*PM World **Journal*** (ISSN: 2330-4480)
Vol. XII, Issue X – October 2023
www.pmworldjournal.com   Advisory

Bridging the Gap between Risk Assessment
and Risk Management with Data
by Mruga Patel

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Mruga Patel

The need for comprehensive and continuous risk management throughout the product lifecycle cannot be overemphasized—from beginning to middle to end. To start, it is useful to incorporate risk management principles during the new product development phase as early as the design stage. This is when lessons learned from the other devices in the field can be assessed and included. This process helps team members prepare for unanticipated failures that can be alleviated or rectified prior to production. In the middle of a product development life cycle, it is crucial for project managers to identify or help the project team identify appropriate data collection sources that will aid various stages of product development and establish a feedback loop system for production and post-production activities. This information assists manufacturers in ensuring that their products are effective, safe, and performing as intended. Risk management is also useful after a product is launched to keep teams better prepared for potential unanticipated failures discovered post-production and better positioned to rectify any related problems that might arrive once a product is in use on the market.

Role of risk assessment and risk management

Mitigating risk involves detailed preparation. Professionals need to know how to perform risk management protocols, which always begins with the overall governance of all assigned projects. When any conceived product reaches the product design and development stages, the project manager ensures that all processes proceed according to approved plans. Even the most diligent of planning and governance will present project managers and manufacturers with an inherent set of various risks, such as increasing costs of production, supply chain issues, evolving consumer demands, potential impacts on the environment and population health, and ongoing regulatory compliance challenges based on specific product- and service-related industry standards.

When project managers initiate an evaluation of business risks early on during the concept stage of design and development, there's an improved likelihood that the entire team can utilize their critical thinking skills to implement response strategies should a product experience flaws during

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[1] How to cite this article: Patel, M. (2023). Bridging the Gap between Risk Assessment and Risk Management with Data, *PM World Journal*, Vol. XII, Issue X, October.

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standard operation settings or during times of user error. This level of planning also helps to make more informed judgments when deciding on an action plan as a component of a risk-based strategy. Early risk management can help to identify potential design flaws and save future resources. It's essential that risk management is at the forefront of any organizational culture for the sake of the overall quality of any device or service.

Many industries today, including the healthcare arena and other sectors where safety risks are more prominent, will be externally governed by regulatory assessment and compliance standards that require proof of risk and quality management to be conducted throughout the product's lifecycle. Regulatory bodies will evaluate manufacturer protocols for ongoing adequacy to further protect consumers. In fact, many such evaluations occur prior to the release of a new product to market, requiring necessary clearances to be met before product launch.

Another crucial element of risk assessment and management today involves a proactive, data-driven process. This requires a concerted effort to perform such tasks as collecting related literature and research, conducting user surveys, and involving in-house stakeholders with the requisite expertise to estimate the threat of risks instead of waiting for feedback from the field, such as consumer complaints. When complete quantitative data are unavailable, especially early in the lifecycle of a new product, organizations can consider semi-quantitative data, which allows for approximate data measures. In this context, there needs to be a way to gather and review relevant data to confirm product safety, effectiveness, and other performance metrics after product release. Organizations that rely on a reactionary approach will not be able to effectively identify potential hazards and implement preventative measures.

Components of data-driven risk assessment and management framework

A data-driven approach to risk assessment and management assumes a specific framework will be implemented. Consider the following steps as a means of gathering data and reviewing and storing it in a meaningful way.

- Identify appropriate data sources, such as market reports and peer-reviewed journals.
- Establish a data collection channel, such as surveys and focus groups.
- Review gathered information to understand if any further actions are warranted, such as risk updates, changes to the product or processes, corrective actions, preventive actions, and field actions.
- Establish a schedule to periodically review data for adequacy of risk files, even if ad-hoc issues require an update to risk files.

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After establishing channels for data collection, proactively reviewing data to assess trends, audit findings, and competitor data can be an effective way to compile meaningful reports as part of the project management review process and then take action as necessary. Inadequate data assessment can lead to a litany of negative consequences, including increased scrutiny from regulatory agencies and notified bodies, non-conformance findings from regulatory agencies, legal liability issues and lawsuits, field actions due to safety issues, poor business and brand reputation, financial loss, and potential delays in product launch.

