

Fail-Safe FMEA

Combination of quality tools
keeps risk in check

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In 50 Words Or Less

- Failing to manage risk puts consumers and entire organizations in jeopardy.
- Using failure mode and effects analysis (FMEA) can help identify risk but isn't enough to avoid potential disaster.
- By combining FMEA with other tools, organizations can ensure their products won't harm the people they're supposed to help.

QUALITY RISK MANAGEMENT principles are used effectively in many areas of business and government—including finance, insurance, occupational safety and public health—and by the agencies regulating these industries.

Risk management's widespread use isn't a surprise because every product and every process has an associated risk. But while there are some examples of the use of quality risk management in the medical product manufacturing industry, they are limited and do not take full advantage of what risk management has to offer. After all, inadequate or ineffective quality risk management can harm patients, product users and company value.



The current focus of the U.S. Food and Drug Administration (FDA) on risk-based determination requires that regulated industries dramatically improve their understanding and use of hazard control concepts.

The appropriate use of quality risk management can help organizations comply with regulatory requirements, such as good manufacturing practices or good laboratory practices.

Quality risk management is a valuable component of an effective quality system's framework. It can, for example, help guide the setting of specifications and process parameters for manufacturing, assess and mitigate the risk of changing a process or specification, and determine the extent of deviation investigations and corrective actions.

An effective quality risk management approach can ensure a high-quality product by providing a proactive means to identify and control potential quality issues during development and manufacturing. Additionally, it can improve decision making if a quality problem arises.

Explaining risk

Risk combines the probability of occurrence of harm with the severity of that harm. Quality risk management supports a scientific and practical approach to decision making during the life cycle of a product. It provides documented and reproducible methods to accomplish the quality risk management process based on current knowledge about the probability, severity and detectability of the risk.

But each stakeholder perceives different potential

harms, computes different probabilities and assigns different severities. In relation to medical products, although there are many different stakeholders—including patients, medical practitioners, government and the industry as a whole—protecting the patient by managing risk should always be of the utmost importance.¹

The manufacture and use of any medical product necessarily involves some degree of risk. The risk to product quality is just one component of overall risk. Product quality must be maintained throughout the product life cycle so the characteristics that are important to product quality remain consistent.

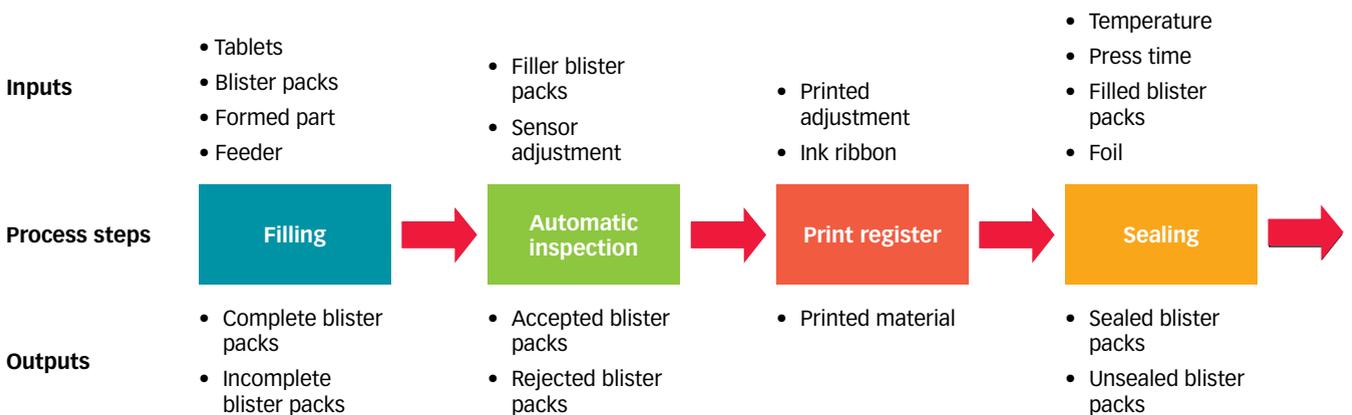
Effective quality risk management can also facilitate better and more informed decisions, assure regulators of a manufacturer's ability to deal with potential risks, and positively affect the extent and level of regulatory oversight.

