are not given the right tools and processes to optimize their writing time. For example, in the absence of good templates, medical writers need to spend time on predefining headings, styles, and formats, which means that less time is available to spend on the scientific content.[7] They might be given PDF files as source documents, which means they must spend time reformatting content taken from these files; or the team might insist on not using a lean approach to presenting the data, and the medical writers are asked to produce long, unwieldy documents full of bulk. Because timelines are rarely extended to accommodate these extra activities, adequate checks for scientific rigor are foregone, errors may be overlooked, and the relevance of interrelated data points may not be captured.[8] As writers face ever-accelerated looming deadlines, they are working longer hours, resulting in increased errors and an overall loss of quality. A study on quality metrics for clinical study reports found that for medical writers whose work rate exceeded the standard work rate by 1.5 times, it was more likely that major sections of the draft clinical study report required reworking than for medical writers whose work rate did not exceed the standard.[9]

Insufficient training

Good and continued training is crucial to ensuring that these regulatory documents are being written by medical writers who have the lean writing skills to present the data with a structure that improves readability and guarantees they are fit for purpose. Training is needed not only on communication of clinical messages but also in interpretation of the data in the first place. Sharma highlighted that the key barrier that medical writers from India face in producing quality regulatory documentation is training because of a lack of a standardized training curriculum.[10] Lack of training can result in flaws in connecting the results to the conclusions, leading to claims that are not adequately supported or are erroneously reported.[8] Diong et al conducted an analysis on research papers and found poor statistical reporting, including implied or gross spin, use of standard errors or the mean to calculate data variability, and lack of P value reporting for primary analyses.[11] This demonstrates a clear lack of understanding on how to be reporting this information, which could be avoided if medical writers had adequate training in this area.

Barriers to document quality

Given that regulatory documentation is critical for drug approval, these documents need to be of a high quality and accurately reflect the data supporting the proposed indication. Review of regulatory documents by subject matter experts during the authoring process ensures that the data have been correctly interpreted and that key messages are supported; however, getting reviewers to provide the necessary input can be challenging. As a result of competing priorities, they often do not have sufficient time for their review, which results in inadequate checks of methods, results, or conclusions and can contribute to the introduction or oversight of errors.[8]

Inconsistencies, both between documents in a submission dossier and between documents and their source data, hinder review by regulatory agencies, resulting in unnecessary questions and responses. Li et al provided an example of the review of an IND submission in which a discrepancy in a definition of a key term, which on the face of it may seem relatively minor, confused a regulatory reviewer who questioned the sponsor in the regulatory response.[12] This error, which would have been simple to correct during document review or quality control, led to wasted time and effort on the sponsor's part and was a fully avoidable delay to approval.

Optimizing efficiency: Impacts of leadership and training strategy on medical writing value

Maximizing medical writing value requires investment in training and thoughtful leadership. How a medical writing department utilizes its writers may impact the value potential of the team. Managers who encourage specialization in a specific document type or phase of development (ie, the creation of functional silos) are working toward short-term efficiencies only. Functional silos can result in inefficiency and employee dissatisfaction.[13] Avoiding those silos is critical for establishing an environment of flexible and creative problem-solving, and writer overspecialization can lead to reduced knowledge, collaboration, creativity, and confidence.[14] This does not mean that medical writers should never work on the same document twice in a row. Indeed, a writer needs to write any one document type several times to become truly confident in the unique features of that document and understand its needs. But by allowing writers to work on multiple document types, in different therapeutic areas, they gain a broader understanding of how the documents relate to each other and how they need modifications for different settings. This broader oversight makes them better able to advise teams and construct documents that are more fit for purpose. Building an agile, broadly experienced team also positively impacts employee satisfaction and career development as it gives the writers more options to work in areas that better fit to their personal character (some writers enjoy writing about pharmacokinetics and others prefer safety topics), which keeps them engaged and gives them growth potential. Effective leadership thus requires investment in cross-training and broader development of writing staff; in other words, it requires seeking to create medical writing "generalists" rather than "specialists." The value of generalists over specialists is known from other industries, and David Epstein, author of *Range: Why Generalists Triumph in a Specialized World*,[15] describes the benefit of more generalized training like this: "The more varied your training is, the better able you'll be to apply your skills flexibly to situations you haven't seen."[16] This book describes many examples of the impact of broader education on the ability to solve problems creatively. The generalist trainee is not

constrained to understanding the same repetitive pattern of working.[15] Likewise, a writer who has written for all phases of development and across a variety of regulatory and clinical document types will have a breadth of experience that lends itself to valuable and creative contributions to document strategy.

