

Improving oversight and management of risks in your global pharmacovigilance operations

This case study is focused on a project with an industry leading research based, top ten, pharmaceutical company. The company is continuously striving to improve their operations and have embraced the regulators expectation of a more risk based approach to ensure they always focus on the areas of greatest impact and value. With this ethos in mind, the company realised that there must be an opportunity to further enhance their PV operations through the application of risk management principles. A particular area of risk was perceived to be the PV operations of local affiliates around the world. Despite procedures and structures being in place to manage these operations, the central function could not be sure that the processes were being performed in alignment with their expectations. Historically the only insight into local operations was via internal audits or regulatory inspections. However, it was deemed that these were too infrequent to ensure compliance. Therefore, the implementation of a process risk management system was identified as the ideal solution to provide oversight of global PV operations.

WCI Solution

The objective of the project was to develop and implement a framework that identifies and quantifies safety related risks, (operational and process) in the local affiliates, in order to focus effort and management time appropriately to mitigate those risks.

The solution was based around a simple risk management framework that combined best practice risk management processes with proven root cause analysis and prioritisation techniques (Failure Mode Effect Criticality Analysis – FMECA), supported by a robust governance structure:



Figure 4 WCI risk management framework

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Identify

A three tier questionnaire and interview process was used to identify specific risks in each local affiliate across the globe

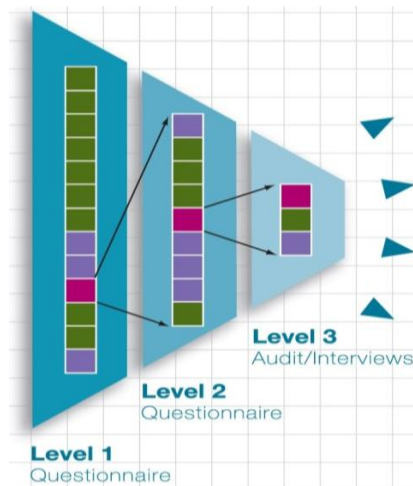


Figure 5 WCI three level risk identification approach

The level 1 questionnaire asked high level questions across the full range of pharmacovigilance processes in order to identify 'failure modes' or risks. The level 2 questionnaire was then used to focus in on the high level risks identified in level 1. If further information was required this was conducted via interview or audit. Using this approach, it was possible to focus in on the areas that really mattered, whilst areas of lower risk could be left. The questionnaire was distributed and answers collated using an online survey tool.

Analyse

The output of the questionnaire was loaded into a database in order to facilitate analysis of the risks. The key component of the analysis step is to determine the potential effect should a risk occur.

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Prioritise and Plan

In order to focus attention on the highest level risks, the effect was utilised to quantify the risks by determining 'criticality', using a tailored risk index matrix. Criticality is calculated by multiplying the impact of the risk by the likelihood of the risk occurring.

Impact		Likelihood	
Description	Score	Description	Score
No impact	1	Unknown	4
Low impact	2	Very possible	3
Medium impact	4	Possible	2
High impact	10	Unlikely	1

Figure 6 Example of a generic risk index matrix

Risks are then assigned a category based on their criticality. The category applied to a risk determined the action to be taken and the timeframe applied to that action.



Figure 7 Example of risk categorisation

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The result of this activity is a clear picture of risks across all local affiliates around the globe:

