Mediso Reduces Time to Submission with Cognition's Guided Compliance Platform

CASE STUDY: MEDISO MEDICAL IMAGING SYSTEMS, LTD

COGNITION®
NAVIGATING PRODUCT DEVELOPMENT

Mediso

CHALLENGES AND GOALS

Mediso Medical Imaging Systems develops complex imaging systems for healthcare and medical research institutions worldwide including SPECT/CT/PET scanning and MRI systems. These systems are part of a larger product family and, while each system is in itself a unique offering, common components are modular and interchangeable. Both the challenge and the opportunity with modular systems are to accurately, efficiently, and reliably share information and avoid repetitive work.

Mediso needed a faster, more accurate, and repeatable way to manage this product family information in a way that could also rapidly generate accurate compliance deliverables for regulatory submissions.

Immediate Goals:

- Reduce the time required to create successful Directive 93/42/EEC and EU MDR 2017/745 submission deliverables for Class IIa and Class IIb medical devices, including hardware and software, to the Notified Body partner
- Improve the accuracy of all submission deliverables so that such deliverables are accepted upon first review by the Notified Body partner

Future Goals:

- Incorporate a more complete "Super Project" approach to product development whereby product development teams can quickly define and configure a product by using existing relevant content across all product families
- Adopt policies, procedures, and deliverables to satisfy the requirement of EU MDD (93/42/EEC) / MDR (2017/745) and US FDA 21 CFR Part 820
- Implement more comprehensive Systems Engineering approaches to overall product development activities to reduce engineering time on documentation and verification of documentation

SOLUTION

Cognition was selected as the vendor of choice because The Cognition Cockpit platform manages design, risk analyses, and test data in a single system, which enables the guidance and enforcement of processes and procedures based on relevant industry standards and regulations. Cockpit templates, together with automated workflows, work instructions, and other information including regulatory guidance and SOPs, provide a structured, enforceable system to guide development teams toward creating a compliant device that will satisfy Notified Bodies.

With all data and information connected, Mediso was able to fully understand the state of any project and the effect any change would have on the project, all in real time; every review, every sign-off, every action was accounted for and auditable.

Cognition was chosen for four primary reasons:

1. Off-the-shelf template set including a natural connection of critical information related to safety risks, requirements (at all levels), and testing results
2. Libraries to support reuse of common components across multiple product lines
3. Automatic generation of submission deliverable documents including trace matrices
4. Competitive pricing and strong industry/regulatory knowledge

DEPLOYMENT HIGHLIGHTS

Reuse of Component Data

The Cockpit platform supports connections to libraries from which projects can share and reuse information and data. Mediso initially populated the libraries with common component information regarding all requirements and tests for each component. Users then selected components from the libraries to be used in current development projects.

This reuse of component data reduced significant time because the components, with their requirements and tests, were instantly added to the current project. The team was assured it was using accurate information—correctly associated requirements with tests—and they no longer had to search in multiple locations to manually find test results and match them to requirements.

By reusing certain components across multiple products, product quality is consistent, and the cost of manufacturing, service, and maintenance is reduced. Overall risk is lowered by using certain common components across multiple products, and reusing component data allows development teams to benefit from "known information," including risks, requirements, and tests.

Risk integration

Cockpit's native integration of risk analysis with design data (requirements and tests) proved to be a powerful approach to product development because it allowed Mediso to make direct, lasting relationships between disparate data types. An example of such relationships is the connection between a mitigation, a requirement, and a test. For every mitigation identified during a risk activity, Cockpit displays the verification of a control (one or more requirements linked to the mitigation) as well as the verification of the effectiveness of a control (tests that are run on the requirements).

As the team made decisions, Cockpit displayed real-time links between the items. They were better informed and, as a result, had a higher confidence in the process and design choices they were making.

Status	Risk ID	Sequence of Events Leading to Hayardous Situation	Risk Information	Required Risk Control Measure(s)	Control Requirements
A	0469	**Failure Mode:** improper ground connection **Effect:** electric shock **Cause:** design problem	**Hazard:** Specific energy hazard **Hazardous Situation:** patient touches parts under voltage **Harm:** Significant Injury **Current Mitigations:** General hardware Verification activities (Inherent Safety by Design) **Risk:** Requires Review	Isolated supply mains **Control Measure Type:** Protective Measure **Risk:** ALARP	CS94617: Transformer isolation ✕ SYS95965: Minimal bending radius of cables ✕ +

Figure 1 - Design Risk Analysis Table

Structured submission deliverables and Traces

Off-the-shelf templates include formally structured documents for submission deliverables. All documents were easily branded by Mediso to match their needs for cover pages, fonts, headers, sections, and other general information. This work was done once and required minimal effort; after that, all new projects start with the Mediso-specific documents as part of the overall project template set.

All of the actions taken and decisions made during development were automatically captured in the necessary documents. The Cockpit approach to structured documents resulted in clean deliverables with all required content, styling, approvals, and electronic signatures.

The documents generated included multiple traces. Cockpit provides a variety of traces off the shelf which Mediso used in addition to adapting others to fit specific trace formats. When changes are made, every item in the trace is automatically updated, which not only saves time but also ensures data integrity.

