SUPPORTING GROWTH WITH GUIDED COMPLIANCE

A Case Study with Microchips Biotech, Inc.:

Realizable Benefits of the Cockpit™ Platform for a Growing Medical Technology Company

Introduction

Microchips Biotech, Inc. develops implantable drug delivery and disease management systems to transform the lives of patients and revolutionize healthcare delivery. Their microchip-based implants help to ease the burden of prescription medication regimens requiring frequent and/or long-term dosing by injection. Microchips' adherence-enabling technology aims to improve the patient experience and clinical outcomes, plus drive efficiencies in care.

Challenges

Prior to adopting Cockpit, Microchips used a document management approach that required a high level of scrutiny across documents within the design history file. When design changes were made in one document, those same changes had to be manually updated in many documents across the entire DHF. In anticipation of a growing project portfolio, Microchips needed a more robust system to support documentation creation, management, and maintenance of trace matrices for design requirements. They began looking for an easy-to-implement design control solution that would add rigor around requirements management and would scale and grow with the company.

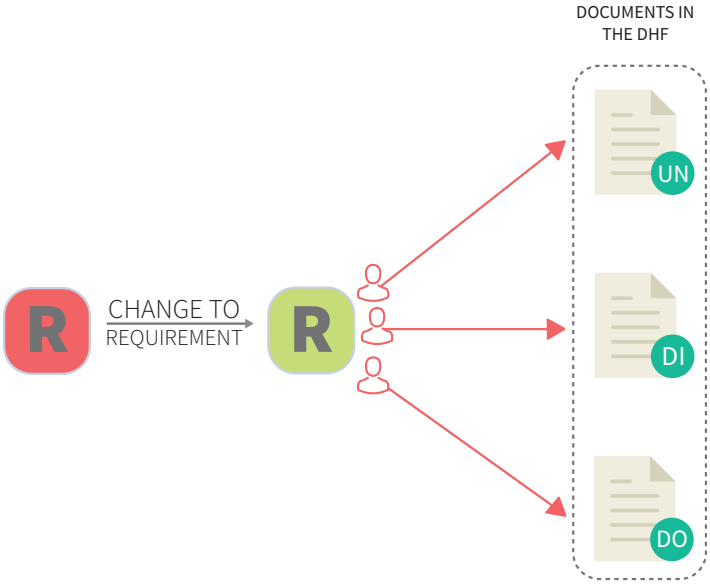

Figure 1: Manual requirement change management

"We realized that as the projects expanded, we needed a solution to support and augment the management of design requirements and risk management activities," says a Microchips senior systems engineer. "Taking on a solution to enhance our capabilities was a priority."

Choosing the Cognition Cockpit™ Platform

After an assessment of the Cockpit solution, Microchips determined that it satisfied their business requirements for a robust, scalable tool that synchronized with their quality management system.

Solution One: Traceability, Templates and Data Management

Microchips' product development process required traceability between design inputs, risks, and design outputs. Cockpit's trace matrix feature provided the ability to examine relationships between these design control elements as the project progressed—a previously manual process for the Microchips team prior to adopting Cockpit. Automatic traceability and trace matrix generation significantly reduced time spent on error checking. Requirements could be linked to other requirements, risks, tests, etc. and generated into trace matrices for review.

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	DI0019	Liquid ingress protection	N/A	VER0006	DO0030	Remote moulding assembly	NO	N/A	VER0012
			DI0073	Touch screen Protection 2	N/A	NONE	NONE				
			DI0015	Remote interface	N/A	VER0008	NONE				
			DI0016	Remote Cable Length	N/A	VER0006	NONE				
UN0002	Device remote control	VAL0001	DI0017	Single push button	RISK0010	VER0005	DO0030	Remote moulding assembly	NO	N/A	VER0012
			DI0018	Biocompatibility	N/A	VER0006	DO0030	Remote moulding assembly	NO	N/A	VER0012
							DO0033	Material specification	NO	N/A	VER0012
			DI0019	Liquid ingress protection	N/A	VER0006	DO0030	Remote moulding assembly	NO	N/A	VER0012
			DI0020	Audible feedback	N/A	VER0009	DO0034	Software code	NO	N/A	VER0013

Figure 2: Cockpit Requirements Trace Matrix

Additionally, Cockpit's design control and risk management templates helped to easily generate new documents. Cockpit's Preliminary Hazard Analysis template, based on Annex C of ISO 14971, has simplified assembly and organization of the risk management parts of the DHF. Using these templates, Microchips quickly populated user needs plus system and subsystem requirements into pre-constructed tables for simple organization and data manipulation.

