- **Canada** – Health Canada Medical Device Incidents and Health Canada Recalls and Safety Alerts databases
- **United Kingdom** – Medicines and Healthcare products Regulatory Agency (MHRA) database
- **Germany** – Federal Institute for Drugs and Medical Devices (BfArM) Field Corrective Actions and BfArM Recommendations databases
- **Switzerland** – SwissMedic Field Safety and Corrective Actions (FSCA) and SwissMedic Recalls databases
- **Australia** – TGA Device Adverse Even Notification (DAEN) and TGA System for Australian Recall Actions (SARA) databases

Other Resources

Other helpful resources include SSCPs, which provide publicly accessible, up-to-date summaries of clinical data and other information about the safety and clinical performance of a medical device. SSCP information can be accessed through https://ec.europa.eu/tools/eudamed/#/screen/home.

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Think Like an Editor: Improving Document Quality for Regulatory Submissions

Speaker

Callie Compton, MA / Senior Technical Editor, Certara Synchrogenix, Nashville, TN

By Paris Karr, PharmD

Quality control (QC) is an integral part of ensuring accurate and consistent regulatory writing submissions. QC can be essentially defined as a process of checking consistency against a standard. However, in a writing context, QC is more specific than just "review."

Considering different types of reviews (data, subject matter expert [SME], and editorial), the omission of each kind can have different implications. Data and SME reviews can be critical for regulatory submissions, whereas an editorial review is often necessary for document appearance.

In her presentation at AMWA's 2022 Southeast Regional Conference, Callie Compton, Senior Technical Editor at Certara Synchrogenix, identified common issues in the QC process and discussed strategies for regulatory medical writers to ensure a successful QC process.

Common Issues

Compton began by outlining several examples of document inconsistency. Such instances can include (but are not limited to) a document not aligning with sources, inconsistent terminology and style conventions, and errors in grammar, punctuation, and/or spelling. Furthermore, she also identified issues that may arise downstream in the QC process, such as inadequate time allotted for QC, vague, unclear expectations and/or instructions, and misplaced expectations for role/review type.

Document Consistency

Compton suggested that identifying specific standards that govern the document is a crucial step for QC. However, before the actual process of QC, regulatory medical writers should consider asking the following questions to ensure document consistency:

- Does my writing align with its source(s)?
- Is my writing easy to navigate?
- Do I write about the same content in the same way?
- Do the same components in my writing look the same?

Regulatory writing may often require checking external sources such as a tables, listings, and figures document or a clinical study report. To ensure that the writing is aligned with external content, it is important to clearly identify sources in the document and to keep them organized. Compton illustrated that source references should specify document identifiers, such as the study identification, version number, or date, if applicable.

Consistent terminology and style conventions are also critical for regulatory documents. Compton pointed out that a style guide can be an important tool to help maintain uniformity when there can be many acceptable writing conventions. A style guide may specify, for instance,

- use of company/drug name
- preferred template/toolbar
- abbreviations/terminology, and/or
- usage (eg, patient vs subject).

Compton elaborated that "style" may refer to 2 different things: writing composition or formatting. In discussing the latter, a QC checklist can help guide the medical writer to consistently perform specific assessments, line edits, and spelling checks as a process.

QC Process

Given its deadline-oriented and collaborative aspects, regulatory writing requires effective time management. Compton pointed out that inadequate time allotments for QC during development stages or at the end of a project can lead to considerable quality risk. For that reason, the start of

the project is a crucial time to accurately estimate or prioritize time for QC.

A writer should consider variables such as the types of checks needed (internal vs external), the deliverable's page count, and document type. For instance, a 200-page original protocol developed with multiple reviews involving an external SME may require considerably more adjudication time than a protocol amendment that only clarifies the study's exclusion criterion. Compton also recommended that writers think about overall timeline, analyze the complexity of content, and quantify available resources.

Vague expectations and/or unclear instructions can also be a common pitfall in the QC process. From her editing experience, Compton suggested that writers be proactive in communicating basic QC info. Ideally, the type of review, specific sections (if only parts of the document need QC), file name/location, and deliverable due date/time should be clearly specified.

Writers help delineate various roles and expectations in the QC process. To illustrate, a SME should provide review as a content expert, not editorial aspects. Compton emphasized the benefit of clearly establishing defined tasks between a writer (document author) and other collaborators.

Think Like an Editor

Regulatory medical writers can efficiently produce high-quality documents by applying consistency with tools and employing a clear starting plan with concrete communication. Moreover, continuing to ask for QC feedback and learning from best practices will only empower writers to gain crucial perspective on the QC process.

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