SOLUTION BRIEF

COMPASS®

Guided Compliance® for Medical Device Product Development

SITUATION

Disconnected data and manual processes introduce a high potential for error in product development and can slow time to market. Companies can improve outcomes with the ability to cost-effectively develop medical devices in compliance with regulatory requirements, structure, and quality processes.

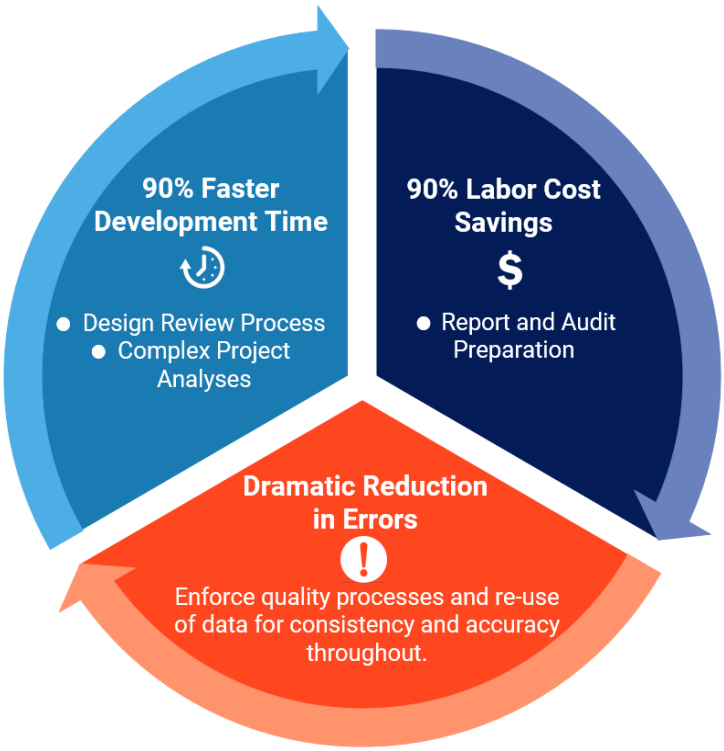
SOLUTION

Compass is a Software-as-a-Service solution that guides and automates the design control process for medical device product development. It is purpose-built to interconnect large amounts of diverse data while automatically applying quality processes—across all company functions and user actions.

Compass enables companies to confidently bring products to market faster by:

- Integrating risk, requirements, and test management;
- Providing template-based step-by-step guided compliance; and
- Automating trace analyses and report generation.

IMPACT



True Value in Quality Investment

An investment in Compass is an investment in value. Compass can save time and money by helping you:

- Evaluate the impact of design choices early;
- Reduce deviations from established processes; and
- Get products to market faster.

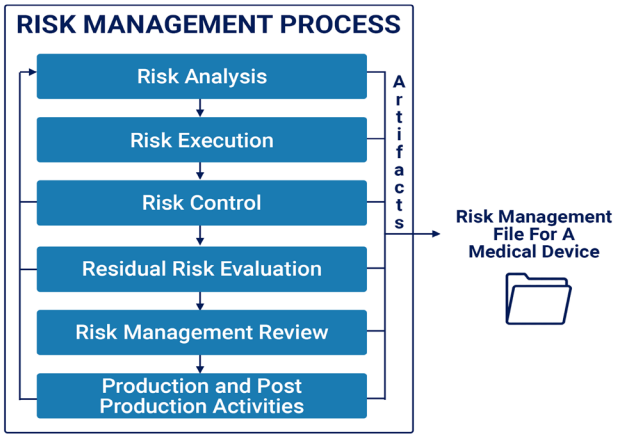
REV 06-2020

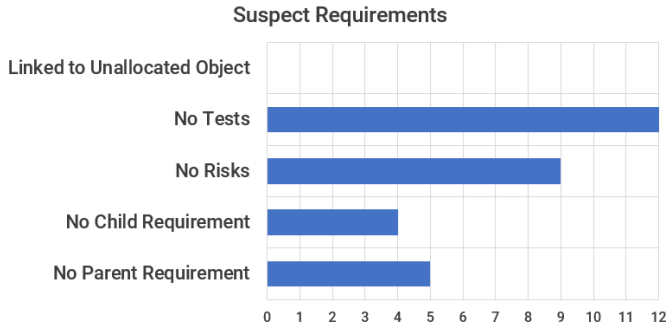
FEATURES

Integrated Risk Management

Supports compliance with ISO 14971 by tightly integrating risk, design, and test management. Real-time assessment of cause and effect provides immediate visibility into the impacts of a change across the design process.

- Risk Management Planning
- Risk Analysis
- Reliability Analysis — FMEA
- Hazard Analysis
- Use Error Analysis
- Supports Risk Management File Content





Design Controls

Step-by-step implementation of rigorous processes to support compliance with 21 CFR 820.30.

- Design/Development Planning
- Design Inputs
- Design Outputs
- Design Review
- Design Verification/Validation
- Supports Design History File (DHF) Content

Test Management

Unifying environment for tests, risks, and requirements maintains consistency and linkages within the product development environment. Clearly connects testing to requirements that are linked to risk mitigation, closing the loop for risk control and implementation. Enables re-use of test methods across projects, referenced within protocols, and summarized within design verification and validation trace matrices.

