



FMEA Framework for Medical Device Development

Analyze and mitigate potential failure modes or risks for device development to ensure quality and accelerate time to market

Failure Mode and Effects Analysis (FMEA) is one of the most used methodologies for quality and reliability and is an effective tool for assessing fault failures, root cause analysis, and failure modes. FMEA is a highly valuable tool to guide the process of development, and is required by various industry standards and regulations.

An important quality assurance function is assessing risk for the critical characteristics of a medical device, throughout its life cycle. This is true for any medical device where compliance is required with either the US FDA, EU, or the ISO-14791 quality standard. FMEA provides a way to assess points of failure in a specific design, process, or system and list the consequences of these failures.

Analyze, prioritize and mitigate failures

Identifying potential issues early on in the process of development, and planning for any hazardous event that may arise can greatly reduce development cost and time, and helps to create reliable, high quality products. The Jama Connect® FMEA Framework assists medical device development teams to conduct comprehensive Failure Mode and Effects Analysis. Using this framework, teams are able to identify, analyze, prioritize, and mitigate failures.

INCLUDES:

- **FMEA framework is included in the Jama Connect for Medical Device Development solution**
- **Procedure Guide for Failure Modes and Effects Analysis (FMEA) for medical device development activities**
- **FMEA export templates and worksheet view**
- **Configuration Guide including relationship rules, item types, workflows, pick lists, and attributes**
- **Medical trial framework and sample data set**

Key Benefits

Quickly assist teams with FMEA, aligned to industry standards

Equip your teams to successfully apply FMEA analysis using the Jama Connect FMEA framework. This framework includes export templates, procedure and configuration guides, and sample data sets specific to medical device development. Take the guess work out of performing FMEA activities with alignment to Jama Connect through this standard framework.

Reduce risk by identifying and addressing failure points early in the design cycle

Identify failure points early in the device development process. With all its different aspects, the FMEA eventually contributes to the general error prevention in medical devices and does also increase their operating reliability. Through early detection and elimination of potential weak points, medical devices are developed and manufactured in such a way that first-error security is ensured and therefore the risk is reduced as far as possible.

Streamline development and reduce cost

The FMEA Framework is included to support teams managing risk using FMEA. Coupled with the risk techniques to satisfy ISO 14971, this framework enables teams to support overall risk analysis to reduce development time and the associated cost. Having the framework included in the solution gives developers and stakeholders the structured, intuitive information system they need to enable collaboration and traceability within the risk management process. By capturing risks and requirements in one tool, your organization streamlines risk management throughout the development cycle.

Faster time to market

Risk management is an inextricable part of the medical device development process. For medical device developers, risks are a core principle of product development. Through the FMEA Framework teams are able to perform FMEA analysis to manage risk and make decisions that improve the time to market of new medical devices.



Jama Software® is focused on maximizing innovation success in multidisciplinary engineering organizations. Numerous firsts for humanity in fields such as fuel cells, electrification, space, software-defined vehicles, surgical robotics, and more all rely on Jama Connect® requirements management software to minimize the risk of defects, rework, cost overruns, and recalls. Using Jama Connect, engineering organizations can now intelligently manage the development process by leveraging Live Traceability™ across best-of-breed tools to measurably improve outcomes. Our rapidly growing customer base spans the automotive, medical device, life sciences, semiconductor, aerospace & defense, industrial manufacturing, consumer electronics, financial services, and insurance industries. To learn more, visit us at: jamasoftware.com.