Beyond training at the document level, building a strong writing team requires leadership that combines informed hiring decisions with day-to-day demonstration of desired behaviors. When regulatory writers were surveyed, the skills they were most recognized for on their teams were leadership and collaboration skills (see The Regulatory Writer's Perspective on page 80), indicating that these soft skills are a critical dimension of the regulatory writer's role. The survey also revealed leadership skills, collaboration skills, and project management as the top areas in which writers desire more training. Managers need to hire staff with the curiosity and team spirit needed to form a solid working group. The managers themselves then need to lead by example of the desired traits that solidifies a team. This includes showing a willingness to ask the right questions and to collect varying viewpoints on a problem (Table 1). It also includes encouraging horizontal relationship-building with other functional areas so that the medical writing team has a shared vision and understanding of goals with those other func- tions.[17] Teammates who learn to collaborate across functional boundaries gain skills faster and increase business efficiencies.[18]

Multiple studies describe a link between employee satisfaction and effective training.[19] A study of human resource employees showed a statistically significant impact of training and development on employee satisfaction and con- cluded with a recommendation to provide training oriented not only to work tasks but also to the developmental goals of the employee (eg, more generalized training opportunities).[20] Not only do generalist skills aid writers' development, but these skills can also help them to progress in their career. The progression from individual contributors to managers to enterprise-level leaders requires multiple "seismic shifts" in thinking, including a willingness to train as a generalist as opposed to a specialist.[21] Supporting this idea, a survey conducted in 2013 revealed that 60% of respondents felt their manager was a "good generalist" with broad transferable skills in people management and leadership, which are necessary for more senior positions in an organization.[22] Broad training strategies, then, need a company's attention for both improving problem-solving as well as positively impacting employee satisfaction and development into more senior roles, all of which elevate the value of the medical writing organization.

Soft skills that increase efficiency and add value

Soft skills, in addition to technical knowledge, are essential for medical writing success.[1,2] These skills are increasingly recognized as an important contributor to competent job performance in a wide range of fields.[1,2,23-36] A recent survey was conducted with human resources and learning development specialists, including C-level executives, senior managers, and managers/supervisors, at companies ranging in size from <1,000 to >50,000 employees in a variety of industries, includ- ing technology, manufacturing financial services, health care, retail, hospitality, telecommunications, and education.[36] The survey found that across industries, the need for soft skills is nearly as difficult to fill as the need for hard skills.[36] The most in-demand soft skills identified by survey participants were critical thinking, communication, and creativity.[36]

However, as the need for soft skills grows, they are only briefly mentioned within the context of medical writing.[1] The Medical Writing Competency Model includes a list of soft skills in a supplementary table of general abilities that are applicable to all medical writers, regardless of their area of specialty.[37] These soft skills include assertiveness, compromise, decisiveness, kindness, conflict resolution, flexibility, leadership, resilience, negotiation, and openness.[37] Many of the soft skills listed in the Competency Model are mentioned in other articles on medical writers and medical writing.[1,2,23-35] Many of these authors identify additional soft skills they believe are also crucial for medical writer and manager competency (Table 2).

Many of these soft skills are relevant to the competency, and ultimately to the value, of all medical writers. An analysis of regulatory medical writing job opportunities posted on the European Medical Writers Association website between 2009 and 2011 ranked the behavioral and social soft skills required of medical writers by the frequency of their appearance in job posting advertisements (Table 3).

