White Paper

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Connected Risk Analysis for Medical Devices

By Cannon Quality Group and MasterControl

Introduction

Risk is not easy to spot, prepare for, and manage. It becomes even more challenging if you're hit by the negative consequences of not uncovering or managing a particular risk, which can result in unplanned costs, additional time, and a poor reputation to not only your company but also the brand.

For these reasons, risk analysis is critical to the medical device industry, and connected risk analysis is essential. With connected risk analysis, you are able to identify what you can and cannot control, and address problems throughout the entire product lifecycle from product development through distribution, with controlled, measured, and appropriate action.

To mitigate risk and be effective in all the methods and strategies discussed in this white paper, it is key that you start your risk analysis for a medical device, in vitro device (IVD), or software-as-a-medical-device (SaMD) product at the beginning of the product design phase and to properly manage it through the manufacturing and distribution phases. This requires a digital solution, which is discussed after we lay the foundation for a strong understanding of risk, connected risk analysis, and important details related to each.

What Defines Risk for Medical Device, IVD, and SaMD Products

Risk has two aspects:

1. The probability of something going wrong.
2. The negative consequences if something does go wrong.

Risk for medical device, IVD, or SaMD products includes predicting the foreseeable use of the devices and reasonably foreseeable misuse.

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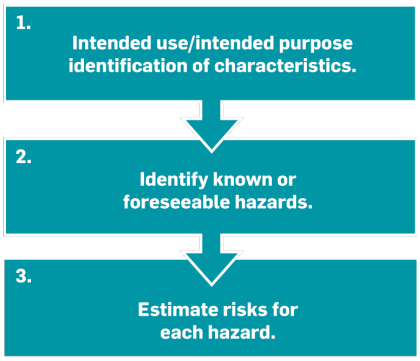
Misuse is use in a way not intended by the manufacturer but which can result from readily predictable behavior. This is critical for Class III medical devices because the classification means that they support or sustain human life, prevent impairment of human health, or present a potential, unreasonable risk of illness or injury.

Misuse can happen at even the distribution phase. A real world example of unintentional misuse is of a distributor taking two separate approved devices and kitting[1] them together for a sales promotion. Their customers usually used the two devices together so they were trying to make their customers' lives easier by bundling them. This created an issue because according to the U.S. Food and Drug Administration (FDA), when you put two separately approved devices together you create a new device. No design documentation or risk analysis was performed to assess the combined products.

The distributor did not realize the impact of what they did. Unfortunately, patients started to get injured. This simple bundling of products with a new SKU put the distributor on the FDA's radar as a manufacturer. Cannon Quality Group helped the company develop an appropriately sized quality system to support their activities and educate the team to ensure such medical device bundling oversights would not happen again.

[1] Kitting in a warehouse is the physical act of finding multiple SKUs, bundling them into a single package, and creating a new SKU for that package before shipping.



These are the basic steps for conducting risk analysis.

What is Risk Analysis

You're aiming to get a product to market, and you don't want anything to hinder your efforts. Risk analysis, in general, for devices in the medical industry is a process and established way of identifying and assessing factors that could affect the success of a product going to market.

For instance, if you're developing a medical device for the treatment of sleep apnea and a formal risk analysis hasn't been conducted, and later it was discovered the product had flaws in the distribution channel or worse, when used by patients, this indicates a failure to apply risk analysis and can incur costly recalls of the product as well as lawsuits brought on by consumers.

The consequences of something going wrong are significant, which is why risk management in the medical device industry needs to be particularly thorough. As just one example, specific risk considerations should include design and use processes in a formal risk management plan that contains initial drafts of a Hazard Analysis or Failure Mode & Effects (FEMAs) documents developed by internal or outsourced engineering, quality assurance, clinical affairs, and risk analysis teams.

In short, formal risk analysis is meticulous, and it enables you to examine all potential risks of a new devices. Using that information, you can choose whether or not to move forward with a decision, and you have a full understanding of how it will impact all aspects of product development and distribution.

What is Connected Risk Analysis

Connected risk analysis is using a digital system to connect internal and external data from disparate sources to help inform strategic decision-making by providing a holistic view of the risks and their potential impact.. In the medical device, IVD, and SaMD industries this is a requirement, not an option.

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A digital, connected system for risk analysis makes it easy to store all information in one central location, and when it's needed, you can easily gather detailed information such as product plans, financial data, safety requirements, supplier information, security protocols, marketing forecasts, and other relevant data.

Connected risk analysis is an essential planning tool that saves you time and money by helping you avoid events like a nonconforming FDA assessment, and the negative consequences for your company and product reputation.

When and How to Use Connected Risk Analysis

Connected risk analysis is useful for medical devices in many situations:

- When you're deciding whether to move forward with a new product or supplier.
- When you're improving safety and managing potential risks in the workplace that will impact the new product and protect workers.
- When you're preparing for events such as equipment or technology failure, theft, staff sickness, or natural disasters.
- When equipment needs to be calibrated and how often.

