Regulatory Writing

Review process in regulatory writing

Section Editor:

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Recently, Phil Leventhal posed the question 'What does it take to go from being a good medical writer to an excellent one?' on EMWA's LinkedIn Discussion Group. My impression is that the responses were written largely with medical communications (that is, texts for publication) in mind rather than regulatory writing per se. Posters made plenty of useful suggestions such as a focus on the target audience and forward planning. Given the involved debate about ghost writing, I was perhaps a little surprised though that there was no mention of ensuring that the thoughts and opinions of (all) named authors are included. According to my understanding, medical writers are channels through which the intellectual authors can express themselves appropriately. This presumably involves interacting and negotiating with authors during review rounds to ensure that the text is representative of the desires of the headline authors.

In the case of regulatory writers, management of review cycles is an essential component of being an excellent regulatory writer. Most regulatory documents necessarily follow a process of 'design by committee'. Thus, many different departments within a pharmaceutical company, and different levels of management within a department, might have a stake in a document, and often, reviewers may have different goals and different priorities. With input from so many sources, review cycles can become chaotic with the result that the final document lacks coherence and vision. A skilful and experienced medical writer should aim to navigate the sometimes bumpy review rounds and come out with a document that is both readable and well-structured while also representing the positions and opinions of the different contributors.

While it is easy to recognize the importance of having effective review rounds, in practice this is harder to achieve. There is no right way and no magic formula. What might work for one writer might not work for another (we are all different). It may even be that what might have been a successful approach for a writer in a past project might not work for a current one because of differences in the nature of the project and also differences in team. There are however, certain tips and suggestions that can perhaps be applied universally.

Fostering goodwill in the team

It may be an obvious point, but it is important to foster goodwill within a team. There are many different details that can help you win over the team and build a rapport. For example, in cases where the responsibility for a relatively trivial task is not clear, you can show yourself willing (German has the pithy expression '*nicht meine aufgabe*' used by those who refuse to budge a millimeter from their job remit). Over-willingness though has its own dangers, as you may find you begin to get lumbered with tasks that should be nothing to do with you (and the time spent may not be billable if you are a freelancer or your line manager may consider that you are wasting your time if you are an employee). The gains in terms of goodwill, however, can be great (and difficult to quantify).

Kick-off meetings

Related to the above point about building rapport, many writers will advocate the usefulness of face-to-face meetings, where you can get everyone in the same room and talking to one another. In a multinational company this will often not be possible, and a video conference or conference call (with some sort of screen sharing technology such as Webex) can be the next best thing. Such meetings are of greatest importance at the beginning of a project to decide on who is responsible for which content and agree on timelines and other project details. These kick-off meetings also generally set the tone and enable you to get a feel for the team members and the team dynamic, who is going to be cooperative, and who is going to be problematic. Leading such meetings is a bit of a black art, and different writers may have different preferred approaches. I do believe, however, that it is important to prepare conscientiously. Make sure you have read the background information and are

DOI: 10.1179/2047480615Z.000000000279

familiar with the project. There is nothing more annoying for a busy person to attend a meeting and think that they are wasting their time.

Adjudication meetings for review comments

As the project progresses, review comments will need to be adjudicated and a consensus reached. Sometimes (but by no means always) a meeting or a conference call is an efficient way of doing this, especially if the meeting enters a kind of brainstorming dynamic. On other occasions, prolonged arguments about minor points will lead to an unproductive meeting. To avoid such situations, a well-prepared hierarchical agenda can help ensure that points are addressed in descending order of importance.

When two headstrong participants do have differing opinions, reaching a successful outcome often involves compromise and negotiation. Hopefully, we will have already formed an idea of who is going to be stubborn, who is going to be reasonable, and so on. To move things forward, you often have to make a concession to some of the participants. Finding an appropriate concession may require certain creativity and perhaps a certain Machiavellian streak.

If some important decisions or agreements have been made, then it is often helpful to send out a summary of these to the participants soon after the meeting while it is fresh in their minds (these will usually not have to be formal minutes). This will also ensure that your understanding of what was said is aligned with that of the others as interpretations of the same meeting can vary greatly. It will also provide a record of these decisions or agreements should a blame game begin later down the line after problems emerge in a project (not necessarily the fault of anyone, circumstances may simply have conspired, but the urge to find scapegoat can be strong).

Further miscellaneous thoughts about review cycles

For the comments themselves, the higher up the management chain you get, you should remember that reviewers are less and less likely to be fully familiar with the project (and also probably spend less time on the actual review). Patience may therefore be required if the reviewers simply don't seem to get it. When this happens, you should also ask yourself whether this lack of comprehension is an indication that the explanation could be improved. Finally, on the Linked-In thread I mentioned in the opening paragraph, one contributor mentioned the need for a thick skin. This is an important point, I think. You should try not to take review comments personally (though reviewers can be rather tactless). First drafts in particular are often just a question of getting something down on paper to get the authors thinking about how to approach the project. This initial act of creation is often the hardest and not always well appreciated.

Conclusion

Although we are often labelled medical writers, or regulatory writers, the writing itself is only one aspect of what we do (albeit an important one). Good writers also need to be facilitators, deal brokers, and negotiators. Even though the actual texts we produce are not always interesting and engaging (though they can be), these additional facets contribute to making our job interesting.

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