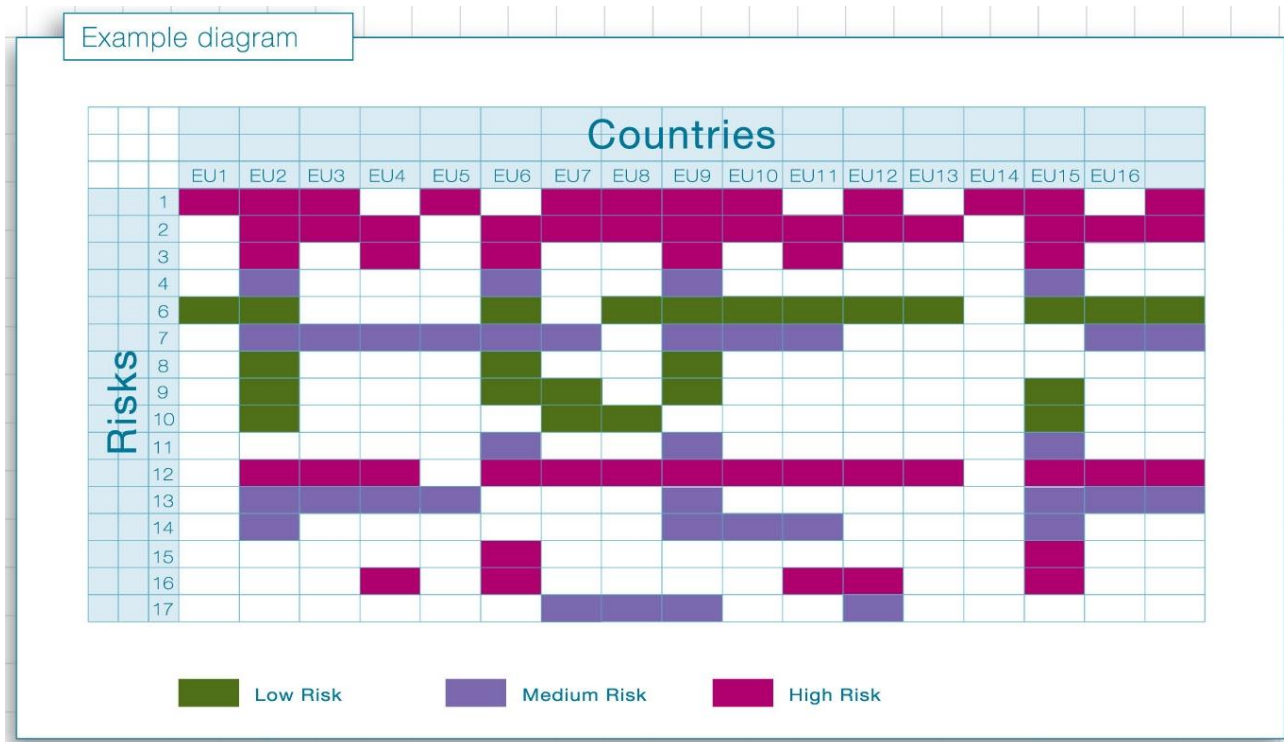


Figure 8 Example of how systemic vs. local risks can be illustrated

The approach quickly and easily highlighted both systemic risks and those local affiliates where an increased level of attention is required. This information was used to further prioritise areas for focus. Industry leading root cause analysis using fault tree diagrams ensured the true root cause is identified. Investing time in this activity maximises the effectiveness of risk minimisation actions and reduces the possibility of the same risk reoccurring elsewhere in the business.

Control and Report

Rigorous tracking of actions to closure is vital to ensure success. The database was employed to track the progress of risk minimisation actions in individual local affiliates.

Monitor

An area often neglected in many risk management processes is assessing the action you have taken for effectiveness. Therefore monitor actions were identified during the planning process to determine if the level of risk has been reduced to an acceptable level by the risk minimisation actions. Monitor actions could include the collection of metrics, the performance of an audit, or repeating risk assessment. In the event that a risk was still present at an unacceptable level the root cause analysis was repeated and new risk minimisation actions put in place.

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Governance

An essential component of the risk management framework was the implementation of a governance structure. The governance structure was designed to ensure unambiguous and concise communication, transparent responsibilities & accountabilities and clear issue escalation. The governance structure was supported by an enabling IT system and standard operating procedures. This guaranteed that implementation was accepted by all stakeholders and that the risk management framework was quickly established as part of day to day operations.

Summary

The implementation of the risk management framework quickly identified the risks that threatened the business. Although the initial level of risks identified seemed daunting, the framework quickly prioritised those risks which needed focus. These were usually systemic risks where one single risk minimisation action could reduce the criticality of a large number of risks. All of a sudden the task in hand didn't seem so daunting and the number of high risks soon reduced. Over time the historical risks have been minimised to acceptable levels and processes stabilised. Minimising the level of risk in the business has enabled the company to focus on proactively identifying risks before they happen, thus the true benefit of risk management has been realised and the QPPV can sleep better at night.

Benefits

- Early identification and prioritisation of risks
- Focusing resources on areas with highest risks
- Facilitates continuous monitoring
- Helps to ensure compliance
- Positive impact on product risk and safety
- Systematic and consistent approach

Proof of solution

The Director of Pharmacovigilance Risk Assessment said: 'Adopting this approach has enabled us to improve oversight of our worldwide pharmacovigilance risks. As a result, we have been able to focus on the areas that really matter, which has enabled us to greatly reduce our risk exposure from a customer and business perspective. We believe that by utilising this risk management framework, we can ensure consistent high standards in our global safety operations, local affiliates and partners. In a recent MHRA pharmacovigilance inspection, the inspectors complimented us on our risk management framework as a key component of how we assure quality within our PV system.'



Simplify what you do