Manufacturers of regulated products are required to have a quality management system and processes for addressing product-related risks. These processes for managing risk can evolve into a standalone management system. While manufacturers may choose to maintain these two management systems separately, it may be advantageous to integrate them because doing so could eliminate redundancies and lead to a more effective management system.

To each their own

Risk management is a complex subject because each stakeholder places a different value on the probability of harm occurring and its severity. As one of the stake-

Partial process map for tablet packaging / FIGURE 1



An effective risk management approach ensures a **high-quality product** by providing a means to identify and control **potential quality issues**.

holders, the manufacturer makes judgments relating to the safety and performance of a medical product, including the acceptability of risks.

Traditionally, risk is assessed and managed in a variety of informal ways based on a compilation of observations, trends and other information. That approach can provide useful information that supports the handling of complaints, quality defects, deviations and resource allocation. But with a more formal approach, industry and regulators can assess and manage risk using recognized risk management tools:

- Basic risk management facilitation methods, such as flowcharts and check sheets.
- Failure mode and effects analysis (FMEA).
- Fault tree analysis.
- Hazard analysis and critical control points (HACCP).
- Hazard operability analysis.
- Preliminary hazard analysis.
- Risk ranking and filtering.

These tools need to be adapted for specific uses. Quality risk management methods and the supporting statistical tools can be used in combination. The combined use of these tools provides flexibility that can facilitate the application of quality risk management principles.

The degree of rigor and formality of quality risk management should reflect available knowledge and be commensurate with the complexity or criticality of the issue being addressed.

Systematic approach

Within pharmaceutical and medical products manufacturing, few tools are more useful than FMEA. In one of its guides for industry—"ICH Q9: Quality Risk Management"—the FDA summarizes some of the most common risk management tools. Among the tools mentioned is FMEA.

The FDA writes in section I.2, "FMEA provides for an evaluation of potential failure modes for processes and their likely effect on outcomes and/or product

performance. Once failure modes are established, risk reduction can be used to eliminate, contain, reduce or control the potential failures. FMEA relies on product and process understanding. It methodically breaks down the analysis of complex processes into manageable steps. It is a powerful tool for summarizing the important modes of failure, factors causing these failures and the likely effects of these failures."²

Furthermore, it mentions that FMEA can be used to prioritize risks and monitor the effectiveness of risk control activities.³ The guide defines FMEA and discusses areas of application but does not provide a method to carry out an effective FMEA. For that reason, a systematic approach is needed.

That approach consists of three interrelated tools: a process map, a cause and effects matrix (also called a prioritization matrix), and an FMEA. Instead of using the FMEA template from the beginning of the process, let's analyze the failure modes for the inputs that have a larger effect on the critical customer requirements.

Process map: As opposed to the commonly used flowchart, the process map is a high-level tool that focuses on process steps, as well as their inputs and outputs. One of the main uses of the process map is to identify process inputs that cause high variability.

The process map usually consists of six to 10 boxes that represent major steps in the process. For each step, the inputs and outputs are identified. Figure 1 shows an example of a partial process map for a tablet packaging facility.

Cause and effects matrix: After the process map is developed, the prioritization process begins. Many companies start to fill in the FMEA template at this stage. That isn't a good practice because in many processes, the most critical steps are located near the middle or toward the end of the process.

Those who use the beginning-to-end approach are likely to be exhausted by the time they start to analyze the critical steps. For that reason, it makes sense to add this intermediate tool.

