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Quality Control in Medical Writing: What It Means and Why It Matters

By **Ben Berkey, Tina Gartside, and Katie Robbins,** inSeption Group

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Applying effective data quality control (QC) to clinical regulatory and publications documents requires a sound process, adaptable to the time crunch of being among the final tasks preceding regulatory submission. However, many organizations do not possess a dedicated QC function. Some companies place responsibility on the medical writer to edit and QC their own documents, on top of their already heavy workload. Other companies may require writers to QC their colleagues' work, placing additional strain on this key role.

Differentiating between these two different skillsets, combined with the development of QC tools and training, is the basis for building internal processes that guard against medical writing-related errors during submission. Perhaps most critical to this effort is facilitating a more collaborative environment between medical writers and their QC reviewers.

RECOGNIZING QUALITY IN CLINICAL DOCUMENTS

Medical writing QC encompasses a complete check of source data, internal consistency, formatting, and an editorial review of clinical documents. Source data comprises validated data points from statistical output, published peer-reviewed articles, presentations at medical conferences, or documents on file at biopharma companies. All data in clinical documents must have retrievable, verifiable source data. In short, QC is a 100% check to ensure documents contain accurate and verifiable clinical data.

A dedicated QC team drives consistency (within single documents and across an entire submission). The value of having another individual's fresh perspective on a document (versus someone who has been working on these documents daily) cannot be overemphasized.

While some QCers have scientific or medical backgrounds, many possess English or journalism backgrounds. They generally are accustomed to catching easily missed errors and have the required experience and familiarity with document structure to ensure consistency across multiple deliverables.

Still, industrywide, no particular skillset or talent level is agreed-upon as the minimum that organizations should seek out. For publication editing, the Board of Editors in the Life Sciences (ELS) provides a certification, but there is no equivalent for regulatory QC and editing. Many companies hire based on referrals from experienced colleagues with whom they have worked and can recommend. It also helps when QCers have familiarity and adaptability relevant to the systems in use.

TIIIIIIIIIME... IS NOT ON MY SIDE

Effective QC takes time, which should be built into the document timeline at the beginning of the authoring process, ensuring reviewers are allotted a reasonable period to be thorough. It should be acknowledged: this is a fast-paced industry. There is significant pressure to produce these documents quickly, be it for a submission or response to an agency's questions. Without a required QC step, some companies compress or even skip QC entirely, particularly with smaller documents. The authoring team may feel the document has had few changes or is straightforward, and thus does not need to be reviewed.

This can stem from a lack of emphasis on the QC process within the industry, but the reality is, more margin for error exists on the front end of a project, and time gets crunched on the back end, making less time for QC. Many moving parts and reviewers are involved in the writing process, and there are typically multiple drafts and team meetings. A QC team may provide its client a timeline of three days, but the client requests the effort be completed in two days. Sometimes, those timelines must be negotiated.

As timelines tighten, QC team leaders have no choice but to assign multiple QC reviewers to one document. Ideally, designated QC leads are able to draw on their experience to determine how long a given document may take to review (i.e., based on the document type, the therapeutic area, the document's complexity level, etc.). Using that information, the QC lead can decide how many people are needed. A QC lead acts as team leader for a document, delegating assignments to other reviewers and ensuring everything gets completed. If completion within the available timeline is impossible, the QC lead helps team members prioritize the documents.

THE NUTS AND BOLTS OF QC

The QC review is not a simple proofread that can be completed as quicky as the reviewers can scan over a document. A dense study report or a submission document pooling data from multiple studies can demand several hours to review a single page. Consider common QC findings of errors that happen easily during fast-paced review cycles with large, cross-functional teams and multiple authors:

- **Textual Inconsistency —** Units of measure that are written incorrectly can lead to confusion or even safety concerns, especially if they pertain to a dosage or efficacy/safety result (e.g., 15 mg vs. 15 kg).
- **Content Inconsistency —** Examples include a 14-day treatment period vs. 14 weeks, as well as incorrect drug names or study numbers (which can occur if a medical writer or contributor copies/pastes similar content from another document and forgets to update it for the current trial).

- **Acronyms and Abbreviations —** Acronyms and abbreviations can be easily confused because they may have different meanings for different companies (e.g., "SD" could mean both "standard deviation" and "stable disease").
- **Accurate and Complete Citations and References —** An experienced QC reviewer can identify sourcing issues and inconsistencies within sources. These include incorrect tables, figures, and listings (TFLs, the most common source data for regulatory documents); incorrect reference citations; and errors within the TFLs themselves.
    - Medical writers often begin with shell documents and draft data outputs. It is common for the source data files (e.g., tables) to be updated during the trial, so it's important for QC reviewers to receive the final sources for data verification. Medical writers focused on draft revisions and team comment resolution may not catch all updates during authoring.

The point is, there may be one medical writer, but each document likely has several contributors, which may lead to the inadvertent introduction of sourcing errors, untracked edits, or versioning issues that make it hard to determine which draft is the most up-to-date. The discovery of such errors by agency reviewers in just a few documents can undermine regulators' confidence in the accuracy of the entire submission.

HOW COLLABORATION AND STANDARDIZATION ENHANCE QC

Regulatory bodies require submitted data to be accurate and to withstand audit, but it is up to each company to determine how they ensure data integrity and organization. Implementing a proactive process that sets QC up for success has proven to be an effective long-term solution. One path to accomplishing this is standardization of best practices applicable to any study or regulatory submission.

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For example, requiring medical writers to provide source data annotations helps save QC reviewers time hunting down source data or requesting clarification from the writer. This eases frustration for both QC reviewers and medical writers, since it is much easier to annotate a document as it is written, rather than attempting to remember (sometimes weeks later) where certain data were sourced. Specificity is even better: providing the clinical study report section for a particular data set is good but providing a table number, or the page/rows from a data PDF, is much more informative.

At its root, such standardization will foster a more open, functional relationship between medical writers and QC reviewers. While some documents are straightforward and assignments can be made through email, it is always helpful to have an established dialogue between a QC reviewer and a writer: the writer can clarify document elements that may seem confusing or ambiguous, detail areas where QC may identify issues, or provide tips for navigating the sources. In effective organizations completing projects smoothly, QC is not an "I email you a document

and you review it" task. It is a conversation and a team effort, strengthened through continued training and the exploration of additional tools to drive both communication and accuracy.

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ABOUT INSEPTION GROUP

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