

# WHITE PAPER

## **Keeping up with the New Pace of Business**

How Risk Management Tools can Improve  
Product Quality in Today's Rapid Lifecycles



# RISK

■ **Repeatable:** Risk Management processes enable an organization to use the same methodology for categorizing all adverse events within the system, regardless of how and when they occurred.

■ **Objective:** Risk Management provides a tool that systematically quantifies the necessary action to be taken as opposed to more subjective methods, which could differ depending on perceptions, human factors and similar constraints.

## Executive Summary

Today's product lifecycle is moving at a speed like never before. A need to keep up with the competition coupled with consumer demand is setting this pace and turning it into a cycle that will not slow anytime soon. With more and more businesses rushing their products to market in order to keep up with this pace, bringing visibility to quality becomes a challenge.

With the product lifecycle moving so fast, many organizations may ask the question, "how can we effectively measure quality?" What can an organization do to keep up with this new pace of business while ensuring the visibility that quality deserves? The answer is Risk Management.

Risk Management within the Quality Management System enables an organization to systematically make decisions in a fast-paced world. It provides a quantifiable method of managing risk—something tangible to look back on (essentially a road map). This "map" shows where risk is present and how to effectively manage it throughout the product lifecycle. It allows organizations to benchmark risk at the design level and process level. It also allows them to do this at the enterprise level to make decisions as a whole beyond Quality—reaching into Governance, Human Capital (HC), Finance, and beyond.

This White Paper will look at how Risk Management provides the framework for handling adverse events in a systematic way—from design, to post-market events, to tracking and trending risk across the enterprise.

## The Elements of Risk Management

Some considerations to keep in mind when looking for a Risk Management solution include looking for processes and tools that will further the ability to categorize, quantify, and ultimately mitigate risk and prevent it from recurring.

To accomplish this, an organization needs a systematic method of handling events that is:

■ **Consistent:** Much like having a repeatable process, ensuring the outcome is consistent is also key to Risk Management. Risk tools are formulaic in nature and are designed to produce an objective and consistent result every time.

This paper will dissect the elements of Risk Management and look into how they help to identify, prevent, and mitigate risk throughout an organization. We will also determine how applying them will allow an organization to not only take the subjectivity out of risk, but to also reduce the risk of product failure in design, in the field, and throughout the enterprise.

First, we will introduce a tool that plays a major role in Risk Management—the catalyst for identifying and weighing risk—the Risk Matrix.

## The Catalyst for Risk Identification

Defining risk is by no means a simple task. Companies spend a lot of time and money in trying to accomplish this, as well as in determining which risks are considered to be critical and which are not. When looking to identify and quantify risk, an essential tool is the Risk Matrix.

Risk, in a nutshell, is the identification of hazards and harms to an organization. A Risk Matrix helps to take these hazards and harms and quantifies them, often by plotting them on a graph.

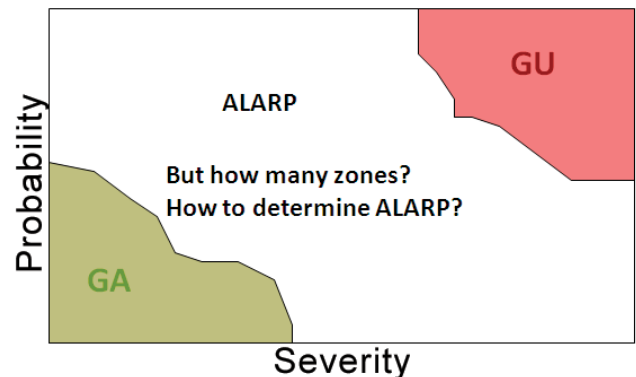


Figure A: The Risk Regions - General Acceptable Risk (GA), Generally Unacceptable Risk (GU), and As Low As Reasonably Practicable (ALARP)

To do this, an organization defines verbal scales, such as severity and frequency, to represent the “x” and “y” axis of the graph and assign numerical values to the scales. The resulting calculation of severity and frequency becomes an organization’s risk.

Some risk calculations are obvious. A high severity and high frequency has a high risk; similarly a low severity and low frequency has a low risk. However, a challenge faced here is to define the risk in the middle, or the “gray area,” for the Risk Matrix. Some organizations will attempt to define this gray area using a concept called As Low As Reasonably Practicable (ALARP), meaning that the cost associated with reducing this level of risk would be grossly disproportionate to any benefit gained. Once these areas have been identified, the organization is left with a “heat map” (See figure B) in which they can begin to plot risk. However, basic mathematics will only go so far. Once the metrics have been defined on the chart, it is still vitally important for a risk team to vet the matrix using historical, real-world scenarios to confirm its effectiveness and accuracy. Once the Risk Matrix has been honed, it can then be applied to the Risk Management process.