Cause and effects matrix / TABLE 1

		Rating of importance to customer	10	9	7	7		
			1	2	3	4	5	
			Correct amount of tablets per blister pack	Completely sealed blister packs	No broken tablets in blister packs	Blister packs' foil is not burned		Total
	Process step	Process input						
9	Sealing	Temperature	0	9	0	9		144
10	Sealing	Press time	0	9	0	9		144
3	Filling	Machine speed	9	0	3	0		111
4	Filling	Feeder	9	0	3	0		111
6	Automatic inspection	Sensor adjustment	9	0	3	0		111
12	Sealing	Foil	0	9	0	3		102

A cause and effects matrix—not to be confused with the cause and effects diagram or fishbone—is used to analyze how a process input affects process outputs. To develop a cause and effects matrix, follow these six steps:

1. Identify the customer requirements and write them in the upper columns.
2. Assign a rating on a scale with one being the least important and 10 the most important. These ratings are assigned from the customer's perspective.
3. Using the process map, list the process steps and process inputs in each row.
4. For each process input, analyze how it affects each customer requirement using the following scale:
 - 0 = the input does not affect the customer requirement.
 - 1 = the input has a hardly noticeable effect on the customer requirement.
 - 3 = the input has a medium effect on the customer requirement.
 - 9 = the input has a strong and direct effect on the customer requirement.
5. Cross-multiply the ratings from steps two and four. For each row, multiply the value of the process input and its corresponding customer requirement. Add those cross-products at the end of each row.
6. Sort the values from step five in descending order.

The end product of using this tool is a list of the process inputs that have the biggest effect on the customer requirements. In this way, you can focus the de-

velopment of the FMEA on those process inputs that really matter to the customer and leave unimportant issues for later analysis.

Eventually, you should analyze all the process inputs and how they could fail. But the key takeaway is knowing where to focus your efforts. Table 1 shows an example of the tablet packaging cause and effects matrix already sorted in descending order.

FMEA: After completing the cause and effects matrix, you can start to fill in the FMEA template. Instead of the beginning-to-end approach, analyze the failure modes of the inputs that are strongly related to customer requirements.

Using the cause and effects matrix, select the process step or input. For that process step or input, consider the possible ways it could fail (the failure mode). Then, for each failure mode, determine the result if it fails (the effect).

After identifying the effects, make a quantitative assessment of the severity. Typical scales range from one (no severity) to 10 (critical to human safety). After the severity rating is assigned, identify the potential causes of the failure mode. In this stage, don't think about causal factors or the immediate causes. Instead, focus on potential root causes.

These are labeled as potential causes because causes have not come into play yet. This is one misconception about an FMEA. It's defined as a proactive tool to identify and prevent the way in which a process, product or system could fail. But in most cases,

Failure mode and effects analysis for tablet packaging / TABLE 2

Process step/input	Potential failure mode	Potential failure effects	Severity	Potential causes	Occurrence	Current controls	Detection	RPN	Actions recommended	Responsibility	Actions taken	Severity	Occurrence	Detection	RPN
What is the process step/input under investigation?	In what ways does the key input go wrong?	What is the impact on the key output variables (customer requirements), or internal requirements?	How severe is the effect to the customer?	What causes the key input to go wrong?	How often does cause of failure mode occur?	What are the existing controls and procedures (inspection and test) that prevent the cause of the failure mode? Should include an SOP number.	How well can you detect cause or failure mode?		What are the actions for reducing the occurrences of the Cause or improving detection?	Who's responsible for the recommended action?	What are the completed actions taken with the recalculated RPN? Be sure to include completion month/year.				
Sealing/temperature	Temp. too high	Burned blister pack	10	Wrong setting	6	Verification of batch record	7	420	Provide infrared temperature device to operator	M. Peña	Temperature device implemented (8/11)	10	4	2	80
Sealing/temperature	Temp. too high	Blister pack not sealed completely	9	Wrong setting	6	Verification of batch record	7	378	Provide infrared temperature device to operator	M. Peña	Temperature device implemented (8/11)	9	4	2	72
Sealing/press time	Too much time	Burned blister pack	10	Machine not set properly	5	Verification of batch record	7	350	Provide a visual display to see time elapsed	J. Rodriguez	Visual display implemented (10/11)	10	3	2	60
Sealing/press time	Not enough time	Blister pack not sealed completely	9	Machine not set properly	5	Verification of batch record	7	315	Provide a visual display to see time elapsed	J. Rodriguez	Visual display implemented	9	3	2	54

RPN = risk priority number

SOP = standard operating procedure

FMEAs are used after the failure has occurred. That issue will be addressed later.

