COMPASS® FEATURE BRIEF

TRACE MATRICES

Powerful and Unique Trace Functionality for Medical Device Companies

AUTOMATED TRACE MATRIX CREATION AND MANAGEMENT

Compass® guides the development of best practice trace matrices with pre-configured templates - as design data is added, connections are established. Once set up, when changes are made, objects are automatically promulgated across every connection in a trace. When a change has the potential to impact dependent relationships in the trace, those relationships can be easily identified for resolution. Compass trace matrices can be adapted to an organization's SOP's and can be exported for reporting purposes.

Why it matters: Automated processes make it easy to apply quality best practices across the trace to ensure every change is accounted for and nothing falls through the cracks – a master map and single point of truth where all actions and their impacts across a product's development lifecycle are recorded.

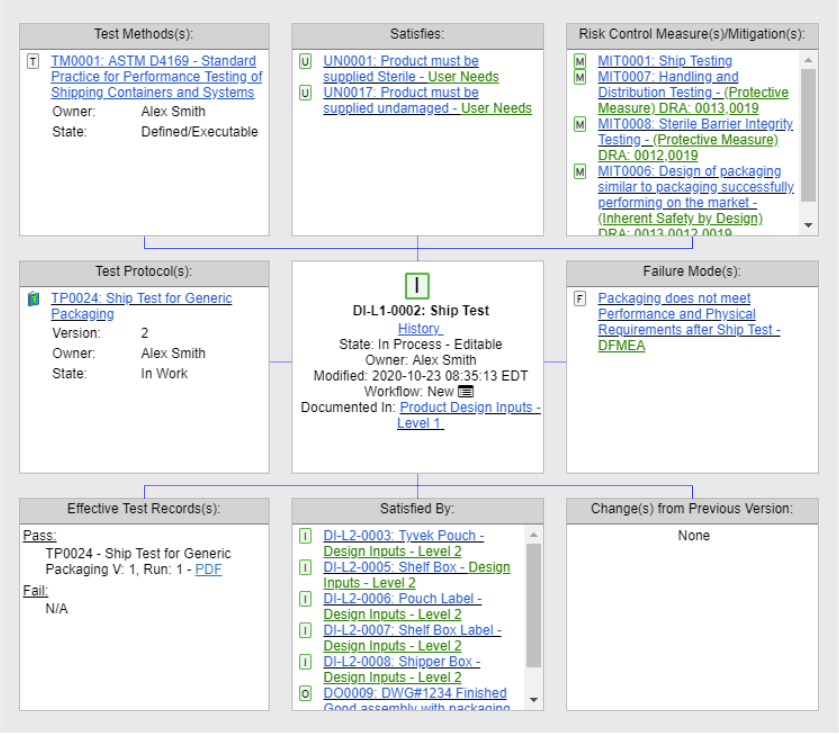

Figure 1 Example of Pre-Configured Trace for an Individual Requirement

"Before Cognition we were manually creating data and data connections that were maintained in paper DHFs that were difficult to scale. Now we are able to create the same data and links in a way that allows Zimmer Biomet to easily maintain large trace matrices. The product has helped us to significantly improve quality, accuracy, and efficiency in our product development process."

Shaun Cronin, PLM Associate Director, Zimmer Biomet

REV 12-2020

3.0 OVERVIEW TRACE

Description here...

