Regulatory Writing

Document authoring and review cycles: Harnessing technological advances

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Regulatory documents are complex beasts, often requiring input from many different authors. Sometimes, different departments will be responsible for authoring certain sections and the role of the medical writer could perhaps be more accurately described as a coordinating editor, who manages timelines and ensures that the contributors are aware of what is expected of them. Regardless of the amount of writing a medical writer actually does on a document, he or she will need to usher the document through at least one review cycle with multiple reviewers before sign-off can happen.

In the traditional approach, the review cycle involves the medical writer (or someone else) sending the document out to the reviewers who then review the document and provide their comments and make changes, usually in track-changes mode. The reviews and comments then find their way back to the medical writer, who then collates and resolves comments. The medical writer might need to arrange an adjudication meeting for particularly contentious comments or in instances where there are contradictory comments made on the same part of the text.

Often, a reviewer copies the other reviewers when providing his or her comments so that additional comments can be made on top of what is already there, thereby saving work in collating changes and comments. In addition, some comments from early in the review round can already be addressed by subsequent reviewers, with a subsequent reduction in the number of issues for adjudication. Although these serial reviews can lead to messy-looking, difficult-to-read documents, track-changes mode in Word® allows the reader to isolate comments and edits by a particular reviewer. Word also has the useful option of only displaying certain type of changes and hiding others (such as formatting changes). Track-changes mode has not always been user-friendly; the feature on early versions was rather clunky and often made documents unstable (especially when lots of hyperlinks were present).

Despite the practice of copying other reviewers into returned comments, the medical writer will find him or herself receiving comments in many different versions. And so the work of sifting through the comments and changes and unifying them in a single document (or transferring to a master copy) can be time-consuming. The upside though is that the medical writer retains considerable control over the document (or ownership as some like to call it).

E-mail-based review rounds are of course still commonplace, but technology does not stand still and applications are now available that not only allow a document to be stored centrally for serial editing but also enable editing and reviewing at the same time (parallel editing). Web-based collaborative review applications now enable a document to be stored in a central location (safely behind the company firewall if appropriate) and accessed by the reviewers (after the necessary permissions have been granted).

For review cycles based on editing documents using these applications, the medical writer sends out a link to the document and instructs the reviewers to make any comments and changes directly on the central document. Now, with this more dynamic process, reviewers can see the comments and changes made by other reviewers. And of course the edits are all in one place, saving time for the medical writer who can now, in theory, spend more time resolving the issues.

There are, however, potential downsides to the use of such technology for document authoring and review cycles. With e-mail-based review rounds, the medical writer can filter out extraneous noise and keep discussion focused. The medical writer has less control over the discussion in a document-sharing approach, and so there is a potential for needless bickering. Another issue that has to be dealt with is version control. With e-mail-based reviews, in the event of problems further down the line, the writer (provided he or she diligently archives the reviewed documents) will have a ready record of who did what and so should be able to identify where a mistake or inappropriate edit occurred. With document-sharing approaches, this becomes more difficult. Reviewers can accept changes (often just to make a document more

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readable if it has been edited by multiple reviewers), but in so doing, may erase a change forever. Regular backups may go some way towards providing a detailed record of changes but all of these might not be captured. If these backups are available and visible to all reviewers (for the sake of transparency for example) but not appropriately labelled, there is a new danger that reviewers may edit the wrong document.

In conclusion, like any new technology, systems to enable collaborative editing have the potential to make our lives easier but it is important to think carefully about the processes involved. The medical writer would be well advised to make an effort to retain ownership of the document to help keep everyone focused.

Document management and publishing systems

Pharmaceutical documentation is often complex. For example, a clinical study report is made up of numerous components (in addition to the synopsis and report body, statistical outputs, a protocol (and amendments), and other study information such as audit certificates and investigator CVs may also be included). Moreover, in recent years, the conduct of the pharmaceutical industry has come under closer scrutiny and there is increasing pressure for greater transparency; therefore, any changes to documents and versions should be duly reflected in an audit trail (to show that there has been no retrospective fiddling with the documents). At the same time, pharmaceutical companies often hold commercially sensitive information that needs to be protected but loss of productivity may result if there are barriers to access for appropriately authorised individuals. To add to the mix, large pharmaceutical companies are also global operations, where the members of a project team who have to work on a given document (or approve it) may be spread over different continents.

The way that pharmaceutical companies produce and publish documents, whether for internal or external readership, is therefore a challenge. To cope with so many requirements, large pharmaceutical companies will likely have a document management and publishing system (often built to specification). In addition to providing password-protected access and a record of any changes to documents, the final published documents may be transferred to document repositories for ready search and access by other individuals (e.g. if you are writing an investigator's brochure update, you may need to have access to certain clinical study reports). Once final, some types of document may need to be distributed outside the company and this should be carefully controlled. For example, an investigator's brochure will need to be distributed to the appropriate investigators; it is therefore important that the persons responsible for distribution are duly notified and receive the correct version of the document itself. The assembly and publishing of documents (usually as a hyperlinked pdf) will often be outsourced or at least performed by someone other than the medical writer (who will nevertheless need to check the final document) as this can be painstaking work.

Of course, a document management system is not in itself going to ensure that all documentation requirements are met. For large pharmaceutical companies, with increasing complex documentation requirements and regulatory burden, such systems can however be considered as a minimum essential requirement.