

Restructuring and Optimizing a Quality Risk Management Program



A biotechnology company was accruing numerous incomplete risk assessments and, as a result, their Quality Risk Management (QRM) program required restructuring. In order to synchronize all documents with the program's overarching policy, targeted modifications were necessary for the procedures and templates utilized in conducting risk assessments. In order to align all documents to the general program policy, specific updates had to be made to the procedures and templates used for risk assessments.

THE CHALLENGE

At the time of the QRM restructure, the company initially implemented a rudimentary QRM process and had a corporate policy document in effect. However, the accumulation of incomplete assessments revealed a lack of adherence to this process. Furthermore, upon reviewing the draft risk assessments, it became apparent that numerous inconsistencies were present within the existing assessments.

These errors were evident by the use of different scoring criteria for the same risk assessment types (i.e. FMEA) performed on similar processes, varying formats for final risk reports depending on which department completed them, and inconsistencies in the tools and templates used for risk assessments. All the above variables led to identified scoring issues in some of the draft risk assessments, as well as final reports that did not contain accurate information relative to the risk assessment being completed.

Azzur Group was tasked with rewriting multiple Standard Operating Procedures (SOPs), including:

Primary Hazard Analysis

Hazard Analysis Critical Control Point

Risk Ranking and Filtering

Hazard and Operability Analysis

Failure Mode and Effects Analysis

THE SOLUTION

The revision of these SOPs involved aligning the guidelines provided with both the corporate policy and the ICH Q9 Guidelines. Furthermore, specific instructions on how to complete the respective risk assessments were incorporated into each SOP.

Taking it a step further, the Azzur team socialized and implemented practical QRM tool templates with specific instructions, including:

Primary Hazard Analysis

Risk Ranking and Filtering

Failure Mode and Effects
Analysis

Risk Report Template

By collaborating directly with individual risk owners, a comprehensive review and, in certain instances, reassessment of risks were conducted, enabling the resolution of numerous pending risk assessments within the document management system. The oldest of these assessments were promptly transitioned to the risk review phase of the QRM process, facilitating an examination of previously proposed mitigations and verifying the accuracy of the previously completed risk assessment.

THE IMPACT

Upon completion of the project, at least five outstanding risk assessments, including a Failure Mode and Effects Analysis (FMEA) for the materials management and logistics department, were reviewed and brought to completion. Additionally, new or revised SOPs were implemented to provide clear guidance to individuals specific to the development of the proper risk assessment teams, tools, and templates. These new procedures are now in use, in addition to new directions for the completion of risk assessments.

In summary, Azzur Group played a pivotal role in ensuring the company's adherence to its internal corporate policy for Quality Risk Management (QRM). Moreover, Azzur Group actively facilitated a clear understanding of the QRM program's requirements among risk assessment owners.