Regulatory Matters

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Editorial

In the ever-evolving landscape of regulatory submissions, where deadlines loom large and the demand for precision is paramount, the role of a skilled project facilitator cannot be overstated. Their ability to navigate the complex web of requirements and streamline the submission process is not just beneficial but often indispensable for medical writing teams operating under extreme time constraints.

A symbiotic partnership between the medical writing team and a project facilitator allows writers to focus on their core task – writing. In this issue of *Regulatory Matters*, Yoko Komatsuzaki and Julia Forjanic Klapproth shed light on how project facilitators serve as central points of contact for the medical writing team and how they foster unity among team members, develop standard ways of working, and ensure project objectives, timelines, budgets, resourcing, and metrics are well-defined and adhered to.

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In regulatory submission writing, a project facilitator is the yin to a medical writer's yang

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Abstract

Authoring and reviewing complex, parallel regulatory submission documents under extremely condensed timelines demands significant effort from the medical writing team. However, a skilled project facilitator can alleviate some of this burden by offering support and assistance across the entire spectrum of regulatory submission writing activities. This symbiotic partnership not only reduces the overall workload for the medical writing team but also enables them to focus on their core writing tasks, ultimately enhancing the quality of their work and reducing stress. Additionally, it provides an avenue for the project facilitator to establish standard ways of working and best practices, which can further enhance efficiency and consistency across multiple submissions.

Regulatory submission writing is an enormous and costly endeavour that begins during preclinical development and continues even after the product has been approved. Marketing applications encompass a series of documents that, combined, may exceed several thousand pages. These include clinical and nonclinical study reports, manufacturing information, and administrative reports.[1] These documents are subject to a stringent set of regulatory requirements and deadlines imposed by the health authorities to ensure the safety and efficacy of products under review. Whether the documents are produced internally or outsourced to a service provider, the medical writing team collaborates within a cross-functional framework and often interfaces with external stakeholders.

In this intricate landscape, project management permeates every facet of preparing a regulatory submission. Project managers are needed at each stage, from initial planning of the nonclinical and clinical development programs by coordinating the writing of the myriad of documents included in a submission, to supporting interactions with the health authorities, and continuing throughout the lifecycle of the marketed product.

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Today's demands on lead medical writers

The medical writing activities required to prepare these regulatory documents represent a microcosm of all these project management activities. Over the last 20 years, the role of a lead medical writer has become ever more complex, developing far beyond writing itself. For example, the following activities must be maintained in addition to drafting, reviewing, and revising the Module 2 summaries for a regulatory submission:

- A project plan must be created and maintained to keep track of the numerous interdependencies.
- Writing resources must be juggled to handle additional writing activities (e.g., owing to the addition of new analyses, sometimes even new studies, and supporting reports).
- Subject matter experts must be corralled (in the face of many competing priorities) to agree on content.
- Messaging plans must be developed and kept up to date as new ideas arise.

- Any quality control activities must be planned, performed, and implemented in the documents.

Monitoring these activities can consume a substantial portion of time, diverting the writer's attention from their core responsibility of producing high quality documents.

Project facilitator as a partner to the medical writing team

In this context, a new role has evolved to take some of these responsibilities of the medical writer facilitating their ability to concentrate on the writing itself – particularly in crunch periods when new data are arriving and the writer needs to be focused on having conversations with the subject matter experts to tease out the story to be told. We have termed this specific branch of project management, designed to support medical writers on these complex projects, project facilitators.

The project facilitator may serve as a central point of contact for logistical and overarching concerns among the medical writing team. While not directly involved in document authoring, they actively participate in every phase of the project, including study start-up, authoring support, review monitoring, quality control, publishing, and project close-out coordination. This role extends beyond mere coordination. They are also valuable at fostering unity among team members by developing trust, flexibility, cooperation, and collaboration within the cross-functional team. They are partners with the lead medical writers, working in tandem to ensure nothing falls through the cracks.

To this end, project facilitators aid their team in ensuring that projects are well-defined with clear objectives, timelines, budgets, resourcing, and metrics. A competent and seasoned project facilitator can make all the difference when it comes to the efficiency with which a regulatory submission is prepared and getting it done on schedule. In addition to having a solid understanding of all standard operating procedures (SOPs), best practices, and work instructions, they must also possess leadership skills that influence the interactions between the cross-functional team. The role of a project facilitator demands a broad variety of skills, including building interpersonal relationships, critical thinking, analytical abilities, budgeting, decision-making, and problem-solving. As Peter Reichert, a leader in the pharmaceutical field, explains, project facilitators can be likened to conductors leading an orchestra, where the project team are the musicians.[2] Just as conductors must be familiar with the entire musical score and anticipate challenging parts, project facilitators need to understand the project's entirety, recognise potential obstacles, and strategise ways to overcome these. Similar to how conductors may improvise or modify the performance, project facilitators may need to help the team see when to adapt and adjust the project as it proceeds.

