COGNITION®

COMPASS® MED

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

SOLUTION SUMMARY

Overview

Compass MED is an intelligent design control solution for all your medical device development needs - including multi-level requirements, comprehensive risk management, automated impact assessment, advanced test management, and 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, tag-based project variants, and bi-directional connectors to Jira and Azure DevOps.

Why Choose Compass MED?

Maximize Efficiency and Data Integrity

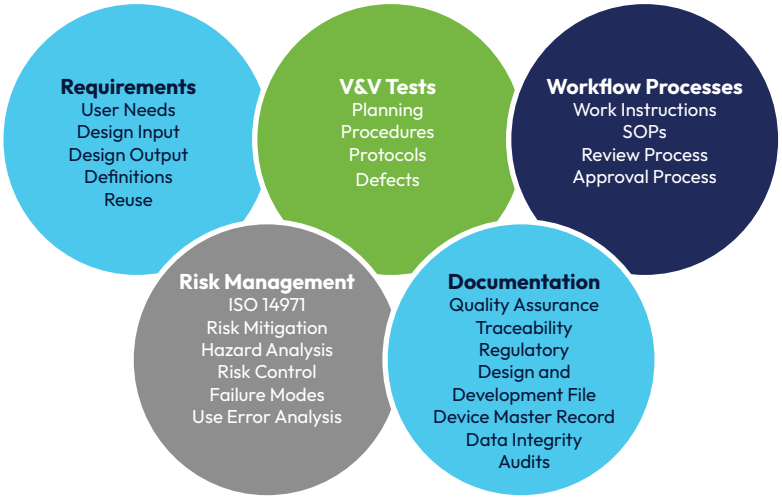
Automate, integrate, and enhance processes across multi-level requirements, risk, and test management, reducing manual data entry and automatically create complex trace matrices. Flexible test campaigns and test plans define which protocols run, which requirements they verify, and who is qualified to execute them, with deviation and defect capture during execution.

Reuse and Project Variants

Start new product variations quickly with tag-based project variants. Select only the content you need by tag and create a new variant without starting over. Reused data maintains traceability back to its source, and changes can be synced in either direction, enabling efficient management of product families 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. Test execution records are approved with electronic signatures designed to support 21 CFR Part 11 compliance, keeping teams audit-ready.



Enhance Collaboration

With both document-centric and data-centric workspaces, Compass MED enables real-time filtering and full traceability across parent and child requirements. Connectors to Jira and Azure DevOps push and pull requirements, test data, and defects on a schedule, on an event, or on demand. Every sync event is audited so engineers keep their tools and quality teams keep their evidence.

Risk Management and Impact Assessment

Fully supports relevant risk standards while maintaining flexibility to meet corporate requirements, with risk items linked directly to requirements for verification. Automated impact assessment flags every suspect link with its upstream and downstream context, and an approval gate holds unresolved impacts until they are closed with an electronic signature.

Key Capabilities

- Live dashboards and reporting
- 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 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
- Test campaigns, test plans, and reusable libraries
- Defect lifecycle tracking
- Tag-based project variants with source traceability
- Comprehensive audit logs
- Data-centric and document-centric workspaces
- One compliant source of truth

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

Ready to move faster? (781) 271-9300 sales@cognition.us www.cognition.us