COGNITION

Safety by Design

Guided compliance for risk reduction in medical device production & commercialization.

Table of Contents

"Inherent Safety by Design"

What are some of the common difficulties or confusion around meeting these requirements?

The most common confusion around meeting requirements of the FDA and other regulatory bodies is that **in most cases these regulations are just guidance.** They are not strict rules that must be followed by a company to meet regulations, but rather just guidance that is open to interpretation. Companies can take different paths to achieve the same end result. That leads to confusion, just because Company A and Company B can have vastly different processes to achieve the same end result.

What is the FDA's Position on Risk Reduction?

The FDA's position on risk reduction is "inherent safety by design," meaning they look to see that risk is designed out of the device prior to approval. However, they do not specify activities, scores, or mechanisms for risk, so medical device developers must determine those independently.

The FDA's position on risk reduction is "inherent safety by design."

Each organization will use its own methods and processes for risk reduction. Many follow the guidelines set in ISO 14971, especially the principle of ALAP: "As Low as Possible". This approach to risk prioritizes mitigating all risk to the lowest possible level, including residual risks.

In order to design a product that is inherently safe, medical device producers should take into account Design Controls, Human Factors Analysis, and risk reduction testing such as Preliminary Hazard Analysis (PHA) and Failure Modes Effects Analysis (FMEA).

Regulations & Risk Reduction

In order to commercialize a medical device, there are a number of regulations and standards the device should comply with. Some of these regulations and standards include:

ISO 13485 - Medical Device Quality Management Systems

ISO 13485 specifies requirements for a quality management system for the design and manufacturing of medical devices.

21 CFR 820.30 - Regulations for Design Control

The FDA requires that companies hoping to market Class II, Class III and certain Class I products follow Design Control requirements that require manufacturers to follow a methodologically-sound process to develop a medical device, with the intent of improving the probability that the device will reach an acceptable level of efficacy and safety.

ISO 14971 - Application of Risk Management to Medical Devices

ISO 14971 is the risk management standard for the medical device industry. It is a nine-part standard which first establishes a framework for risk analysis, evaluation, control, and management, and also specifies a procedure for review and monitoring during production and post-production.

ISO 62366 - Application of Usability Engineering to Medical Devices

The FDA recommends that manufacturers follow human factors or usability engineering processes during the development of new medical devices.The goal is to ensure that the device user interface has been designed such that use errors that occur during use of the device that could cause harm or degrade medical treatment are either eliminated or reduced to the extent possible.

Guided Compliance

What is the importance of using guided compliance for design controls and risk management?

When submitting for regulatory approval, companies need to demonstrate that they have used a well-defined, documented design control and risk management process in place, along with evidence that they are following it. **Using a predefined, guided approach to compliance--created with common regulatory standards in mind--allows teams to establish their processes and provide evidence of process adherence.**

Cognition's Cockpit Platform provides templates for PHA and FMEA exercises, Design Controls, and Human Factors. Their templates are configurable to meet common standards and regulations, such as ISO 13485, 21 CFR 820.30, ISO 14971, and ISO 62366.

Automatic Traceability

Building connections between requirements & risk.

User Needs and Validation			Design Inputs, Risk and Verification				Design Outputs, Risk and Verification				
ID	User Need	Validation Tests	ID	Design Input	Risk ID	Verification Tests	ID	Design Output	Essential	Risk ID	Verification Tests
UN0001	Display	VAL0001	SPR0019	Liquid ingress protection	N/A	VER0006	DO0030	Remote moulding assembly	NO	N/A	VER0012
			SPR0073	Touch screen Protection 2	N/A	NONE	NONE				
UN0002	Device remote control	VAL0001	SPR0015	Remote interface	N/A	VER0008	NONE				
			SPR0016	Remote Cable Length	N/A	VER0006	NONE				
			SPR0017	Single push button	RISK0010	VER0005	DO0030	Remote moulding assembly	NO	N/A	VER0012
			SPR0018	Biocompatibility	N/A	VER0006	DO0030	Remote moulding assembly	NO	N/A	VER0012
							DO0033	Material specification	NO	N/A	VER0012
			SPR0019	Liquid ingress protection	N/A	VER0006	DO0030	Remote moulding assembly	NO	N/A	VER0012
			SPR0020	Audible feedback	N/A	VER0009	DO0034	Software code	NO	N/A	VER0013
			SPR0021	Overdose protection	N/A	VER0007	DO0034	Software code	NO	N/A	VER0013

During the design controls and risk management stages, requirements, risks, tests, etc. are automatically connected using the platform and can be easily displayed in a trace table.

The Cockpit Platform's automatic traceability is one of the most powerful capabilities of the tool. The automatic trace tables that are generated in the back end save teams valuable time during their product development process. **Instead of spending hours making connections between market requirements, design inputs, validation and verification tests, etc. teams save this time because Cockpit does it for them, automatically.**

During the design controls and risk management stages, requirements, risks, tests, etc. are automatically connected using the platform and can be easily displayed in a trace table. In the Preliminary Hazard Analysis (PHA) template, Cognition provides fields for teams to enter in harm-hazard combinations that eventually flow to risk controls. Once risk controls have been developed, teams will want to connect them to requirements that were created during the Design Controls process. Cockpit will automatically pull the risk controls and requirements into a trace table, allowing teams to create the necessary connections.

Case Study: Epic Sciences, Inc.

A common problem companies have is that they are wasting time managing their data when they could be using that time to create and develop new products. Epic Sciences, Inc. was one such company. Before adopting Cockpit, they were using a manual process with Microsoft Word and Excel. They were spending 80-90% of their total development time on planning and documentation, with only 10-20% of overall time going to actual product development.

They wanted to reduce time spent manually maintaining consistency throughout project documents, and to have the ability to baseline an entire project platform.

> As a result of implementing the Cockpit platform, Epic Sciences says, "we have observed happier testers and a much deeper level of testing conducted early on and throughout the project. With less time focused on manual tracing and finding related regression tests across repositories, the software test team has bandwidth to do much more exploratory testing early on so bugs are caught much sooner when it is far less costly from a time and expense perspective."

After working with the Cognition Application Engineering team, Epic Sciences was able to fully implement the Cockpit Platform into their product development process. After implementation **they saw a 10% decrease in time spent on planning, a 15% decrease on time spent working on documentation, and a 25% increase in time spent actually executing product development activities.**

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