User Needs and Validation		Design Inputs Level 1 Requirements and Verification		Design Outputs	
User Need	Validation Tests	Design Inputs Level 1 Requirements	Verification Tests	Design Outputs	Essential?
UN0001: Product must be supplied Sterile Documentation Trace: 5.1 USER NEEDS - User Needs	NONE	DI-L1-0002: Ship Test Documentation Trace: 5.1 FUNCTIONAL - Product Design Inputs - Level 1	TP0024 - Ship Test for Generic Packaging V: 1, Run: 1 - PDF [PASS]	DO0009: DWG#1234 Finished Good assembly with packaging and labels Documentation Trace: 5.1 Assembly Drawings - Design Outputs	YES
				DO0004: DWG#1200 Tyvek Pouch Documentation Trace: 5.3 Component and Material Specifications - Design Outputs	YES
		DI-L1-0010: Aging Documentation Trace: 5.1 FUNCTIONAL - Product Design Inputs - Level 1	NONE	DO0004: DWG#1200 Tyvek Pouch Documentation Trace: 5.3 Component and Material Specifications - Design Outputs	YES
		DI-L1-0011: Sterilization compatibility Documentation Trace: 5.1 FUNCTIONAL - Product Design Inputs - Level 1	NONE	DO0004: DWG#1200 Tyvek Pouch Documentation Trace: 5.3 Component and Material Specifications - Design Outputs	YES
		DI-L1-0012: Sterile Barrier Integrity - no seal leaks Documentation Trace: 5.2 PERFORMANCE - Product Design Inputs - Level 1	TP0024 - Ship Test for Generic Packaging V: 1, Run: 1 - PDF [PASS]	DO0004: DWG#1200 Tyvek Pouch Documentation Trace: 5.3 Component and Material Specifications - Design Outputs	YES
				DO0013: Seal Parameters Documentation Trace: 5.4 Production and Process Specifications - Design Outputs	YES
		DI-L1-0014: Pouch Seal Strength Documentation Trace: 5.2 PERFORMANCE - Product Design Inputs - Level 1	TP0024 - Ship Test for Generic Packaging V: 1, Run: 1 - PDF [PASS]	DO0004: DWG#1200 Tyvek Pouch Documentation Trace: 5.3 Component and Material Specifications - Design Outputs	YES
				DO0013: Seal Parameters Documentation Trace: 5.4 Production and Process Specifications - Design Outputs	YES
		DI-L1-0015: Seal Width Documentation Trace: 5.3 PHYSICAL - Product Design Inputs - Level 1	NONE	DO0004: DWG#1200 Tyvek Pouch Documentation Trace: 5.3 Component and Material Specifications - Design Outputs	YES
				DO0013: Seal Parameters Documentation Trace: 5.4 Production and Process Specifications - Design Outputs	YES
		DI-L1-0016: Compatible with EO sterilization Documentation Trace: 5.4 INTERFACE - Product Design Inputs - Level 1	NONE	DO0009: DWG#1234 Finished Good assembly with packaging and labels Documentation Trace: 5.1 Assembly Drawings - Design Outputs	YES
				DO0004: DWG#1200 Tyvek Pouch Documentation Trace: 5.3 Component and Material Specifications - Design Outputs	YES
UN0017: Product must be supplied undamaged Documentation Trace: 5.1 USER NEEDS - User Needs	NONE	DI-L1-0026: Shelf Box Storage Documentation Trace: 5.3 PHYSICAL - Product Design Inputs - Level 1	NONE	DO0009: DWG#1234 Finished Good assembly with packaging and labels Documentation Trace: 5.1 Assembly Drawings - Design Outputs	YES
		DI-L1-0002: Ship Test Documentation Trace: 5.1 FUNCTIONAL - Product Design Inputs - Level 1	TP0024 - Ship Test for Generic Packaging V: 1, Run: 1 - PDF [PASS]	DO0009: DWG#1234 Finished Good assembly with packaging and labels Documentation Trace: 5.1 Assembly Drawings - Design Outputs	YES
				DO0004: DWG#1200 Tyvek Pouch Documentation Trace: 5.3 Component and Material Specifications - Design Outputs	YES

Figure 2 Example of Pre-Configured Overview Trace Matrix

INTEGRATED RISK MANAGMENT

Compass tightly integrates risk management with requirements and test management, and uniquely manages all of the interactions in a single system. As a result, the impact of *every* change across *every* function is traced and accessible, not just requirements and tests.

Why it matters: by including risk as part of every action, rather than bringing in risk data from another system when needed, it provides for true accountability, auditability, impact analysis, and planning. It also properly treats risk management as defined in ISO 14971.

