COMPASS® FEATURE BRIEF

RISK MANAGEMENT

Industry-Leading Risk Management for Medical Device Companies

BUILD SAFER, COMPLIANT PRODUCTS

Building medical devices is a privilege that comes with inherent risks. Devices have a direct and immediate impact on the longevity and quality of life for patients. Whether we realize it or not, we all know someone who benefits from a medical device. As engineers, designers, developers, scientists, and manufacturers we take our responsibility to our end customers seriously, and are grateful for the opportunity to make a meaningful impact in their lives with our work.

Part of our responsibility is ensuring the safety and efficacy of our devices. Designing safe devices is a base level requirement that goes without saying. This is why Cognition built Compass. Compass is a SaaS solution that supports a comprehensive risk management process by allowing device manufacturers to assess risks that come from fault conditions, normal uses, failures, or expected misuses.

"Our post-market surveillance identified a particular rate of harm was actually higher than what was currently documented in our Hazard Analysis. With Cognition, that update was able to be instantly applied to not only the hazard analysis document, but also auto-update the risk index value in three dFMEAs, ten pFMEAs, and five design verification protocols."

Interventional Medical Device Company

GUIDED RISK MANAGEMENT SUPPORTED BY REGULATORY STANDARDS

Compass has the ability to embed global and/or regional regulations and standards to guide the user through the risk analysis process. Compass poses simple questions and uses the answers to auto-populate risk analysis tables.

Why it matters: Working directly from standards and regulations, like ISO 14971 or EU MDR, is the most efficient way to achieve rapid compliance. Using standards and regulations as a starting point means your technical documentation is audit-ready, submission-ready, and easily supports process inquiries.

Question	Answer(s)	Perspective	Potential Hazard(s)
(A.2.3) **Is the medical device intended to be in contact with the patient or other persons?** *Factors that should be considered include the nature of the intended contact, i.e. surface contact, invasive contact, or implantation and, for each, the period and frequency of contact.*	Inner protective packaging may contact skin of patient for limited duration ✕ Details Add item here...	Patients ✕	HAZ0003: Immunological agents ✕ +
(A.2.4) **What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?** *Factors that should be considered include:*	Outer pouch is composed of Tyvek and mylar polymer, inner protective component is PET. These materials are commonly used in packaging and have no known compatibility concerns with medical device or sterlization methods. ✕	Users ✕	HAZ0008: Data ✕ +

Figure 2 Example of Embedded Questions to Identify Characteristics That Could Impact Safety as Part of Preliminary Hazard Analysis

RISK-FIRST DESIGN THINKING

In other regulatory prep tools, risk management is not a native integration. Compass, on the other hand, was built with a risk-first approach that places high emphasis on the value of tightly integrating risk management in the design control process with requirements and tests.

In Compass, you are guided through the process of creating a:

- Risk Management Plan
- Preliminary Hazard Analysis
- Use Error Analysis
- Design FMEA
- Design Risk Analysis

Why it matters: Each risk task must be addressed individually, since the goals of each task are fundamentally different. However, it is imperative that they are all integrated and tell a cohesive story of how the device is designed for safety, and what controls are in place to ensure that safety.

ID	Sequence of Events Leading to Hazardous Situation	Hazardous Situation	Probability P1	Hazard	Harm	Currently Implemented Control Measures	Current Control Measure Type	Probability P2	Probability	Severity	Risk Acceptability	Required Risk Control Measures	Required Control Measure Type	Residual Probability P1	Residual Probability P2	Residual Probability	Residual Severity	Residual Risk Acceptability	Verification of Risk Control Implementation and Effectiveness	Justification
12	**FAILURE MODE:** Unable to maintain sterility within pouch **EFFECT:** Infection due to non-sterile product used **CAUSE:** Incorrect design and specification of materials Incorrect design of interface of tyvek pouch with shelf box	Non-sterile Product	2 - Unlikely	HAZ0019: Specific biological hazard	HARM0023: Repairable major injury	MIT0006: Design of packaging similar to packaging successfully performing on the market	Inherent Safety by Design	3 - Possible	3 - Possible	4 - Significant	UN	MIT0008: Sterile Barrier Integrity Testing	Protective Measure	1 - Very Unlikely	2 - Unlikely	2 - Unlikely	4 - Significant	AC	Currently Implemented Risk Control Measures Design of packaging similar to packaging successfully performing on the market DI-L1-0002: Ship Test - FUNCTIONAL - Product Design Inputs - Level 1 TP0024 - Ship Test for Generic Packaging V: 1, Run: 1 - PDF [PASS] Required Risk Control Measures Sterile Barrier Integrity Testing DI-L1-0002: Ship Test - FUNCTIONAL - Product Design Inputs Level 1 TP0024 - Ship Test for Generic Packaging V: 1, Run: 1 - PDF [PASS]	Risk deemed mitigated to an acceptable level, no further actions

Figure 3 Example of a Complete Risk Analysis Table

SEQUENCE OF EVENTS MANAGEMENT

Unlike other risk management tools, Compass not only manages individual risk data points, like hazards, hazardous situations, and harms, but it also manages the sequence of events that ultimately lead to a patient being harmed. While the individual risk data points can be stored in a library and reused, it is this unique sequence of events as a whole that must be mitigated against.

