COGNITION®

SOLUTION SUMMARY

COMPASS® PRO

Improve efficiency, enhance data integrity, and accelerate time to market

OVERVIEW

Compass PRO is an intelligent design control solution for all your medical device development needs - including multi-level requirements, comprehensive risk management, and test management.

Specifically engineered for medical device manufacturers and contract design organizations, Compass PRO increases efficiency and enhances data integrity with real-time traceability, work instructions that accommodate guided compliance templates, regulation references with submission-ready documents, change once, update everywhere functionality, and more.

WHY CHOOSE COMPASS PRO?

MAXIMIZE EFFICIENCY AND DATA INTEGRITY

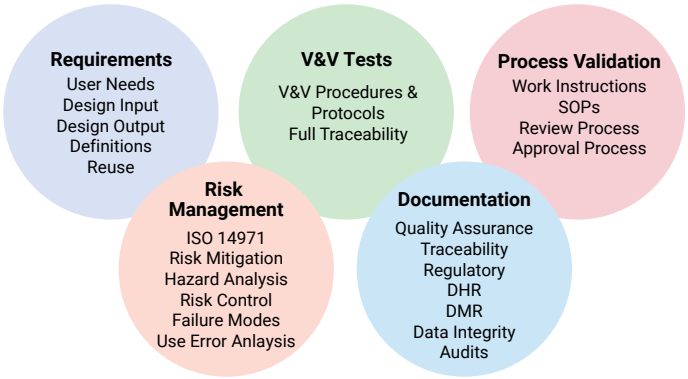
Automate, integrate, and enhance processes across multi-level requirements, risk, and test management, reducing manual data entry, easily build connections between items, and automatically create complex trace matrices. Supports data centric workspaces to manage individual items as well as automatically generating submission-ready formal documentation.

REUSE AND REPOSITORIES

Start new product variations quickly and easily. A single "item" to be used across multiple projects as well as many places within a single project. Other projects can browse repositories and leverage existing content. If the library project is updated all projects reusing the same requirements can be notified, and user decides if appropriate.

STREAMLINE AUDITS AND SUBMISSIONS

Documents, reports, and traces are created through customer-defined, reusable templates so users will always have the approved documents needed for their use and for delivery downstream to regulatory or other groups. The power of structured documents becomes clear: embedded work instructions, data table sections, signature pages, narrative content, instant export, or connection to external systems, etc.



Design Control for Medical Device Development Requirements, Risk and Test Management, Structured Content, Traceability, Submission-Ready Documents

ENHANCE COLLABORATION

With both a document-centric and data-centric workspace across every functional area, Compass PRO enables you to add real-time filters, to allow tracing up to parent requirements, as well as tracing down to child requirements. With more connected and consistent information and guided compliance templates, you'll save time and resources while enhancing collaboration and reducing risk.

COMPREHENSIVE RISK MANAGEMENT

Fully supports relevant risk standards and regulations while providing complete flexibility to meet corporate standards. Risk items are often linked with requirement items for verification of implementation. This type of connection between actual data items, and not just text, brings confidence to development teams and is invaluable during design review and regulatory audit both pre and postmarket.

KEY CAPABILITIES

- Integrated requirements, risk, and test management
- Guided compliance templates (ISO 14971, IEC 62366, ISO 13485, 21CFR 820.30 and (EU) 2017/745)
- Automated trace matrices
- Change once, update everywhere functionality using structured data elements throughout
- Built-in and configurable workflows with authoring, reviewing, and releasing information
- Instant exports of submission-ready documents
- Reusable documents, data, and test methods
- Comprehensive audit logs
- Data-centric workspace tables and document-centric formats

TRANSITION WITH EASE

- Out-of-the-box and/or configurable workflows
- Seamlessly import/export data and documents/reports
- Easily integrate with other systems
- Scale up incrementally

Ready to Move Faster?

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