Quality Risk Management Case Study

Agenda

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◆ Integration of Risk Management and CAPA
ICH Q9 Framework

1 - Initiate QRM Process

- Quality Risk Management (QRM) activities are undertaken by interdisciplinary teams.
- The QRM report starts with a Project Charter, which presents the rationale for the risk assessment.
- Along with the interdisciplinary team members, it includes the business case, problem statement, goal statement, scope, benefits, and project plan.
2 - Risk Assessment

Risk assessment consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards.

Three fundamental questions are often helpful:

- What might go wrong?
- What is the likelihood (probability) it will go wrong?
- What are the consequences (severity)?
2.1 - Risk Identification

- Risk identification addresses the "What might go wrong?" question.
- To start the risk identification phase, a **Process Map** showing all the process steps and process inputs for each step must be developed.
- The importance of the Process Map is to identify all the input variables that could go wrong and have an impact on the product.
Once all the process steps and inputs were identified, each one is analyzed through a **Cause & Effects Matrix** (also called C&E Matrix or prioritization matrix).

- Each process input is analyzed against its impact to the **Critical-to-Quality outputs** (fill defects, mixups and labeling issues).
- This tool is used to **filter** all the important variables that have an effect on the critical-to-quality (CTQ) output variables.

### 2.1 - Risk Identification

The ratings used for the C&E Matrix are illustrated below:

<table>
<thead>
<tr>
<th>Rating</th>
<th>Relationship</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No relationship between input and output</td>
</tr>
<tr>
<td>1</td>
<td>Remote relationship between input and output</td>
</tr>
<tr>
<td>3</td>
<td>Moderate relationship between input and output</td>
</tr>
<tr>
<td>9</td>
<td>Strong relationship between input and output</td>
</tr>
</tbody>
</table>
Once the C&E Matrix is completed, the Weighted Scores are sorted in descending order and classified as to the relationships among the inputs and the output variables:

- red means strong relationship (150+)
- yellow means moderate relationship (61-149)
- green means low relationship (1-60)
- no color means no relationship (0)
2.2 - Risk Analysis

- Risk analysis is the estimation of the risk associated with the identified hazards.
- It is the qualitative or quantitative process of linking the likelihood of occurrence and severity of harms.
- In some risk management tools, the ability to detect the harm (detectability) also factors in the estimation of risk.
From the C&E Matrix developed for the risk assessment, those input variables that have a strong relationship to fill defects, mixups and labeling issues (shaded in red), were analyzed through an FMEA.

The severity, occurrence, and detectability ratings for the FMEA are shown below:

<table>
<thead>
<tr>
<th>Rating</th>
<th>Severity</th>
<th>Occurrence</th>
<th>Detectability</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Critical</td>
<td>Always</td>
<td>Never Detected</td>
</tr>
<tr>
<td>4</td>
<td>Major</td>
<td>Highly</td>
<td>Rarely Detected</td>
</tr>
<tr>
<td>3</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Frequently Detected</td>
</tr>
<tr>
<td>2</td>
<td>Minor</td>
<td>Rarely</td>
<td>Almost Always</td>
</tr>
<tr>
<td>1</td>
<td>No Severity</td>
<td>Never</td>
<td>Always Detected</td>
</tr>
</tbody>
</table>

RPN = Severity x Occurrence x Detectability
2.3 - Risk Evaluation

- Risk evaluation compares the identified and analyzed risk against given risk criteria.
- The purpose of sorting the RPNs in descending order on the FMEA developed during the risk analysis step is to rank them by their impact on risk.
In order to determine which ranking was assigned (red, yellow, or green), the following rationale was used:
- red means High risk (60+)
- yellow means Moderate risk (27-59)
- green means Low risk (1-26)
Risk control includes decision making to reduce and/or accept risks.

The purpose of risk control is to reduce the risk to an acceptable level.

The amount of effort used for risk control should be proportional to the significance of the risk.

Decision makers might use different processes, including benefit-cost analysis, for understanding the optimal level of risk control.
Risk reduction focuses on processes for mitigation or avoidance of quality risk when it exceeds a specified, or acceptable, level.

Risk reduction might include actions taken to mitigate the severity and probability of harm.

Processes that improve the detectability of hazards and quality risks might also be used as part of a risk control strategy.

The implementation of risk reduction measures can introduce new risks into the system or increase the significance of other existing risks.

Hence, it might be appropriate to revisit the risk assessment to identify and evaluate any possible change in risk after implementing a risk reduction process.
3.2 - Risk Acceptance

- Risk acceptance is a decision to accept risk.
- Risk acceptance can be a formal decision to accept the residual risk.
- For some types of harms, even the best QRM practices might not entirely eliminate risk.

For the risk assessment, the team presented recommended actions for those inputs with High risk (shaded in red) and Moderate risk (shaded in yellow) identified in the sorted FMEA.

For those actions implemented as part of the risk assessment, the company must recalculate the Risk Priority Numbers (RPN) once the actions are implemented and their effectiveness verified.
4 - Risk Communication

- Risk communication is the sharing of information about risk and risk management between the decision makers and others. Parties can communicate at any stage of the risk management process.
- The output/result of the quality risk management process should be appropriately communicated and documented.

5 - Risk Review

- Risk management should be an ongoing part of the quality management process.
- A mechanism to review or monitor events should be implemented.
- The output/results of the risk management process should be reviewed to take into account new knowledge and experience.
Once a QRM process has been initiated, that process should continue to be utilized for events that might impact the original quality risk management decision, whether these events are planned (for example, results of product review, inspections, audits, change control) or unplanned (for example, root cause from failure investigations, recall).

The frequency of any review should be based upon the level of risk.

Risk review might include reconsideration of risk acceptance decisions.
It is recommended to integrate the risk assessment process with the corrective actions and preventive actions (CAPA) system. Although both systems can operate as separate entities, the best results are obtained when the proactive risk assessment process is integrated with the CAPA system.

– In this way, potential failures can be identified and prevented before they do occur.
For More Information...

Fail-Safe FMEA
Combination of quality tools keeps risk in check
by José Rodríguez-Ménez and Manuel L. Pérez-Rodríguez

Thanks !!!