Medical writers are recognized by drug development stakeholders, including study sponsors and government agencies, as valuable contributors to drug research and regulatory processes.[32] Part of that value lies in their technical understanding of how to craft thought and their regulatory understanding of the needs of the various documents. Yet their soft-skill com- petency is an equally important aspect of their value for their ability to pull teams together and keep stakeholders focused on messaging, timelines, and collaborative work ethics. Their ability to manage projects brings an essential value to their role. As noted by Ohms, a good project manager shepherds their projects and understands the interplay of the different functional areas involved.[38] Ohms points out that the 4 features of an exceptional project manager are

1. Respecting others earnestly,
2. Knowing when to speak and let others speak,
3. Understanding the details driving the project, and
4. Taking the time to self-assess and maintain focus. All of these fea- tures typify the skills that a good medical writer needs to have to successfully complete their projects on time and with a well written document.

Feedback from regulatory agencies on the value of medical writers

The AMWA working group's survey designed for regulatorswho review documentation prepared by medical writers gave some valuable insights into how the agencies perceive the role of medical writers and the value they bring to regulatory documents (see The Regulator's Perspective on page 72). Regulators recognized and acknowledged the value that medi- cal writers add to the regulatory documents they work on. They believe that medical writers improve document quality, which, unsurprisingly, is extremely important for regulatory reviewers. They confirmed that poor document quality can hamper the ability of the reviewer to provide an assessment, which in turn delays the drug approval process and in some cases can even sensitize reviewers to subsequent submission documents from the same sponsor.

These survey results provide meaningful data to support how we present ourselves within our organizations and how we should develop our medical writers – quality is clearly highly valued by regulators, and the regulators' feedback illustrates the need for a sufficient supply of highly trained writers. Ultimately, the regulatory reviewers made it clear that they are looking for lean but fully developed documents that make the scientific rationale clear and show how it is supported by the data. When training medical writers, we must equip them to lead teams to create documents that are concise and clearly present the message. There is also a clear need to focus on team management and soft skills that enable writers to lead and guide the authoring teams.

We can conclude that many regulatory reviewers understand the role of medical writers and

Table 1. How to ask good questions

Common Pitfalls	Effective Inquiry
Start with yes-or-no questions.	Start with open-ended questions that minimize preconceptions. ("How are things going on your end?"; "What does your group see as the key opportunity in this space?")
Continue asking overly general questions ("what's on your mind?") that may invite long off-point responses.	As collaborations develop, ask questions that focus on specific issues but allow people plenty of room to elaborate. ("What do you know about x?"; "Can you explain how that works?")
Assume that you've grasped what speakers intended.	Check your understanding by summarizing what you're hearing and asking explicitly for corrections or missing elements. ("Does that sound right – am I missing anything?"; "Can you help me fill in the gaps?")
Assume the collaboration process will take care of itself.	Periodically take time to inquire into others' experiences of the process or relationship. ("How do you think the project is going?"; "What could we do to work together more effectively?")

Adapted from Edmonson et al.[18]

believe that they make the job of the reviewer easier. Medical writers are clearly valued and respected by regulatory agencies, and these take-home messages should empower the medical writing profession and help to shape the ongoing training of medical writers.

Optimizing the role of the medical writer

To optimize the role a medical writer plays on cross-functional teams, we need to understand the skill set that these writers require to play this role well. Ultimately, a good medical writer must master 3 main areas: writing skills, understanding the regulatory needs of the documents they are writing, and inter- personal skills to effectively manage projects.

Writers need to have excellent writing skills to effectively communicate the thoughts and vision of the document from their teams. This involves not only knowing how to structure thought in well-formed sentences but also how to structure the document in such a way that a reader comprehends how the various data points build on each other to form the intended messages. Developing a good medical writer, therefore, must begin by having someone who already has a talent and passion for writing and then must progress to guiding them to hone their craft. Like any talent, writing skills get better with training. Teaching a writer to write better requires having someone who already has the skills to take the time to review and revise the text of the learning writer to show them how to improve. This is an investment of more than just giving them a well-written document and asking them to emulate it. It needs a trainer who will pull apart what the writer wrote, reconstruct it, and then take the time to explain why and how. People learn by making mistakes, and it is only when we are shown those mis- takes and understand how to avoid them that the learning pro- cess takes place.

