

Leadership Behind the Scenes: A Backstage Approach to Effective Medical Writing

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As medical writers, you've undoubtedly experienced the need for leadership in your writing projects. Have you been conflicted as to how to best establish leadership despite having no clear authority over team members? How can we motivate teams to accomplish medical writing goals and help deliver quality documents? How can we do this in a proactive, efficient, and streamlined way? Behind the scenes, we steer discussions, coordinate reviews, manage timelines, facilitate consensus, and harmonize global teams, all while writing the document at hand. Leadership is an integral part of our medical writing lives.

Imagine the following scenario: Debbie sits at her desk, a partially finished document on her monitor. Fingers on her keyboard, she hesitates, but not for loss for words. She knows how to write the report but faces a quandary that affects all medical writers: she is missing some team comments yet is tasked with meeting the timelines. The last conference call did not resolve as much as hoped and left her with no clear direction. Additionally, the data have been updated again. In this familiar scenario, leadership and efficiency are needed, and sometimes the best option is ... YOU.

In this article, we offer solutions to several scenarios like Debbie's that are applicable to contract, in-house, and freelance medical writers alike. We share experiences from seasoned medical writers compiled through informal surveys and discussions with our peers and collectively provide real world ideas on how to lead without authority, exercise diplomacy to your advantage, and provide insight on time management and personal efficiency. We provide guidance on how you can implement these strategies and takeaways into your everyday practice, including being able to identify project-, team-, and time-management solutions that will help

you grow as a medical writer and exercise positive and effective influence within your medical writing projects.

Leading Without Authority

Leading without authority takes courage to establish yourself as a knowledgeable leader, not only from a writing standpoint but also in understanding all aspects of developing and completing medical writing projects. This approach also takes work in understanding disease states, indications, document-management processes, standard operating procedures, and templates, as well as the guidance and regulations that drive our industry. Last, leading without authority requires empathy in order to put yourself in your team members' shoes and understand what is driving their decisions, all while being committed to the quality and realistic management of the document.

Scenario 1

Debbie just sent out the third version of "Draft 1" for team review. She receives an email that the team has changed directions (again). Debbie is asked to abandon the third draft, return to the first draft (with some content from the third draft), and provide a new fourth draft in the next 2 to 3 days. What action should she take?

Although frustrated, Debbie knows the document is connected to a corporate goal. She also realizes it's a good time to take a quick break to relax and do something she enjoys. Returning to her desk, she checks her availability and contacts her supervisor about this unanticipated draft.

Asking for support may be her best option, rather than taking everything on herself. Debbie can

- Put a meeting on the calendar with the authoring team to discuss any questions she may have regarding this new direction.

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- Check to ensure she understands the agreement for the number of drafts and the timelines.
- Recommend writing that can be done by a team member or another medical writer.
- Ask for more writing time, when appropriate, or a reduction in team review times.

To be successful in leading without authority, as the medical writer, you need to be prepared, be kind but firm, and know your stuff.

Scenario 2

Debbie is excited that a project is finally going through approval. She unexpectedly receives an email from team management questioning the document's accuracy and expressing surprise at the 1 day approval turnaround. What good options does she have?

This individual reviewed the document a week before; however, Debbie knows the document must be approved by this individual. Although taken aback at this turn, Debbie understands this person reviews many items per day, manages 6 people, and attends numerous meetings. Does she remember last week?

Debbie realizes that clarifying the issue is the best option. Debbie can

- Take a step back to consider her approach to the situation rather than sending a premature email.
- Use empathic, fact-based language, such as:
 - “Your statistician was an integral part in reviewing and confirming the data analysis in the document; her input has been invaluable.”
 - “My apologies; it was my understanding that you had previously reviewed the document and the approval step is typically only a formal step to approve the document in the system.”
- Include in her response that she is available by phone to discuss further, if needed.
- Inform the entire team that document approval may be delayed and provide a revised timeline if appropriate.

To be successful in leading without authority, as the medical writer, you need to be prepared, be kind but firm, and know your stuff. Understand what is potentially driving the behavior (eg, corporate goals, being caught out of the loop) but stay committed to the quality and realistic management of the document. Use empathic language to soften the defensive nature of a person, as this approach would allow your audience to remain open to the facts you are presenting. It's not about being right or wrong. It's about building a successful relationship and demonstrating your value to the team.

Team Diplomacy

Team diplomacy involves seeking to gain the perspective of your team members and navigating conflicting opinions in such a way that everyone is pleased with the outcome. Being a diplomatic leader requires building trust and gaining respect, being willing to listen, communicating rather than dictating, and using questions to solicit ideas.

Scenario 3

Debbie is waiting on comments from the last team member. Time is running out, and she suspects that the response may come later than expected. What good options does she have?

Although not ideal, if the team member is not a primary reviewer, it may be possible to proceed without those comments. Knowing her team member's role is critical to this option. During the kick-off meeting or initial interactions with the team, Debbie should clarify the hierarchy and roles within the team.

