COGNITION®

SOLUTION SUMMARY

COMPASS® / COMPASS PRO
for Medical Device Product Development

Compass / Compass PRO ("Compass") are pre-configured, out-of-the-box, SaaS solutions purpose-built for the medical device industry to connect data across all functional areas of medical device product development including risk, requirement, and test management. Compass leverages regulations such as 21 CFR 820.30 as well as standards ISO 13485, IEC 62366, and ISO 14971 as the foundation of the software design.

Compass enables compliant product development by ensuring the process of authoring, reviewing, and releasing documents is enforced via workflows and built-in document templates, which automates a complex workflow between those interconnections to ensure compliant development. It provides an adaptable set of document templates for the entire product design control process from user needs to validation, with a focus on risk, requirement, and test management.

Saving time and resources, it maintains documentation and supports submissions as well as provides automatic generation of the master trace matrices and documents for the Design History File (DHF), Technical Documentation Records, and audit support.

KEY FEATURES

- Specifically engineered for medical device companies
- Highly configurable and adaptable processes to match your SOPs
- Flexible work environment for different design definition approaches
- Supports data-centric and document-centric workspace environments
- Seamless data and document sharing
- Optimal risk analysis processes and test management capabilities to produce high quality products
- Real-time data traceability across all requirements, risk, and test processes
- Simple onboarding, training, and implementation process
- Automatically generates submission ready documents which streamlines audit support
- Integrates with third party applications (e.g. Jira)

WHAT SETS COMPASS APART

Process-Based, Out-of-the-Box Functionality	Structured Data	Industry-Leading Risk Management	Traceability
Compass offers pre-configured document templates using our guided compliance approach. Data-centric working tables are also available, enabling filtering and table organization in a personalized format, optimizing individual work.	Structured data contains specific information, each with a unique identifier, which may be used in multiple locations, exist over time, be reusable, be connected to child/parent/peers, and enable action at a distance.	Compass provides medical device companies an advantage with its risk-focused approach that places high emphasis on the value of tightly integrating risk management in the design control process with requirements and tests which ensures high quality products.	Compass builds best practice trace matrices via preconfigured templates, enabling connections to be established as data is added and automatically creating output documents and views.

LEARN MORE

To learn more about Compass/Compass PRO please download Why Medical Device Companies Choose Compass for a Structured Approach to Product Development or reach out to us at sales@cognition.us.