Writers also need to understand the unique purpose of each type of regulatory document. Many of these documents contain similar information, but the intention of each document differs. Some are meant to communicate to investigators, others are meant to communicate to regulatory reviewers, and all of them need to tell a slightly different part of the story for different purposes. Medical writers not only need to learn the theory of the regulatory requirements specified by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use and other agency guidelines that define what each document is meant to do but also need to be given sufficient guided practical training to see how teams build, discuss, and craft these documents.

This includes having the opportunity to see feedback from agency reviewers on different types of documents and be part of teams who revise the documents in response to this feedback. Think of the difference between learning to fly a plane by reading the instruction manual and spending 10,000 hours in the air with a coach. Only the latter produces a seasoned pilot. This is an instance in which the concept of a generalist compared with a specialist becomes salient. Ensuring that a writer has practical experience on a broad spectrum of documents across a clinical development program gives them more depth of knowledge and makes them more versatile overall. It means they can truly advise teams on what fit for purpose looks like for different document types and that they help teams

Table 2. Important soft skill-based competencies not listed in the medical writing competency Model[1]

Soft Skill	Cited in:
Project management	Pal 2019,[24] Limaye 2020,[25] Saleh 2020,[27] Guillemard 2014[28]
Time management	Heisel-Stoehr and Schindler 2012,[23] Flaherty 2014,[26] Nice 2016[30]
Multitasking	Heisel-Stoehr and Schindler 2012,[23] Pal 2019,[24] Nice 2016[30]
Critical thinking	Flaherty 2014,[26] Guillemard 2014[28]
Cultural competency	Heisel-Stoehr and Schindler 2012,[23] Flaherty 2014[26]
Ability to work independently	Heisel-Stoehr and Schindler 2012,[23] Pal 2019[24]
Work ethic	Heisel-Stoehr and Schindler 2012,[23] Flaherty 2014[26]
Attention to detail	Heisel-Stoehr and Schindler 2012,[23] Nice 2016[30]
Networking	Heisel-Stoehr and Schindler 2012[23]
Self-motivation	Pal 2019[24]

Table 3. Top-Ranked Soft Skills in EMWA Job Ads for Regulatory Medical Writers: 2009-2011[23]

Behavioral Skills	Percentage of Ads	Social Skills	Percentage of Ads
Leadership, team working	62	Communication	47
Networking	56	Interpersonal	22
Organized	33	Work independently	18
Time management	30		
Detail-oriented	27		
Multitasking	15		
Conflict management	10		

Ads, advertisements; EMWA, European Medical Writers Association.

achieve that.

Finally, to optimize the value of a medical writer, we need to ensure that writers can train on the soft skills identified previously. This requires creating a safe environment that empowers them to challenge their boundaries as they learn how to assert themselves and corral teams. This training should come initially through demonstration, as novice writers witness experienced writers steering their teams and collaboratively working alongside other functional areas to develop documents. As writers develop, they must be granted increasing responsibility for running simpler meetings with an experienced writer there to support them, if needed. The acquisi- tion of soft skills can be the most challenging dimension of writer development. Many writers are not extroverts by nature, and gaining the confidence to speak up and challenge subject matter experts often means overcoming their natural tendency to sit back and let others lead. By creating a situation in which writers first learn by example, writers are then allowed to execute within a safe environment and finally function independently once they have the necessary skills. We must give them the encouragement and security to grow without fear of embarrassment or risk of failure. In this way, we nurture strong, confident writers who have the wherewithal to collaborate with even the most demanding teams. Through training and development with a focus on both technical and soft skills and identification of growth opportunities for new and developing writers, we can continue to address the challenges discussed here and foster the next generation of regulatory writers.

Author declaration and disclosures:

The authors note no commercial associations that may pose a conflict of interest in relation to this article.