An example that illustrates this dynamic is a product with a flaw detected during verification testing (the qualification stage of product development) that the team had not previously considered, thus resulting in a lack of design factors being implemented to mitigate risk. Recent research took a comprehensive look at some popular products that experienced recalls due to poor product designs.[2]
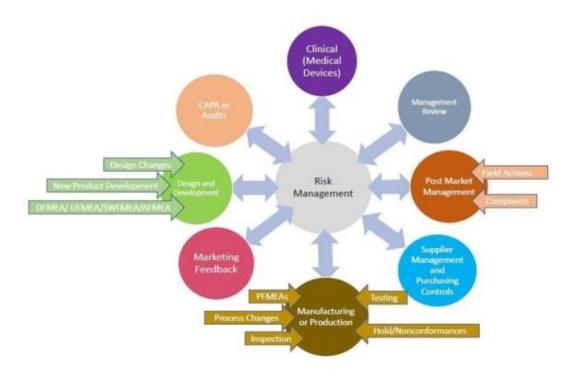

Figure 1: Project Management Essential: Critical Sources of Data feeding into Risk Management

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[2]. Fay, Owen. "The Top 10 Products That Were Recalled Due to Bad Product Design." *Poll the People*, 8 Mar. 2023, pollthepeople.app/bad-product-design/.

The flow chart in **Figure 1** depicts critical risk mitigation elements for project management and shows how risk management can be attained. In this sense, risk is defined as any prospective occurrence that could negatively influence any project being managed. Risk, as it relates to project management, refers to potential issues that, when they materialize, become problems that must be resolved, or the project may experience unforeseen consequences. Identifying and responding to these events in anticipation is known as risk management. In project management, when risk is considered the centerpiece, the manager remains informed about what could go wrong and the likely source(s) of the issue(s). The field actions (right side of the flowchart) that were taken previously can provide insight into issues and help devise an action plan to manage existing issues and avoid future problems. When done effectively with quality data sources that are reviewed appropriately, project leaders can guide their teams through an entire project with minimum risks associated with their project and the product being developed. It is important to assess these data sources from time to time throughout the project to conduct the confidence check and ensure the project is progressing as intended with no unanticipated risks arising.

Making effective use of collected data

Once a mechanism for collecting and reviewing production and post-production data is established, manufacturers can then develop an escalation path for incidents that exceed the established business criteria. This can include, for example, a trend higher than the threshold, a non-conformance that does not meet product claims, or a complaint reporting an adverse event. Project managers should also have mechanisms in place to assess any issues, including the safety risks associated with the use of a defective product. Project managers can then make informed decisions and develop appropriate action plans based on the results of these types of assessments.

Another practical method that warrants consideration is establishing a predetermined schedule for monitoring the suitability of risk files on an ongoing basis by reviewing the sources of quality data and the information gathered from them. A schedule can be created by assessing what works best for an organization, whether more frequent or periodic reviews. Risk management files can be updated ad hoc outside periodic reviews as frequently as needed, especially if new hazards are introduced to the risk profile. When project manufacturers observe an increase in complaints or non-conformances related to production or design and development, they can investigate the impact of such failures. Even a low occurrence of issues can cause harm if the level of severity of the issue is high, potentially necessitating a corrective field action determination.

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The future of data in risk assessment and management

Now more than ever, it is essential for manufacturers and project managers to correctly incorporate data into their risk assessment and management protocols. This means identifying the type of data to use to reduce the potential for risk and collecting the best information from identified data sources. That's why it is important for project managers to utilize appropriate data to efficiently evaluate any problems or occurrences that can lead to extreme situations, such as a potential field action assessment decision that impacts safety. When data are correctly gathered, project managers can use information to reliably uncover the potential for new products, find ways to expand the business, and allow for more informed decisions.

About the Author

Mruga Patel

Chicago, IL, USA

Mruga Patel, MS, ASQ-CQE/CQA, is the manager of design quality engineering at a leading medical device manufacturer and has more than 10 years of experience in the medical device industry. Mruga is a subject matter expert on risk management and manages a team of engineers that oversee a wide variety of product portfolios. She has experience in the design and development of medical devices (class I, II and III implants and instruments), fielding notified bodies and FDA audits, supplier qualification and audits, and conducting internal audits. For more information, contact mruga_27391@yahoo.com.