Quality Operations Support

Quality, Compliance, & Regulatory

CAI

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Quality Operations Support

Project Overview

A CAI team was assigned to support the creation, revision, and deployment of quality procedural documentation for a major global pharmaceutical company. The company was newly formed and was building a new library of global procedures using a brand new eDMS. Authors were overwhelmed and unable to meet document deadlines.

CAI's responsibility was to streamline the creation, review, approval, and maintenance of the company's QMS procedural documents to drive consistency, provide clarity to users, and check compliance to industry standards and regulations. This included continuous quality improvement of the documentation process and procedural content to verify adherence to company standards.

QMS Documentation Effort

As the authors compiled their documents, CAI edited them for accuracy, clarity, consistency of terminology, formatting, grammar, and content based on the related template, purpose and scope of the document as well as user friendliness.

When the CAI team was assigned to the Quality documentation group, which oversees the global QMS documentation library, the new company's EDMS, documentation procedures, and templates were in place. However, document deadlines were being missed regularly. The CAI team quickly realized this was due to the company's authors being overwhelmed with the new documentation procedures and EDMS. The authors were also trying to meet their own daily business goals, and both were unattainable.

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Challenges	CAI Solution
• A high volume of documents (A range of 20 to 55 per month over the life of the project).	• Tools to track and monitor status of each document were developed.
• Project team members worked remotely in different countries. • Authors did not always meet project timelines for document submission or respond to the CAI's team review questions in a timely manner, which compressed the timelines.	• Constant communication with each other, our client colleagues, and the authors was critical to the project's success. • We interacted daily with each other and our immediate Quality group colleagues, reporting on work in progress, work in planning, and any hurdles encountered, as needed. • Initial team meetings were set up with each author at project launch to build team relationships.
• Technical editing is a manual process	• Checklists were developed for the technical editing and subsequent peer review processes.
• Not all authors proficient in MS Word.	• New author training was developed, continuously improved, and delivered to familiarize authors with the document templates, styles, and the creation process.
• Not all authors understood the new EDMS, documentation, and technical editing processes.	• Training was developed and delivered to support the users in line with the company's new EDMS and documentation procedures and standards. • Team engagement increased when CAI interacted with new authors to apprise them of the new documentation and technical editing processes.
• Various methods of feedback and commenting to authors had been employed.	• Standardized processes for feedback and comments to authors were established at project launch and throughout document technical edit/review.

Value Delivered:

CAI responded to the various challenges presented in several ways. Initially, CAI recommended author and one-to-one coaching. Then, the CAI team's ongoing daily contact with the company's authors made all the difference in answering their process and document formatting questions, which helped prevent time wastage and effort associated with multiple rewrites.

Success of the project can be summed up with the CAI team having processed approximately 850 documents and vastly improving the lead time of document preparation to approval.

At the end of the project, the CAI team received from Helene Proquin (Head of Transition Management), on behalf of the company's leadership team and the Quality Manager of the Quality Documentation Group, a commendation that stated:

"To our amazing team in recognition of their quality of work and delivery of service on time. Many of the [colleagues they supported] … attended the meeting to say thank you and farewell after 3 years.

"Our collaboration with [the three CAI team members] over the last months and various projects has been nothing short of exceptional. The [Quality Management] team would like to thank and recognize the CAI team for their support, guidance, and team spirit. They have been instrumental in the successful set up of our new Quality Management System".