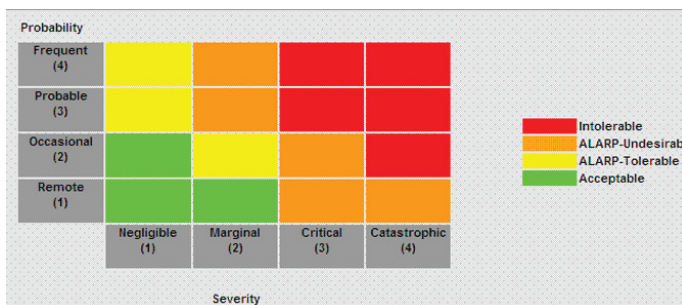


Figure B: The Risk Matrix

## Risk in Design

The first element to consider is risk in design. Using this process, potential product risk is measured in the initial design. This is especially important because an organization can mitigate the risk of in-field failures by identifying risk before the product is released. By creating visibility into product design risk, an organization is better prepared to manage any adverse events post-market.

An effective way of accomplishing this is to look into the design of a product, determine potential failure points and take steps to mitigate the effects of these failure points. Analyzing risk in design helps to anticipate failures, serving as a proactive approach to risk. Tools such as Failure Mode and Effects Analysis (FMEA) make this possible. FMEA is used to foresee failure and allows an organization to take action before the product is even produced. FMEA approaches risk from every possible angle of

product design. It looks at each and every element of the product and poses the question “where are the potential failure points of this component?” It then looks into how these failures can be avoided. The end result is a product that has been analyzed to the core and has essentially benchmarked quality at each possible point of failure.

This approach to quality only begins at FMEA. Once the anatomy of the product has been given the green light, the organization must look at the aesthetics of the product—what the customer sees. Where FMEA looks at individual components, the Hazard Analysis approaches the product as a whole. This approach to tackling design risk ensures the product has been infused with quality from the inside out and has had its risk of failure greatly reduced. However, even the greatest efforts may still yield some residual risk. As an organization encounters post-market adverse events, Risk Management also provides a method to quickly and effectively identify and mitigate high-risk events.

## Risk in Process

Process-based risk involves analyzing the risk of events as they happen, in the post-market. In this scenario, the product has already been released to the customer and post-market data regarding adverse events have started to come in.

With a multitude of these events entering the system, an organization may be left with data paralysis—there is so much information visible to them, they don’t know how to approach it. Yet, they need to figure out how they can focus on the events that have the most impact on the business. This process is simplified through the use of tools such as Risk Assessment, which uses quantitative risk as a filtering agent—it filters the critical from non-critical events. Without it, an organization is left with a multitude of adverse events unable to determine the critical from the non-critical. It is akin to looking for “needles in a haystack.”

Risk Assessment uses tools like the Risk Matrix to determine which events are most critical and then assigns an action based on the outcome. For example, if the risk of an event is unacceptable it may warrant a Corrective and Preventive Action (CAPA). Conversely, if the risk of an event is low, it can be immediately corrected.

A benefit to process-based risk is that as events are entering the system and being filtered a risk history is building. Using this collective information, an organization can then create a Risk Portfolio, one that incorporates the entire risk history of a particular product or product line. Using this Portfolio, events with similar risks can be handled in the same manner, meaning that future adverse events can be handled more efficiently.

Organizations are able to focus on events that have the most impact on the business by collecting post-market adverse events and filtering by risk. But it doesn't stop there. The resulting actions from post-market risk mitigation can foster changes to other operational areas, such as design. This transfer of risk-based data, from post-market to design, effectively closes the loop within the product quality lifecycle.