Solution Two: Supporting Microchips' Growth with Cockpit

Microchips wanted a partner who would train, collaborate, and provide ongoing customer support. They recognized value in the ability to refine the out-of-box templates and wanted to learn the basic skills needed to customize templates easily and on their own. Through personalized, one-on-one and small group training sessions, Cognition's Application Engineers supported Microchips' proficiency in template customization while also helping with documentation integration efforts. The Cognition team's deep product knowledge and understanding of how the software could be adapted allowed them to quickly develop creative solutions to customize Cockpit to fit Microchips' needs.

"Cognition's support of our team has been outstanding," says a Microchips senior systems engineer. "We can translate the software tools, templates and documents to new projects as they come online. Cognition has been a reliable partner throughout."

Conclusion

Microchips implemented the Cockpit platform to manage requirements and risk management for medical device development. Cognition understands the needs of small, growing medical device companies and has developed a useful tool that is easy to set up and intuitive to use from the start. The medical device-specific templates supported development of comprehensive documentation that meets quality and regulatory requirements. Cognition's knowledgeable team and their ability to provide instruction and training specific to a growing company's internal design control document structure are a key element in the process.

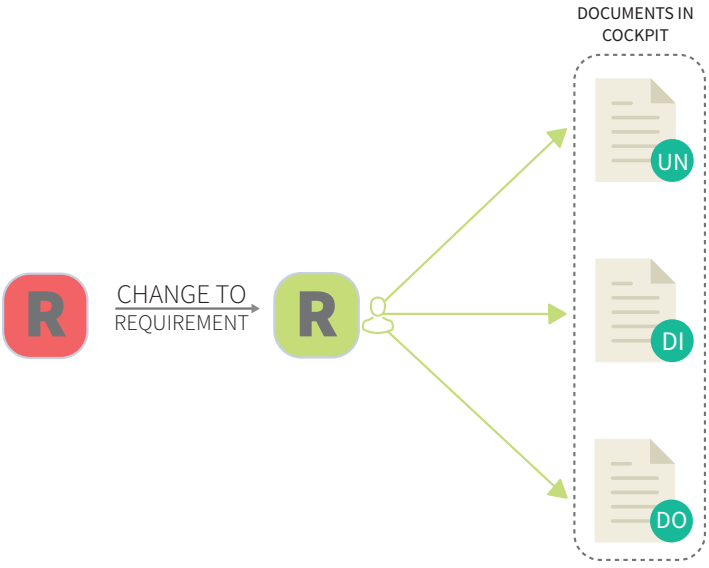

Figure 3: Cockpit supports automatic requirement change management

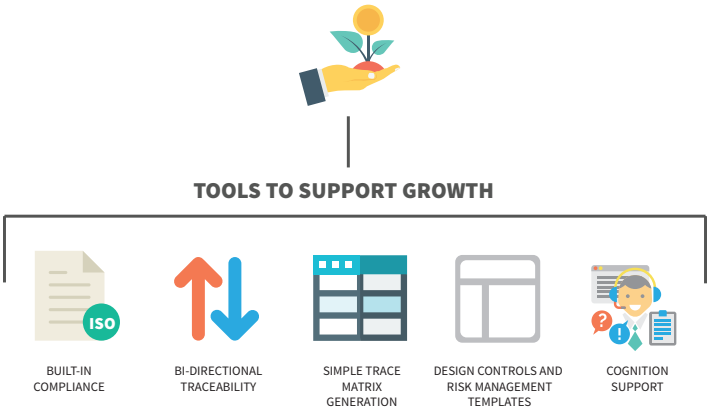

Figure 4: Cockpit tools to support your organization's growth

"Cockpit has been enormously important to us as we have implemented and developed our design control processes," says a Microchips senior systems engineer. "As an emerging medtech company going through natural processes of developing a requirements management system, Cognition has made this easier for us."

For more information on Cognition's products and services, please visit our website: www.cognition.us or reach out to the Cognition Sales Team: sales@cognition.us.

For more information on Microchips Biotech please, visit their website: microchipsbiotech.com/.

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