- Test Methods
- Test Protocols
- Test Runs
- Design Verification and Validation

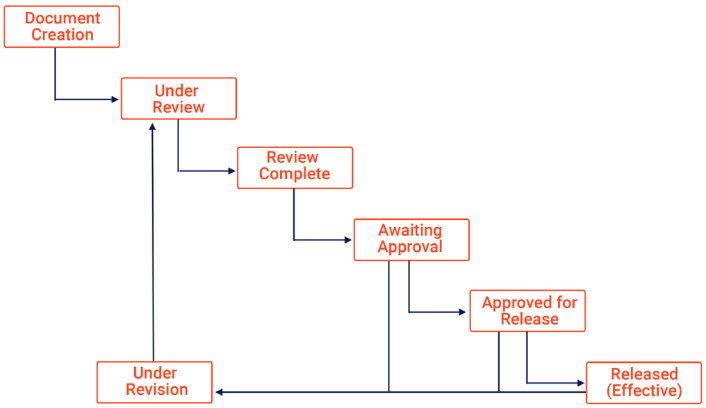
Verification of Risk Control Implementation and Effectiveness
Required Risk Control Measures Improved Interlock SPR0007: Physical Interlock – FUNCTIONAL – System Requirements PR00101 – Electrical Tests Protocol V: 1, Run: 2 – PDF [PASS]

Trace Matrices

Trace Matrices created by Compass provide confirmation that the inputs align with the outputs and show connections among risk, design, and testing components. Clear visualization of data connections enable tracking to completeness throughout the design process from user needs to verification and validation (V&V).

- Supports complex trace matrices with tens of thousands of items/traces
- Traces are automatically generated and updated — no manual tracing
- Quality processes flag potential errors

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



Document Management

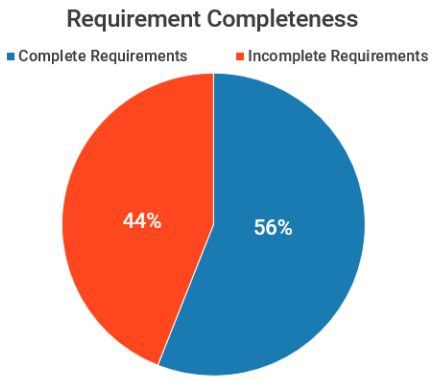
Easy management of the review process via workflow to verify collaboration, approval, and release with auditable sign-off.

- Versioning/History
- Reviews/Approvals
- Configurable Workflows
- Part 11: Electronic Records and Electronic Signatures

Project Management

Complete real-time visibility into status and progress of all aspects of the project.

- Complete Audit Trails — including changes and signatures
- Role-based Access and Privileges
- Metrics, Reports, and Dashboards



REGULATIONS AND STANDARDS

Compass supports many standards and regulations. It provides compliance with critical parts of the following standards among others:

- 21 CFR 820.30
- ISO 13485
- ISO 14971
- IEC 62366
- EU MDR

INTEGRATIONS

Open REST API for integration with other platforms.

- Supports import and export in an industry-standard ReqIF format.
- Connector for SQL-based applications.

HOSTING AND SECURITY

Compass is a Software-as-a-Service offering that is hosted, managed, and maintained by Cognition and accessible from anywhere by its customers. Cognition provides a fully secure environment with guaranteed 99.9% uptime.

USE CASES

21 CFR 820 Compliance	Design History Files	Time to Market	Remediation
Medical device manufacturers wanting to market in the USA must comply with FDA 21 CFR 820 Quality System Regulation (QSR). Compass provides a templated approach and step-by-step guidance aligned to this regulation.	Key elements of the Design History Files (DHF) are created, supported, and maintained within Compass. These files are controlled from a single point of data, ensuring alignment across documents and preserving the history of the design.	Disconnected, manual processes in product development are time-intensive and error-prone. Compass connects data across all functional areas, automates processes, and reuses data to speed time to market while reducing errors and risk.	To successfully exit remediation, companies must establish a stable process to prevent reoccurrence. Compass provides the tools to support exiting remediation via evidence from the documents, reports, and automatic creation of audit trails.

VALIDATION SERVICES

Compass software validation uses a risk-based approach to validation following AAMI TIR36 and GAMP®5 standards and pre-built software validation protocols, test scripts, and reports. Our optional validation services subscription offers comprehensive validation with reports delivered to you and retained by Cognition for audit logging.

NEXT STEPS

To learn more about Cognition's guided compliance solution for medical device product development or to request a demo of Compass, please visit us at www.cognition.us/solutions/compass or email us at info@cognition.us.

ABOUT COGNITION

Cognition Corporation, headquartered in Lexington, Massachusetts, develops, sells, and supports product development and compliance solutions for the life sciences industry. Our Software-as-a-Service solutions enable customers to structure their data and automate processes with built-in quality processes to save time and money and get products to market faster.

COGNITION®

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