Plan, Lead, Deliver:
A Framework for Regulatory Writing Success

Q: Is your team simply writing a dossier, or are they following a clear strategy?

A: The most effective teams do both, but strategy should come first. Preparing a submission package entails developing a detailed project plan and adopting a well-coordinated strategy to usher a dossier through the various stages of compilation, review, quality control, editing, and completion.

Success in preparing a dossier for submission to regulators hinges on the approach the writing team takes, including how they plan, communicate, coordinate, and resolve differences. In other words, their leadership and project management skills are every bit as critical as their ability to communicate clearly, conclusively, and impartially.

The Need for Leadership at Multiple Levels

The complexity of preparing a regulatory submission calls for strong leadership across multiple levels to ensure that deadlines are met, divergent views explored, quality issues resolved, and resources allotted efficiently. Otherwise, there is a risk that the project can be derailed, delaying submission and ultimately, product availability for patients.

The scope of the project requires that an experienced senior manager be responsible for overseeing the team of medical writers and their work. This leader is charged with setting the direction, creating alignment across the diverse teams, promoting transparency, and ensuring accountability for meeting deadlines and quality standards.

The individual medical writers who are drafting the various document modules must also demonstrate leadership skills in executing the overall plan and accepting responsibility for meeting expectations with their contribution.

The Essential Pre-work

Ideally, a medical writing team is established and led by a senior manager. This team will consist of experienced senior medical writers who act as document owners for each component of the submission. They are primarily responsible for developing each document and may be supported by one or two medical copy editors, or other support writers, to prepare patient narratives and appendices, a regulatory publisher, and a clinical trial transparency associate, if needed. The medical writing team can also interact with other important representatives from other groups associated with the submission, such as, Medical Affairs, Statistics, Pharmacokinetics, Regulatory Affairs, and Clinical Operations, in a wider cross-functional team.

The medical writing team has much to do in advance of entering the first keystroke, beginning with convening a kick-off meeting to train all involved on their role, explain the tasks ahead, and clarify the standards expected. Members should also understand the methods for communicating with one another and the pathway for escalating issues or sharing achievements.

The next step is to develop a project plan with input from all key stakeholders to define the scope of the project, assign responsibilities, and lay out a detailed timeline. While it is helpful to include day-to-day milestones and interdependencies in the timeline, revising the entire schedule if there is a one or two-day lapse in completing a step should be avoided.

At this point, the team should agree on key messages and a storyboard of how they'll be presented, since defining the end message in advance will help maintain focus throughout the process. The plan should include a checklist that maps out what information will be needed for each module and who will be responsible for securing it. This is an extensive effort that can't be completed in an afternoon.

It is vital to involve reviewers at this early stage to brief them on what will be expected of them to avoid conflicts at a later stage – conflicts that put the timeline at risk. Will their focus be on scientific accuracy, compliance, or formatting? The goal is to prevent the sudden appearance of a "wild card" reviewer who weighs in at the end of the process, perhaps disagreeing with content that has already passed multiple approval stages.

For efficiency's sake, reviewers should be instructed to:

- Provide clear and constructive comments (rather than open-ended questions) and alternative text where applicable. Conceptual comments or those that invite further discussion can delay progress.
- Hold discussions outside of the document review system as needed to reach consensus.
- Refrain from making editorial comments, as these will be addressed later.
- Make global comments once if they apply to multiple sections.

Best Practices for Managing the Project

To enhance the quality of the submission and shorten the preparation timeline, medical writers should adopt a well-coordinated strategy that entails:

- **Convening regular status meetings of the cross-functional team.** These meetings allow all involved to stay informed, the lead writer to stay abreast of co-authors' progress, and team members to share helpful tips and tricks.

- **Creating a shell document** using source documents such as the protocol and including pre-agreed results text, in-text tables, and conclusions (based on key messages),

with extensive placeholders for the study results. The existing text can be reviewed and agreed upon during the shell development; only the draft results will need to be reviewed later, as the rest of the document will have been "locked down."

- **Holding structured comments resolution meetings (CRMs)** with mandatory attendance. Addressing conflicting or non-consolidated comments from reviewers is typically one of the greatest and most time-consuming challenges medical writers face. Such meetings should be scheduled as soon as the overall timeline is agreed upon, and if a key decision maker cannot attend, a suitable backup should be appointed. To control the process, comments should be circulated prior to the meeting and categorised as "accepted without discussion," "rejected with reasons," or "require further discussion at the CRM." It is helpful to set time limits on each discussion and to annotate adopted resolutions in the draft.

- **Employing technology to the fullest extent possible.** Centralised authoring/review platforms are available to monitor progress, track changes, control versions, collaborate in real time, and ensure adherence to timelines. Such automated tools also facilitate the flow of information between modules. Comprehensive, electronic documentation provides an audit trail for accountability and compliance as well as facilitating communication across geographically dispersed teams.

- **Applying rigorous quality controls to maintain consistency in terminology, standards, and information across documents.** Consistency across documents is, in fact, the biggest driver of quality in the process. Ideally, quality review teams should not have been involved in preparing the draft so that they can bring a fresh perspective and minimal bias to the task. Their ability to spot inconsistencies will be aided by providing them with a style guide or cheat sheet on what to consider. Customised checklists can also help them ensure that the document aligns with regulatory guidelines around document content, structure, and formatting. Quality control reviews should be conducted on a rolling basis as sections are ready, rather than once all components are completed.

- **Convening a signature meeting for final approval.**

Navigating a complex submission landscape with confidence and efficiency demands that medical writers carry out a well-coordinated strategy. Through proper planning, following a set of established best practices, and relying on available tools, medical writers can not only transform complex data into clear, concise, and scientifically robust documents, but they can also minimise the risk of queries and delays along the way.

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