In terms of facilitating communication across the project team, the project facilitator can assist in keeping team members connected. They are in regular communication with the medical writers working on the project and can see tasks where they need a helping hand, such as setting up meetings or reaching out to team members to get missing source material. They will participate in key meetings such as the kick-off meeting, which is a chance for the project facilitator to familiarise themselves with the team and determine pre-

ferred communication methods and frequency. They may also use this time to set goals and priorities, working closely with the project team early in planning to obtain their input on all major decisions. Through this process, they will get to know the team better and establish the standard ways of working. The project facilitator can make note of team dynamics, training or knowledge gaps, and even mentoring opportunities for team members new to a submission.

Cornerstones of the project facilitator role

As submission projects get into full swing, they require constant and effective collaboration between medical writers and a diverse, multidisciplinary team comprising clinical, statistical, regulatory, safety, and other functional experts. Project facilitators play a crucial role in supporting the medical writing teams by focusing on the following six key activities.

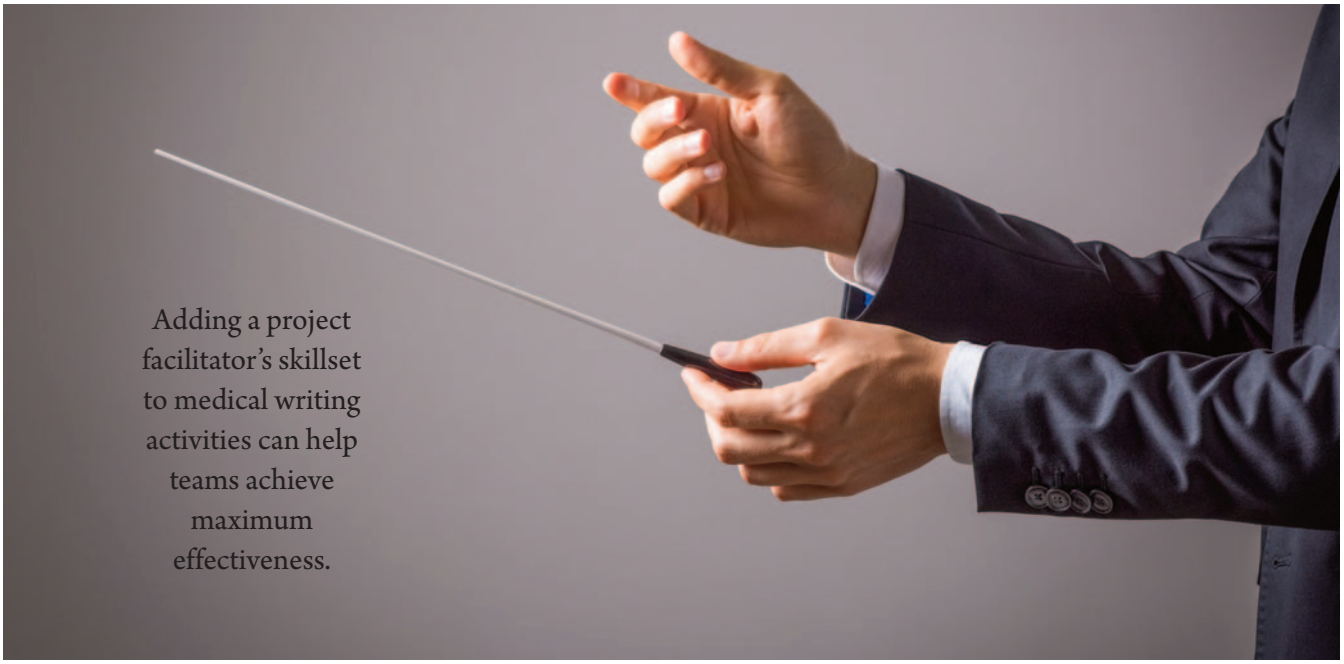
1. **Creating and maintaining project timelines**
   Helping a team stay focused on timelines ensures the project stays on course. The project facilitator diligently monitors the progress of the timeline throughout the authoring, review, and approval periods and, together with the medical writing team, flags up changes in scope that may result in timeline shifts. They will recognise deviations from the plan (when the rest of the team may be focused on other things) and act swiftly to develop contingency plans that bring the project back on track. They will organise meetings between the writers and the key stakeholders to renegotiate the timeline and make decisions in a timely manner. They are often tasked with providing the revised project timelines to the project team promptly.