To carry out connected risk analysis you need to identify possible threats, estimate the likely impacts, and estimate the likelihood that these threats will happen. To be thorough in your efforts, collaboration is key. Best practice is to include others who might have different perspectives in the same department or other departments for their input.

Identify Possible Threats

The first step in connected risk analysis is to identify the existing and possible threats that may be faced. Risk analysis begins with compiling data from across the organization. The key is to develop a list of these threats and determine if any of them are applicable to your device.

The following table illustrates one potential way to complete the first step in connected risk analysis. Please note that not all of these examples will apply to your device.

List of Existing and Possible Threats

Threat	Definition of Threat	Applicable Y/N
Human	Loss of a key employee or employees.	
Financial	Going over budget, interest rate changes, lack of funding, or stock market fluctuations.	
Natural	Natural disasters or disease.	
Operational	Disruption to supplies and operations, failures in distribution, or loss of access to essential assets.	
Political	Changes in foreign influence, FDA regulations or government policy, or public opinion.	
Procedural	Failures of accountability, controls, or internal systems.	

Product	Experiencing issues with product quality, taking too long on key product development milestones.
Reputational	Damage to brand reputation, loss of customer or employee confidence.
Structural	Dangerous chemicals, equipment failure, or any situation where staff, products, or technology can be harmed.
Technical	Advances in technology, technical failure.

Once you have compiled the list, consider the systems, processes, or structures that you use and analyze risks to any part of these. For example, ask yourself what vulnerabilities you can spot within them.

Estimate the Likelihood and Impact of Risk

After you've identified the risks your new device is facing, it's time to calculate both the likelihood of the threats being realized and their possible impact to the organization, product, environment, and potential patients.

A quick way to calculate the risk is to estimate the probability of the risk/event occurring and then multiply this by the amount it will cost your company to correct things if it occurs. This provides a value for the risk. For example, if a product recall will cost the company $2M and the risk is high, this would result in a significant expense, and it may be too costly to proceed without addressing the risk early in the design phase and leveraging a digital QMS.

Consider Risk Management Options

Once you've identified the value of the risks your device product faces, you can start to look at ways of managing them. Risk is managed in 4 ways: avoiding the risk, sharing the risk, accepting the risk, or controlling the risk.

With connected risk analysis you can avoid the risk by putting risk and compliance measures in place early in the product lifecycle, which should ideally happen at the design phase.

Instead of avoiding the risk, you could also choose to share the risk with business partners or suppliers but because of limited control or oversight with partners and suppliers, this may not be the best route to ensure FDA compliance, and sharing the risk could put you at more risk.

Another option is to accept the risk. If your organization can do nothing to prevent or mitigate a risk, this may be an option because of supply chain disruptions or pressure to go to market faster. However, it's not the best option because prioritizing time to market over quality could expose your company to greater risk later, e.g., receiving recurring FDA 483s, lawsuits because of product defects, etc.

The last option is to control the risk and reduce its impact. This is an involved process. You can use experiments to observe where problems occur and find ways to introduce preventative and detective actions before you introduce the activity on a larger scale. Examples of preventative actions could include health and safety training or proper handling of incoming supplies and outgoing products. Efforts to control risk and reduce its impact through experimentation can be a costly endeavor, which can be avoided if you use connected risk analysis starting at the design phase and continuing throughout the medical device's lifecycle.

A digital QMS has all you need for connected risk analysis.

1. A methodical approach to determining and managing risk.
2. The ability to track and analyze the recurrence of issues, which streamlines your ability to recognize and mitigate long-term, systemic risks.
3. A digital, connected solution that unifies risk-related activities and documentation.

A Connected, End-to-End Solution

In the medical device, IVD, and SaMD industries it is required that internal and external data from disparate sources be connected. An integrated software solution is critical to compliance. A digital QMS is the ideal tool for integrating disparate systems and having an end-to-end solution that ensures you have everything you need for effective risk analysis, including the following:

- A methodical approach to determining and managing risk.
- The ability to track and analyze the recurrence of issues, which streamlines your ability to recognize and mitigate long-term, systemic risks.
- A digital, connected solution that unifies risk-related activities and documentation.

Maintain Accurate and Accessible Documentation

As mentioned earlier in this paper, risk analysis starts with gathering data from across the organization including proper documentation and procedures as well as data analysis, and the information will be compiled to form the final assessment.

When you enter the product design phase, data should be collected using a digital QMS. Without which, you will be gathering up paper-based and digital documentation, procedures, and data analysis from multiple systems, and there is a strong chance that you will introduce errors that lead to an inaccurate final risk assessment. It is important to select a digital QMS provider that can integrate existing systems as well as remove paper from the process.