References

1. Clemow DB, Wagner B, Marshallsay C, et al. Medical Writing Competency Model – section 1: functions, tasks, and activities. *Ther Innov Regul Sci*. 2018;52(1):70-77.
2. Clemow DB, Wagner B, Marshallsay C, et al. Medical Writing Competency Model – section 2: knowledge, skills, abilities, and behaviors. *Ther Innov Regul Sci*. 2018;52(1):78-88.
3. Clemow DB, Wagner B, Marshallsay C, et al. Medical Writing Competency Model – section 1: functions, tasks, and activities. *Ther Innov Regul Sci*. 2018;52(1):70-77. Supplementary material, Table S2. Accessed February 24, 2021. https://static-content.springer.com/esm/art%3A10.1177%2F2168479017721585/ MediaObjects/43441_2018_5201070_MOESM2_ESM.pdf
4. American Medical Writers Association. Medical writing certification examination candidate study guide. February 2018. Accessed February 24, 2021. https://cdn.ymaws.com/www.amwa.org/resource/resmgr/ certification/Forms/2018/MWCStudyGuideResourceList.pdf
5. Bhardwaj P, Sinha S, Yadav RJ. Medical and scientific writing: time to go lean and mean. *Perspect Clin Res*. 2017;8(3):113-117.
6. Oshiro J, Caubet SL, Viola KE, Huber JM. Going beyond "not enough time": barriers to preparing manuscripts for academic medical journals. *Teach Learn Med*. 2020;32(1):71-81.
7. Billiones R. Document templates for medical writers. *Med Writing*. 2014;23(1):17-21.
8. Brown AW, Kaiser KA, Allison DB. Issues with data and analyses: errors, underlying themes, and potential solutions. *Proc Natl Acad Sci USA*. 2018;115(11):2563-2570.
9. Purcell TJ. The application of metrics to determine the work rate for producing the first draft of the clinical study report: a case study. *Drug Inf J*. 2005;39:171-175.
10. Sharma S. Development of medical writing in India: past, present and future. *Perspect Clin Res*. 2017;8(1):45-50.
11. Diong J, Butler AA, Gandevia SC, Héroux ME. Poor statistical reporting, inadequate data presentation and spin persist despite editorial advice. *PLoS One*. 2018;13(8):e0202121
12. Li H, Hanna K, Petteway S. Ensuring quality of regulatory clinical documents. *Qual Assur J*. 2010;13(1-2):14-20.
13. Ismail K. 5 Signs your organization is too siloed. CMS Wire website. Published January 29, 2018. Accessed March 8, 2021. https://www. cmswire.com/leadership/5-signs-your-organization-is-too-siloed/
14. Gleeson B. The silo mentality: how to break down the barriers. Forbes website. Published October 2, 2013. Accessed March 8, 2021. https://www.forbes.com/sites/brentgleeson/2013/10/02/the-silo-mentality- how-to-break-down-the-barriers/
15. Epstein D. *Range: Why Generalists Triumph in a Specialized World*. Riverhead Books; 2019.
16. Knowledge@Wharton. Don't underestimate generalists: they bring value to your team. Published July 9, 2019. Accessed March 8, 2021. https:// knowledge.wharton.upenn.edu/article/ generalists-vs-specialists/
17. McPherson L. 5 Ways to break down organizational silos. Zapier website. Published December 11, 2018. Accessed April 8, 2021. https://zapier. com/blog/organizational-silos/
18. Edmonson AC, Jang S, Casciaro T. Cross-silo leadership. Harvard Business Review website. Published May 2019. Accessed March 8, 2021. https://hbr.org/2019/05/cross-silo-leadership
19. Schmidt S. The relationship between