At Cognition, we place high emphasis on the value of treating risk management properly in the design control process. To dig deeper into our view of the right approach, read the article published in MDDI Complying with ISO 14971:2019 by our Compass Product Line Manager, Ben Higgitt.

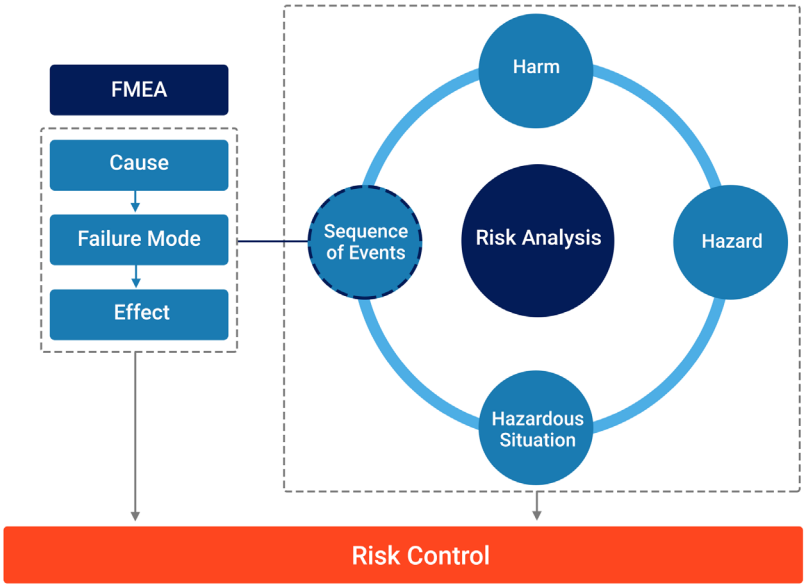

Figure 3 Fully Integrated Risk Management

SCALABILITY

Compass trace matrices scale to tens of thousands of trace items consisting of any type of design data – no matter the size of the trace the connections between inputs and outputs can be quickly proven. Individual trace matrices can be combined to create a master trace of the entire development project.

Why it matters: large and complex projects are the hardest to troubleshoot and manage – and are difficult to communicate to notified bodies - without smart, scalable, and accurate data management. It is common for a medical device to generate an overview trace of more than 10,000 data items which most systems cannot handle. Compass is explicitly designed to support this scale.

