

Overview

Compass MED is an intelligent design control solution for all your medical device development needs - including multi-level requirements, comprehensive risk management, enhanced test management with execution capabilities, and integrated human factors engineering aligned with IEC 62366.

Specifically engineered for medical device manufacturers and contract design organizations, Compass MED increases efficiency and enhances data integrity with real-time traceability, guided compliance templates, audit-ready documentation, integrated defect tracking, and seamless connections to your broader engineering ecosystem.

Why Choose Compass MED?

Maximize Efficiency and Data Integrity

Automate, integrate, and enhance processes across multi-level requirements, risk, and test management - including integrated test execution and defect capture - 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 audit-ready formal documentation.

Reuse and Repositories

Start new product variations quickly and efficiently using structured reuse and tag-based project derivatives. A single "item" can be leveraged across multiple projects or product variants. With bi-directional synchronization, updates can flow between source and derivative projects—eliminating redundant work and enabling efficient management of product families and platform-based designs at scale.

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, real-time traceability across requirements, risks, tests, and defects, instant export, or connection to external systems, etc.

Enhance Collaboration

With both document-centric and data-centric workspaces, Compass MED enables real-time filtering and full traceability across parent and child requirements. Connected data and guided compliance templates improve efficiency, collaboration, and reduce risk. Integrations with Jira and Azure DevOps allow teams to work in preferred tools while maintaining traceability and eliminating duplicate data entry.

Comprehensive Risk Management

Fully supports relevant risk standards while maintaining flexibility to meet corporate requirements. Risk items are directly linked to requirements for verification, enabling true data-level traceability that strengthens design reviews and regulatory audits. Automated impact assessment highlights affected risk controls and linked items, ensuring continued compliance and product safety.

Key Capabilities

- ✓ Integrated requirements, risk, and test management with execution tracking
- ✓ Guided compliance templates (ISO 14971, IEC 62366, ISO 13485, 21 CFR 820.30, EU 2017/745)
- ✓ Automated trace matrices with real-time traceability across requirements, risks, tests, and defects
- ✓ Change once, update everywhere with automated impact assessment and suspect link identification
- ✓ Configurable workflows for authoring, review, and release
- ✓ Instant export of audit-ready documents
- ✓ Reusable data and tag-based project derivatives with bi-directional sync
- ✓ Comprehensive audit logs
- ✓ Data-centric and document-centric workspaces

Transition with Ease

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