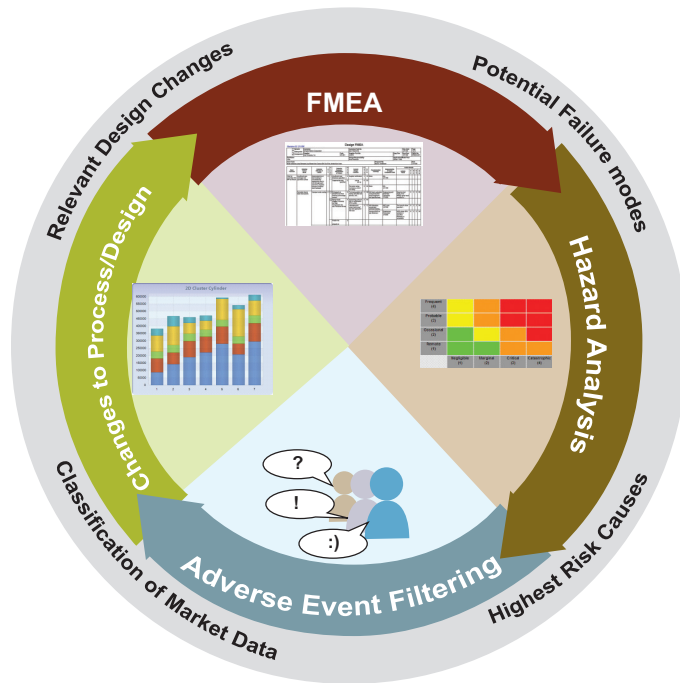


Figure C: The Risk-Based Quality Lifecycle

Design risks are identified (Failure Modes) and highest risk causes are analyzed and mitigated. As post-market feedback comes in, top risks are filtered, and CAPA activities initiate changes to the process and/or design, closing the loop on Quality Improvement.

The collection and dissemination of risk-based data does not just apply to Quality Management. Risk Management methods transcend Quality to incorporate the entire enterprise.

## Enterprise Risk Management

The overall goal of Risk Management is to identify risk, mitigate that risk and then prove that the risk was reduced. The reality is that risk is not just limited to Quality Management. An organization needs to look at risk from an enterprise perspective and implement controls on a strategic level to mitigate those risks. Risk affects different areas across the organization, such as Human Capital, Governance, Finance, Security, Safety and Health, Environmental and more.

Many times, risk that occurs in one area of the enterprise can be tied to risk in another. Pinpointing these similarities can help the organization to find trends in risk, and put processes in place to mitigate the chance of these risks recurring.

Defining risk in various operational areas also allows an organization to standardize risk across the enterprise and come up with a common method for managing risk throughout the enterprise. This puts the organization on common ground from an enterprise perspective and enhances the visibility of risks that are associated in each area.

The goal of Enterprise Risk Management (ERM) is that although everyone views risk differently, the core process should remain the same. If an organization can create an ERM methodology then they've successfully standardized the way they identify risk. From there, the organization can find ways to look at any correlations behind risk and apply these methods throughout the organization.

## Conclusion

Risk and Quality have often gone hand in hand, and for good reason. Reducing risk leads to higher quality of an end product—higher quality leads to lower costs, stronger brand equity and increased demand, among other benefits.

Risk Management processes provide the tools necessary to result in a method that is repeatable, takes an objective approach and offers consistent results. These tools within the Quality System also enable an organization to know where the potential failure points of a product are and how to mitigate them in order to control the risk. It allows them to have a plan in place in the event that a failure does occur in the field—but the process does not end there. Risk Management can also go well beyond Quality, extending to the entire enterprise.

With product development moving at a speed like never before, organizations cannot afford take a reactive approach to risk—not if they want to remain competitive. To successfully keep up with the new pace of business, organizations need a more proactive, quantifiable means of benchmarking quality. Risk Management provides the elements for an organization to do this successfully by making risk quantitative, something that can be measured—and ultimately, mitigated.

## About EtQ

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Founded on March 4, 1992 by former lead auditors of Underwriters Laboratories, EtQ has always had a unique knowledge of compliance processes related to GMP, Quality, Safety, and Environmental Health and Safety (EHS) Management. This year, EtQ celebrates 20 years of excellence and continues to be the leading FDA Compliance, Quality, Safety and EHS solution provider for identifying, mitigating and preventing high-risk events through integration, automation and collaboration. EtQ encompasses a wide variety of industries, providing solutions for FDA Compliance, Quality, EHS, Aviation Safety, and Food Safety Management. EtQ uses best in class integrated modules and enterprise application integration to manage and measure these compliance processes and execute organizational change. EtQ's solution, Reliance, is an enterprise suite of modules designed to foster operational excellence in businesses with modules and utilities such as eMDR, eValidator, Complaint Handling, Risk Management, CAPA, Document Control, Employee Training, Supplier Rating, FMEA, Audits, and many more. EtQ has been providing software solutions to a variety of markets for 20 years. For more information, please visit <http://www.etq.com>.



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