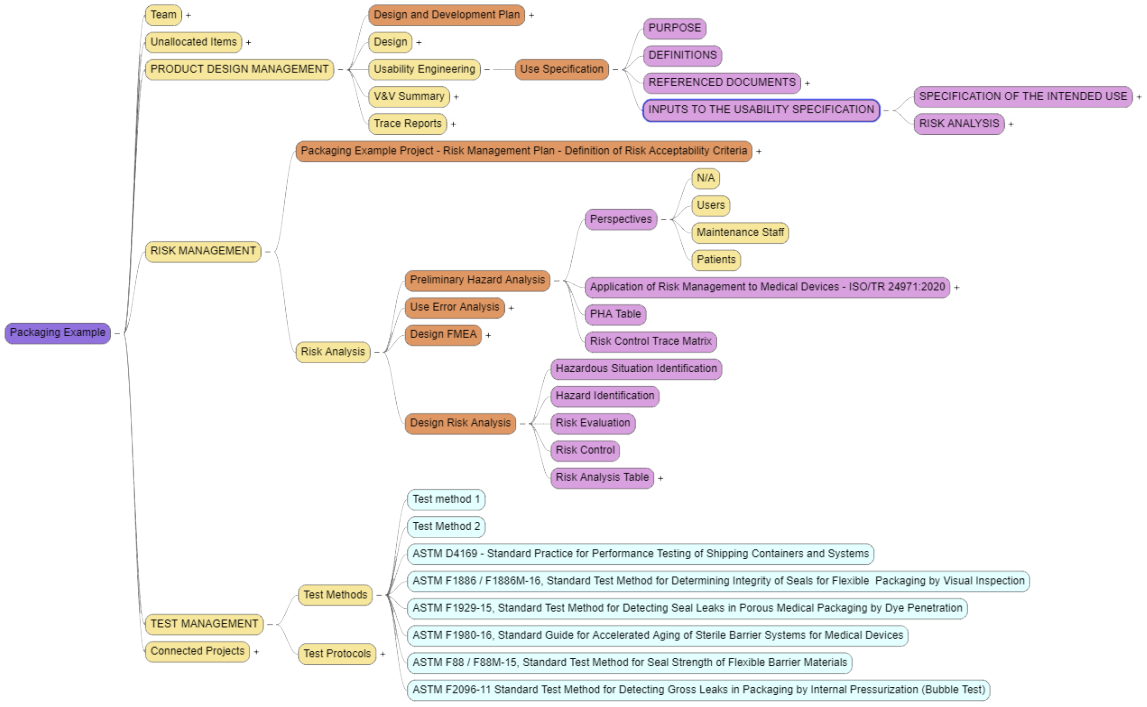

Figure 4 Sample Trace Data Visualization

REUSABILITY

Compass can include data from outside of the current project, in trace matrices. This means that risk, requirements, and test data from data libraries can be re-used.

Why it matters: enables organizations to save significant time and effort by re-using risk, requirements, and test data rather than recreating the same data points over and over again.

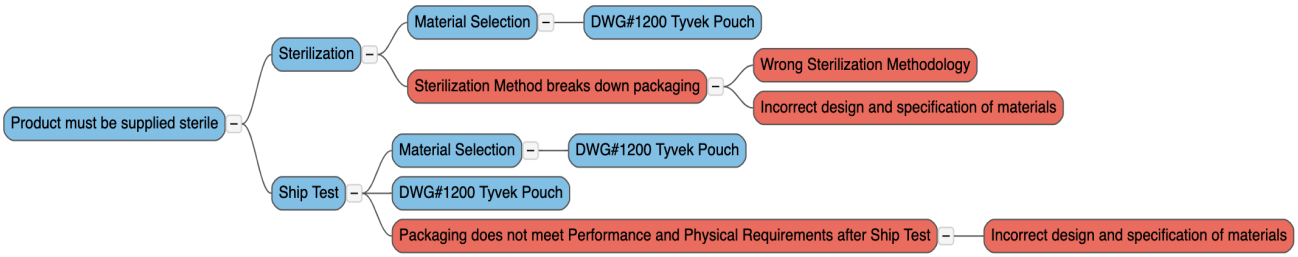

Figure 5 Requirements Reusability

TRACEABILITY WITH COMPASS

Compass' trace functionality is an important tool for medical device development organizations because it provides:

1. A 360-degree view of the project – risks, requirements, and tests - real-time and historic for the most informed planning, development, and impact analysis;
2. Audit and submission-ready content – trace matrices can be exported as documents to support auditing, regulatory submissions, or for process inquiries; and
3. Guided compliance – pre-configured templates and traces are built to support compliance with relevant industry standards like ISO 13485, ISO 14971, 21 CFR 820.30 and Part 11, and IEC 13485.

All together, these features translate to significantly more efficient product development with considerably less risk – that means Compass trace functionality can help you achieve regulatory compliance faster, while reducing cost and reworks.

Why Compass for Traceability?

Compass trace functionality is based on close to two decades of experience working with the largest companies in the medical device industry on best practices. The ability to integrate risk, requirements, and test management within trace matrices, and to automatically establish and update relationships in the trace, makes it easy for companies of any size to implement and realize the benefit from our unique approach to traceability.

Compass offers custom traceability to meet your needs as well as pre-configured trace templates including:

- Complete requirements trace
- Essential outputs trace
- Risk control implementation trace
- PHA risk implementation
- Validation test trace
- Verification test trace

NEXT STEPS

To learn more about Compass' trace functionality, schedule an introductory call or request a demo.

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®

REV 12-2020