satisfaction with workplace training and overall job satisfaction. *Hum Resource Dev Q*. 2007;18(4): 481-498.
20. Ozheser B. Impact of training on employee motivation in human resources management. *Procedia Comput Sci*. 2019;158:802-810. https://doi.org/10.1016/j.procs.2019.09.117
21. Watkins M. How managers become leaders. Harvard Business Review website. Published June 2012. Accessed April 8, 2021. https://hbr. org/2012/06/how-managers-become-leaders
22. Crane H. Specialists or generalists: what do employers really want? The Guardian website. Published November 5, 2013. Accessed March 8, 2021. https://www.theguardian.com/careers/careers-blog/specialist- generalist-what-do-employers-want
23. Heisel-Stoehr S, Schindler TM. Pharmaceutical medical writing competencies: comparing self-perception with employers' expectations. *Med Writing*. 2012;21(3):225-231. https://doi.org/10.1179/2047480612Z.00000000049
24. Pal M. 7 Essential skills to look for when you hire a medical writer. Kolabtree Blog website. Published August 19, 2019. Accessed February 24, 2021. https://www.kolabtree.com/blog/7-essential-skills-to-look- for-when-you-hire-a-medical-writer
25. Limaye N. Medical writing: the language and art of scientific communication. DIA Global Forum website. Published May 2020. Accessed February 24, 2021. https://globalforum.diaglobal.org/issue/may-2020/medical-writing-the-language-and-art-of-scientific-communication/
26. Flaherty K. Soft skills: the critical accompaniment to technical skills. *AMWA J*. 2014;29(2):70-72.
27. Saleh M. A medical writer's skillset. Health Writer Hub website. Published July 13, 2020. Accessed February 24, 2021. https://www. healthwriterhub.com/a-medical-writers-skillset
28. Guillemard M. Medical writing skills: ten must-have attributes. Health Writer Hub website. Published January 13, 2014. Accessed February 24, 2021. https://www.healthwriterhub.com/medical-writing-skills/
29. Henning A; Trilogy Writing & Consulting. Growing medical writing teams: strategies and best practices. *Int Clin Trials*. February 2020; (special issue):10-14.
30. Nice K. What skills do you need to be a good regulatory medical writer? Impact Pharmaceutical Services website. Published August 25, 2016. Accessed February 24, 2021. https://www.impactpharma.com/blog/what-skills-do-you-need-to-be-a-good-regulatory-medical-writer/
31. Smith K, Winter-Vann A; Trilogy Writing & Consulting. The need for, and benefit of, good medical writing. *Int Clin Trials*. February 2017;(special issue):10-13.
32. Archer R, Johnson MR, Chipps E. Evaluating the role of the regulatory writer. *Clin Researcher*. 2019;33(9). Published November 12, 2019. Accessed February 24, 2021. https://acrpnet.org/2019/11/12/evaluating-the-role-of-the-regulatory-writer/
33. Klapproth JF. Strategic benefits. *Int Clin Trials*. 2011;2011:72-75.
34. Klapproth JF. Do you measure up? Trilogy Writing & Consulting website. Published May 2016. Accessed February 24, 2021. https://www. trilogywriting.com/publications/do-you-measure-up/
35. Klapproth JF, James LC. How to build a medical writer: medical writing apprenticeships—new training for a new breed. *AMWA J*. 2019;34(2): 76-78.
36. Volzer D, Burgess J, Magda AJ. Reimagining the workforce 2021: closing the skills gap through education. Wiley Beyond website. Published February 2021. Accessed June 17, 2021. https://edservices.wiley.com/wp-content/uploads/2021/02/202102-ReimaginingtheWorkforce2021- report-WES.pdf
37. Clemow DB, Wagner B, Marshallsay C, et al. Medical Writing Competency Model – section 1: functions, tasks, and activities. *Ther Innov Regul Sci*. 2018;52(1):70-77. Supplementary material, Table S1. Accessed February 24, 2021. https://static-content. springer.com/esm/art%3A10.1177%2F2168479017721585/MediaObjects/43441_2018_5201070_MOESM1_ESM.pdf
38. Ohms C. 4 Skills an exceptional project manager can't survive without. Pharmaceutical Online website. Published July 22, 2020. Accessed October 29, 2021. https://www.pharmaceuticalonline.com/doc/skills- an-exceptional-project-manager-can-t-survive-without-0001