After you identify the potential root causes, rate the probability of occurrence on a scale from one (low probability of occurrence) to 10 (high probability of occurrence). Then determine the current controls used to detect causes or failures and rate their effectiveness on a scale from one (controls are 100% effective) to 10 (controls are not effective).

At this point, you can calculate the risk priority number (RPN) by multiplying the severity, occurrence and detectability indices. But that's not the end of the FMEA process. The next step is to sort the table in descending order of RPNs. In that way, the inputs with higher RPNs (most critical to the customer) will be located at the top of the table, while those with lower RPNs (least critical to the customer) will be toward the bottom of the table.

Not sorting RPNs from highest to lowest is another

error many organizations make. This is the essence of the FMEA—to prioritize efforts to prevent the most critical inputs to failure. It does not mean you won't manage the least critical inputs; it's a matter of prioritizing.

This is aligned with what the FDA expects: that an organization's actions are commensurate with the risk to and impact on patient safety.

After calculating and sorting the RPNs, the real work begins. At this stage, it's possible to identify and implement actions to reduce the RPN. After those actions are implemented, the new RPN must be calculated. This is the fundamental nature of the FMEA process—continuous improvement. Table 2 shows an example of an FMEA for a tablet packaging process.

Making the link

At this point, you can integrate the FMEA process with one of the systems used most frequently by an FDA-

regulated industry: the corrective action and preventive action (CAPA) system.

Many organizations devote valuable resources to a proactive FMEA. Others focus on the CAPA system to manage the failures within their processes. A select few get the maximum benefit of combining both.

The true preventive actions—actions implemented to eliminate the root causes of nonconformances before they occur—can be easily identified via an effective FMEA initiative. That means you can identify the potential failure modes and their root causes, and then implement the actions required to prevent the occurrence of those causes.

But, in an imperfect world, failures occur. When that happens, an organization immediately activates its CAPA system to initiate an investigation geared to finding the root causes and implementing the appropriate CAPAs.⁴ In the vast majority of situations, those systems work independently. But do they need to?

True preventive actions can be identified using the FMEA tool. Then, those actions are incorporated into the preventive action portion of the CAPA system. When a failure does occur, the CAPA system is activated. But because potential failure modes and their causes are part of the FMEA initiative, a disconnect exists. For that reason, the CAPA system should provide feedback to the FMEA tool to revise and update the FMEA accordingly.

FMEA gone wrong

Often, organizations face situations in which the FDA alerts them of the wrong use of some tools. Here are excerpts from two warning letters issued by the FDA regarding the incorrect application of the FMEA tool during the past decade:

1. Lack of integration of the FMEA process with a performance test. An organization received customer complaints about its tubing, which was assembled incorrectly. As part of the investigation, the organization conducted a performance test, the result of which showed that the incorrect assembly did not affect the product.

But the organization did not update its FMEA, which stated that the incorrect assembly compromised the functionality of the device.⁵ As a result, it left itself vulnerable to future occurrences of the same issue.

2. Lack of definition of the FMEA indexes for severity, occurrence and detectability. An orga-

nization received customer complaints about device failures, so it rushed to develop a reactive FMEA based solely on the major cause of complaints: contamination.

When it developed the scales to rank severity, occurrence and detectability, it did not provide a rationale for each scale. The organization only provided the indexes and the calculated RPN.⁶

These two examples show how the use of FMEA alone isn't enough to guarantee product quality. While FMEA is a proactive tool within an organization's risk management system, it is a dynamic component that must be handled correctly using the following tips:

- Perform an FMEA using a teamwork approach.
- Use a systematic method to complete the FMEA with help from a process map, and cause and effects matrix.
- Prioritize the order in which the process inputs will be evaluated using the FMEA tool.
- Sort RPNs in descending order.
- Identify all potential root causes.
- Identify and implement CAPAs for each root cause.
- Recalculate RPNs after CAPAs are implemented, not before.

Doing so will ensure your FMEA is as effective as possible and your products are safe in the hands of the people they're meant to help. **QP**

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