Why it matters: Our extensive research shows that connecting FMEA and Risk Analysis through the Sequence of Events component allows you to maintain the work done in FMEA while identifying control measures to be reused in the risk analysis assessment should they effectively contribute to lowering the risk. This method, in our view, is the right approach to complying with ISO 14971. *To dig deeper, read the article published in MDDI, "Complying with ISO 14971:2019," by our Compass Product Line Manager, Ben Higgitt.*

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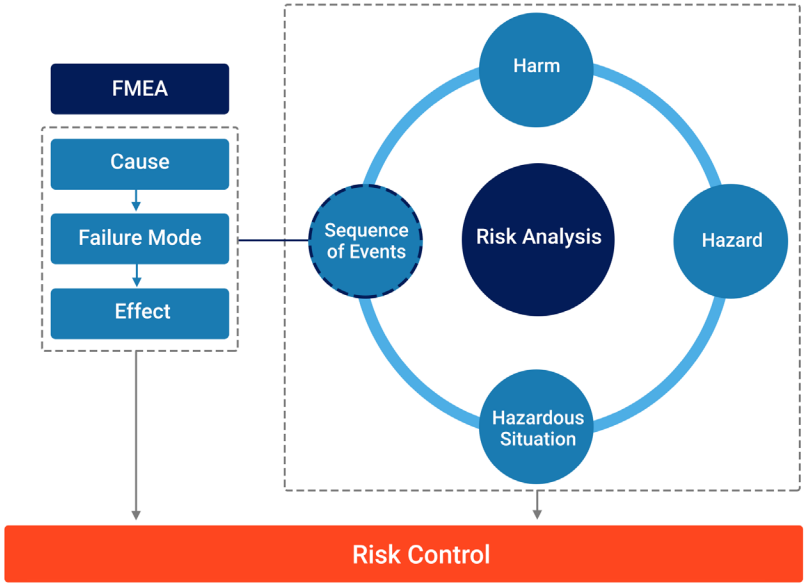


Figure 4 Fully Integrated Risk Management

INTEGRATION OF RISK, REQUIREMENTS, AND TESTING

Risk control measures must be implemented into the design to control the risk. In Compass, risk management and requirements management are tightly integrated, along with test management, this enables real-time assessment of the impact of every change across every function.

Why it matters: Analyzing risk in isolation is not enough. Risk control measures must be implemented with a clear, traceable, audit trail.

Verification of Risk Control Implementation and Effectiveness
Required Risk Control Measures Improved Interlock SPR0007: Physical Interlock – FUNCTIONAL – System Requirements PRO0101 – Electrical Tests Protocol V: 1, Run: 2 – PDF [PASS]

Figure 5 Example of a Risk Control Table in Compass

RISK MANAGEMENT WITH COMPASS

Compass's risk management functionality is an important tool for medical device development organizations because it provides:

- Guided compliance supported by regulatory standards.
- Comprehensive management of the sequence of events that lead to a hazardous situation.
- Tight integration between risk management, requirements and test management.

Why Compass for Risk Management?

Compass was developed for teams that want to go above and beyond regulatory compliance and build safe and innovative devices that truly have a profound impact on the lives of their patients. Compass risk management functionality was developed by Cognition with a decade of experience with our enterprise solution, Cockpit, working with the largest companies in the medical industry on best practices.

Our risk-first design thinking makes it easy for companies of any size to implement and realize the benefit of a more comprehensive approach to risk management. Additionally, Compass gives you confidence in your risk analysis because it allows you to easily define and enforce your risk acceptability to ensure consistency throughout your project - the same definition of acceptability is applied to all risk documents.

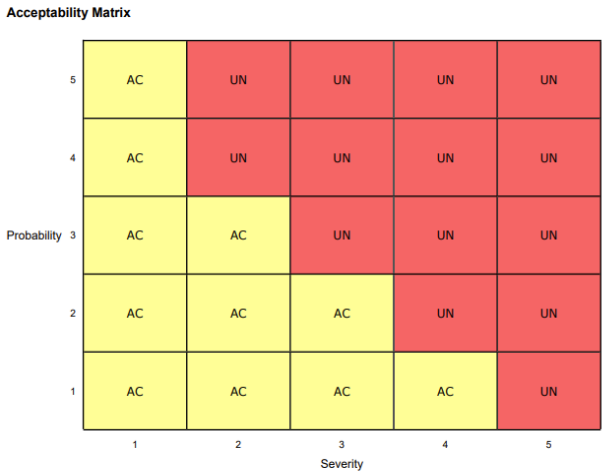


Figure 6 Example of a Risk Acceptability Matrix in Compass

NEXT STEPS

To learn more about Compass Risk Management functionality, schedule a call with our risk subject matter expert or request a demo.

ABOUT COGNITION

Cognition Corporation develops, sells, and supports risk-first product development and compliance solutions for the medical device and pharmaceutical industries and is trusted by the world's leading life sciences companies. Its Software-as-a-Service platform enables customers to structure their data and automate processes with built-in quality to save time and money and bring products to market faster.

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