Disconnected systems and paper documentation can rapidly result in quality issues. As just one example, a medical device remanufacturer and MasterControl customer was facing numerous challenges caused by using paper-based systems:

- Slow turnaround times for reporting. In part, this was because paper reports could get wet, become wrinkled or discolored, and ultimately they were illegible.
- Not knowing the status of employee training. They had trouble ensuring that people were appropriately trained and following the correct process on the shop floor.
- Difficulty managing documentation. Keeping track of all the necessary documentation was increasingly difficult.
- Lack of transparency. With paper, it's difficult to gather accurate data, and make well-informed business decisions.

The medical device remanufacturer digitized operations, and saw significant improvements. Illegible reports are no longer a concern because they are now completed electronically. The system keeps track of which employees have completed training, and it prevents shop floor workers from performing any task they haven't been trained on. Document control is automated, and nobody needs to search for documents to chase someone down for a signature because everything is routed to the right person for review. The system tracks each lot through every step, and the company can offer customers more accurate timelines for delivery.

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>
> – CEO and President
> *MasterControl Customer*

Digitization has resulted in numerous benefits. The company's CEO and President remarked, "It would take months to get SOPs created and filed. We're getting the SOPs, validation, and training done in a third or even a quarter of the time."

By eliminating paper and digitizing, it is possible for those in the medical device industry to work more quickly while maintaining accuracy and achieving impeccable quality.

Prioritize Risk Management and Get to Market Faster

All too often, organizations compromise quality and the risk management process in favor of speed-to-market, which can bring compliance efforts to a halt. The reality is that by prioritizing quality and risk management, an organization can streamline compliance and get to market faster.

Regulatory bodies such as the FDA and the International Organization for Standardization (ISO) are placing increased importance on risk management. For example, ISO 13485 is the most often used medical device QMS regulatory standard. The most recent iteration of ISO 13485 stresses a greater consideration of risk in areas from training to documentation of risk management in product realization.

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> – Vice President of Quality and Regulatory Affairs
> *MasterControl Customer*

A startup medical device company achieved its first 510(k) approval for a product that captures heart rate and electrocardiogram (EKG) data and continuously transmits it to health care providers in real time. With their life-saving product, speed to market was a top priority – quality-related delays or setbacks in pursuing regulatory compliance were not an option.

To achieve regulatory compliance in a short amount of time, the startup needed to infuse quality into every phase of the device's product lifecycle and ensure that all the required documentation was complete and accurate. With a digital QMS, they achieved their goal.

"It's very rare for a company to go from ground zero to being ready for an audit within six months. And we were able to do that," said their Vice President of Quality and Regulatory Affairs.

A connected risk analysis approach mitigates ambiguous requirements definitions. Product requirements need to be specific, consistent, and accurately put into a digital QMS. This will allow both internal and external audits to run smoothly.

What to Look for in a Digital QMS

In general, look for a digital QMS that has all the tools you need to mitigate risk in one place. This typically includes document control, CAPA management, design controls, audit management, supplier management, training management, analytics and reporting, and risk management.

Be sure you understand all the features available so you can make a well-informed decision about the type of system that will meet your needs. Best-in-class solutions offer the following:

- **Risk tolerance thresholds** – The system guarantees that organizational risk tolerance thresholds are employed and followed for risk-related activities.
- **Automated workflows** – Electronic workflows that route documentation to get the necessary signatures for execution, review, and approval of risk activities and documentation.
- **Risk evaluation** – Configure multiple risk types for evaluating different categories of operational risk and be able to analyze hazards associated with a variety of processes or activities.
- **Reporting tools** – Run reports to analyze risk and risk assessments.

Conclusion

In summary, connected risk analysis is vital to the medical device, IVD, and SaMD industries. With all that is at stake, there can be no margin for error.

Risk management will be most effective when it is conducted throughout the product lifecycle – from product design through the manufacturing and distribution phases. This requires a digital, end-to-end QMS, which ensures that you use a consistent method to estimate and mitigate risk. With this approach to risk, you can be successful in your efforts to get a compliant, life-changing product to market quickly.

About Cannon Quality Group

Cannon Quality Group (CQG) was founded in 2010 as a full-service outsourced quality management company serving the medical device, Medtech, pharma, IVDR, SaMD, and general life science community with right-sized quality management system solutions. The company has supported over 200 Medtech companies by setting up initial quality systems, performing internal audits, supplier audits, managing document control, performing validations, or serving as a completely fully outsourced quality department. Although statistics say most Medtech startups fail, 88% of past clients are still in business and 30% have been acquired or gone public. To learn more, visit Cannon Quality Group online or call (925) 944-9468.

About MasterControl

MasterControl Inc. is a leading provider of cloud-based quality, compliance and production management software for life sciences and other regulated industries. Our mission is the same as that of our customers – to bring life-changing products to more people sooner. The MasterControl Platform helps organizations digitize, automate and connect critical processes across the regulated product development life cycle.

Learn more at mastercontrol.com.

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