If this team member's comments are essential, it may be necessary for Debbie to accommodate late comments. It is important that Debbie be mindful of work/life balance, however, while ensuring the document moves forward.

She could

- Call the reviewer to better understand when the comments will arrive. This not only ensures the reviewer is aware of the importance of their input but also will help Debbie to plan accordingly.
- Send another email but carbon copy someone that the team member is accountable to or respects.
- Draft the email and include language regarding the updates that only requires confirmation from the reviewer. This is frequently more straightforward than asking for revised text directly.
- Reiterate timelines and the urgent need for their response in addition to the consequences of a missed deadline.
- Be persistent; ask more than once.

Scenario 4

Debbie is not getting the answers she needs at comment resolution meetings. There is significant dissent among team members, with no resolution in sight. Furthermore, the team frequently reverses their decisions after the meetings. Is there hope?

To try to resolve this issue, Debbie could

- Ensure that the project stakeholders attend the comment-resolution meetings to address unresolved issues. This requires that Debbie understands the team dynamic.
- Break down multiple comments to an overarching comment or question to help focus the team to a more concise discussion.
- Ask the question, “Does the team agree?” as a means to prevent unnecessary discussion.
- Take the discussion offline with the key team members. Occasionally, it may be helpful to request that key team members discuss internally with one individual assigned to inform Debbie of any decisions.
- Be sensitive to cultural differences. Some team members may not directly contradict a team member in a meeting but may share information more readily with Debbie privately.

Credibility is built on effective communication with your team. Whether you need to “tease out” comments from a reviewer or obtain team consensus, thinking creatively about how to best communicate and build rapport with individual team members while maintaining your boundaries is necessary to ensure your effectiveness.

Personal Efficiency

Time management and personal efficiency are on everyone’s mind, with buzz words like “productivity hacks” all over the internet. In our world, carving out these efficiencies is essential for our medical writing work, because time translates into money. This can take the form of targeted best practices for document management to understand and capitalize on personal preferences, work habits, and discipline.

Scenario 5

Debbie receives unconsolidated review comments from the team, at different times and in different formats, and some are past the deadline. What is the most efficient approach for Debbie to deal with this?

Debbie can

- Understand the make-up of the team and their individual level of contribution to the progress of the document.
- Triage incoming comments by complexity and priority—work on those requiring follow-up first, which allows

progress while simpler comments are reconciled and incorporated.

- Keep a master document. As comments are triaged, incorporate revisions likely to be essential, and make notes of those that need team confirmation.
- Mark text or comments to be discussed with the team with an easily searchable symbol (eg, \$\$).
- Leave global changes until the end, keeping an ongoing list of global changes within the document to make after other comments are reconciled.
- Send relevant sections of the document (with specific questions and instructions) to targeted reviewers for quick and critical input.
- Maintain version control—this is essential. Devise a naming convention that captures the chronology and source of comments.
- Communicate! One set of consolidated comments for each draft is typically expected.
- Proactively assess the effect on timelines and anticipate delays.

Scenario 6

Debbie contemplates how to proceed given missing review comments for her clinical study report and an unexpected data update. Other project timelines have now overlapped because of delays. Does she have too many balls in the air?

Debbie must

- Get organized with a spreadsheet across all projects—this is worth the time investment.
- Reel in the chaos by prioritizing what she can do and identifying where she might need help.
- Delegate! It is essential, however, to provide appropriate training to anyone helping out, with thorough instructions and realistic expectations.
- Parse out blocks of time to work uninterruptedly on one task—darting back and forth is less efficient. Specific goals for these blocks of time is helpful.
- Eliminate distractions—Debbie can respond to urgent emails at designated times, then turn off her email and phone.
- Capitalize on when she works best and stick to it—this is important.
- Remind contributors of the consequences of continued delays for critical path issues.
- Ask for a summary of changes for data updates to help focus revisions.
- Take advantage of collective insight through AMWA online resources and the Engage forum. She is not alone!

Leadership qualities such as being proactive and confident can make a world of difference in how you approach challenging tasks and situations. This can translate into time savings and efficiency in all aspects of a medical writing project. From knowing how to anticipate when you need help to interacting with difficult team members who are unable to review in a timely manner, confidence can ultimately help you get the job done.

Conclusion

Being a medical writer is a wonderfully rewarding career and always keeps you on your toes. Every team and project are different, not to mention the constant change that goes with writing drug and device documents. Asserting behind-the-scenes leadership is often critical to the successful conclusion of a writing project, which in turn builds your team's confidence in you as a writer and valued team member. Being able to communicate effectively and diplomatically is essential in developing successful relationships with your teams. Although this profession can be demanding at times, developing strategies that make you more efficient is key. In the end, sometimes the best option is how you personally approach each challenge. Sometimes the best option is you!

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