



SAFETY ASSESSMENT

Operations & QA Quality Risk Management Projects Building Bridges Instead of Walls: A Case Study

Quality Risk Management (QRM) may be an industry buzz word, but Charles River has taken the concept to a whole new level. We don't just train employees on how to effectively perform QRM principles, but integrate QRM into daily life at all our Safety Assessment sites.

Built in partnership between Operations/Business Optimization and Quality Assurance personnel, our QRM program extends beyond the guidelines of the systemic approach outlined in the International Conference on Harmonisation (ICH Q9) to follow a new paradigm. Assigned leads at each site actively seek new QRM projects and opportunities on a regular basis, allowing us to conduct successful QRM projects globally, and at a record pace. The new model centers on training personnel throughout all levels and departments to use the concepts to implement meaningful changes in day-to-day operations. Doing so encourages employees to pursue and communicate innovative ideas and solutions, while supporting interdepartmental and cross-site collaboration.

Launched in 2017, this "project assignment" approach to Safety Assessment QRM entails quarterly global Business Optimization webinars, in which embedded QRM leads at each site partner with Operations and QA to identify areas for improvement, take ownership of projects, and collaborate to complete defined tasks. The approach has not only flourished, but sparked a new synergy among employees. Marked by significantly reduced risk and noteworthy time and financial savings, the program has since its inception successfully produced hard and soft

cost savings from tens to hundreds of thousands of dollars, per project, globally. These are savings we can then pass along to clients. The initiative has also inspired a sense of renewal and commitment to partnership between QA with Operations at sites across the globe.

Situation/Challenge:

In a case study detailing our QRM program success, a project initiated at the Charles River Spencerville site (Spencerville) in 2017 shows how a single site QRM project was later expanded with effective implementation throughout seven sites. The project centered on the preparation of electronic Pathology Tumor SAS files that are required for FDA submissions associated with safety assessment carcinogenicity studies. The Spencerville team had noted a significant time delay in the generation of the files, in both the extraction and conversion process, and in the subsequent QC and QA auditing process.

Risk Question:

How can the risk associated with manual file editing and formatting after extraction, and the associated time delay throughout the process, be reduced?

Results/Conclusion:

After mapping the process with Charles River staff, the Spencerville QRM lead discovered that the most significant time delay was associated with an intermediate manual formatting and QC step following extraction of the files from the data collection system. Because it had a lengthy manual editing and formatting process for numerous data endpoints in the extracted data, this also caused significant time delays during subsequent QC and QA auditing of the files. Upon this discovery, the QRM project lead began reaching out to Charles River IT peers to investigate possible solutions.

An IT specialist in Charles River Montreal who was very knowledgeable in Charles River's Tumor SAS file generation process helped the team map the logistics and differences in the processes across all the sites; with this accomplished, they began brainstorming what could be created and implemented to fix the problem. Evaluation of the QRM steps from the various safety assessment sites allowed the team to produce a script program tool that automated the conversion process after extraction. The script not only significantly minimized risk by eliminating the previous lengthy manual editing and formatting step after extraction, but it also automated quality control of the files for Operations, flagging any items in the raw data that may need attention and storing them in a separate QC file.

Summary:

The QRM project significantly reduced the risk inherent in the Tumor SAS file generation process, allowing Charles River to provide clients with data in less time, with less chance of error. Minimizing risk is of utmost importance to Charles River; doing so helps us to ensure reliability and consistency across all sites, while meeting our customers' needs and exceeding their expectations. QRM projects such as the one in this case study are innovative ideas and tools to provide seamless study execution; it is our top priority, and of the highest standard of excellence that is synonymous with Charles River.

This approach to Quality Risk Management has allowed Charles River to build bridges of collaboration and innovation, rather than walls – not only between Operations and QA, but also across sites, and even countries, within the Charles River family. Our Quality Risk Management initiative is helping Charles River to share our passion for excellence with our clients and further drive our purpose of creating healthier lives.