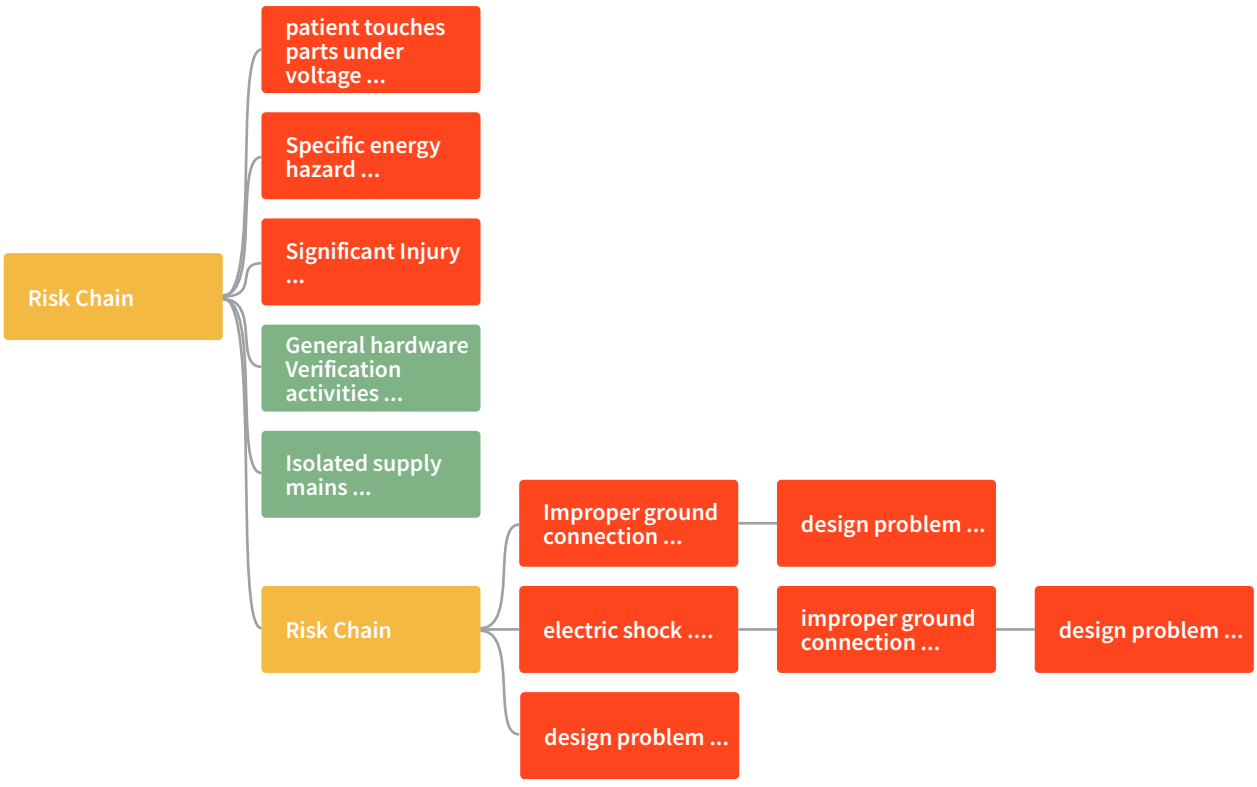

Figure 2 - Design Risk Analysis Trace

RESULTS/ OUTCOME

Mediso found that the Cockpit templates helped to improve overall design quality, reduce time to submissions, and allowed engineers to spend more time on designing the device and less time on creating the formal documentation. The Cockpit processes ensured that teams were following the prescribed behaviors as specified in the overall corporate quality processes and procedures as well as guiding compliance with industry standards and regulations.

» Dramatic time savings and efficiencies:

- Reuse of component data saved significant time and money: every test, every analysis was completed once and used over and over again
- Templates got Mediso up and running quickly
- The dFMEA and Design Risk Analysis (DRA) templates, with their embedded work instructions and automated workflows based on relevant standards and regulations, saved significant time and increased accuracy
- Greatly reduced manual data verification, including complex traces.

» Faster, more accurate documentation for DHF and other regulatory submission deliverables

» Improved data integrity – through processes and integration of design, risk, and test data

» Mediso's Notified Body partner commented on improvement in accuracy and timeliness of submission deliverable

> *"Cockpit has brought us savings and efficiencies in multiple different areas, and has enabled us to create accurate, auditable documentation for regulatory submissions. It has enabled us to transition to a highly structured process for managing our design data,"*
>
> said Miklos Czeller, R&D Director at Mediso.

ABOUT MEDISO LTD

Mediso Ltd. specializes in the field of nuclear and molecular imaging focused on the development, manufacturing, sales and servicing of multi-modality in-vivo imaging systems. With its 30 years of expertise and 1,250+ clinical installations, Mediso is among the leaders in diagnostic imaging, providing the unique, triple modality AnyScan® SPECT-CT-PET hybrid systems.

For more information, visit www.mediso.com.

ABOUT COGNITION CORPORATION

Cognition develops, sells, and supports 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.

For more information, visit www.cognition.us.

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