2. **Tracking project budget status**
   A review of milestones in parallel with the budget on a regular basis can illuminate areas of low or high efficiency. The project facilitator continually monitors the budget throughout the life of the project and assesses any impacts on the budget due to changes in scope, timelines, or resourcing. If the required resources will cost more than the anticipated amount, they will discuss with the relevant stakeholders and take appropriate action. This may involve developing a revised cost plan.

3. **Monitoring changes in resources**
   Active engagement helps teams achieve maximum effectiveness. The project facilitator maintains a comprehensive resourcing plan throughout the duration of the project, detailing the roles and responsibilities of each team member. They proactively identify and help address any resourcing bottlenecks resulting from competing priorities, mediating discussions within the medical writing team to balance workloads and prevent burnout. If adjustments to resources are needed, they may assist the writers in organising a thorough handover to ensure a seamless transition. Considering that medical writers often exceed a 40-hour workweek while managing multiple documents simultaneously, the expertise of a skilled project facilitator is essential in effectively coordinating resources.

4. **Facilitating cross-functional communication**
   Clear communication is imperative for teams to thrive. The project facilitator maintains several open lines of communication with the team, utilising formal check-in meetings and informal chats to ensure that all team members are kept informed about project details such as timelines, budgets, resources, and pending deliverables. They aid in strategic planning by organising reviews and comment resolution meetings, clarifying the timing and roles for each team member. Recognising the time constraints faced by everyone, they ensure appropriate involvement of individuals in each step. Emphasising efficiency, they encourage teams to limit the number of reviewers per document and consolidate feedback into one set of comments per function. If necessary, the project facilitator can engage senior management to enforce these guidelines. As the project nears completion, they may assist in coordinating efforts with the quality control and publishing teams, confirming timelines, deadlines, and source document availability to alleviate the burden on the medical writer.

5. **Optimising the delivery of necessary inputs and outputs**
   Medical writers must possess the ability to sort through vast amounts of data, extract information from various sources, reconcile differences of opinion, and deliver well-written documents. With a firm understanding of the interdependencies within a submission, the project facilitator can aid the medical writing team in obtaining all necessary inputs from the subject matter experts on an ongoing basis (e.g., literature, new analyses, and review comments). Additionally, they facilitate the timely delivery of drafts for review or approval and oversee progress to ensure adherence to deadlines. Weekly check-in meetings provide a platform for collaborative discussions among the team regarding these inputs and outputs.



6. **Assisting the medical writing team with risk management**
   A close examination of the issues and risk that impact productivity is the first step in troubleshooting and reaching resolutions. The project facilitator invests time in identifying and understanding risks to the successful completion of the project. By monitoring all changes as the project evolves and working closely with the medical writing team to understand their needs and ensure these are met, they proactively address resourcing constraints and bottleneck situations and any other concerns as they arise. Keeping the end in mind, namely, the timely submission to a health authority, any risks impacting this goal need to be identified and mitigated. Working with the medical writers and clinical and regulatory teams to address these situations, the project facilitators can help avoid or overcome these risks.

Another area the project facilitator can support the medical writers and project team with is the coordination and running of a "lessons learned" meeting after a submission is complete. They can keep a running tab of issues that arise during the project and use these as a starting point for discussion during the meeting. As they were monitoring progress throughout the project, they are in a good position to recognise both efficient and problematic areas, and the project facilitator's perspective can help maintain balance in this conversation. Emphasising positive aspects boosts team morale and engagement. Striking a balance between addressing issues and acknowledging successes fosters a collaborative and motivated team.

Conclusion

The addition of a project facilitator's skillset to medical writing activities can help teams achieve maximum effectiveness. The project facilitator's ability to engage stakeholders early in the submission process, manage priorities, build consensus, and create an environment that embraces change has a profound impact on team effectiveness. As projects have grown more complex, with more stakeholders involved, more regulations to consider, and a general push to have drugs reach the patient sooner, their contribution is a valuable addition to medical writing teams.

Disclosures and conflicts of interest

The authors declare no conflicts of interest.

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Author information

Yoko Komatsuzaki, MPH, has 10 years of experience as a project manager/project facilitator, partnering with medical writing teams on multiple projects and submissions. Prior to this, Yoko spent 10 years of her career as a project manager overseeing and managing clinical trials and registries.

Julia Forjanic Klapproth, PhD, has been a medical writer since 1997, and co-founded Trilogy Writing & Consulting in 2002. She was president of the European Medical Writers Association twice. In 2022, Julia received the American Medical Writers Association (AMWA) Harald Swanberg Award for distinguished service to the medical writing community.