COGNITION®

SOLUTION OVERVIEW

Compass® PRO for Comprehensive Medical Device Development

A SOLUTION THAT GROWS WITH YOU

Disconnected data and manual processes introduce a high potential for error in product development and can slow time to market. Companies can streamline and optimize the processes related to the management of design control data such as requirements, risks, and tests to expedite time to market, improve audit readiness, and simplify regulatory submissions by using modern tools specifically designed for the medical device industry.

Cognition® provides the first and only, industry-specific solution designed for medical device companies. Compass® PRO is a Software-as-a-Service (SaaS) solution that streamlines the design control process for medical device product development. It is purpose-built to interconnect large amounts of diverse data while automatically applying quality processes across all company functions and user actions.

Compass PRO enables companies to confidently bring products to market faster by:

- Integrating risk, requirement, and test management data into a single, connected tool;
- Facilitating the easy reuse of data through data libraries;
- Streamlining usability analysis in line with IEC 62366-1:2015;
- Supporting compliance with ISO 13485:2016, 21 CFR 820.30, and ISO 14971:2019;
- Enabling data export for storage in a document management system;
- Providing effortless reporting on traceability; and
- Customizing/extending functionality to meet your business needs and processes.

A SINGLE SOLUTION FOR MANAGING DESIGN CONTROL DATA

Compass PRO provides unmatched connectivity between risk, requirement, and test data. With a 360-degree view of your project, you get real-time and historic traceability for the most informed planning, development, and impact analysis.

UNIFIED ENVIRONMENT

Compass PRO creates a unified environment for risks, requirements, and tests, maintaining consistency and linkages within the product development environment. It connects testing clearly to requirements that are linked to risk mitigations, closing the loop for risk control and implementation.

DESIGN AND DEVELOPMENT

Compass PRO provides step-by-step implementation of rigorous processes, with a strong emphasis on requirements management, to support compliance with 21 CFR 820.30 and ISO 13485/EU MDR. Managing requirements as objects enables connections across design management and quality systems.

FLEXIBLE RISK ENVIRONMENT

Compass PRO uses formalized Risk Acceptability criteria that reflect and enforce the customer's quality system procedure. Furthermore, it separates Hazard Analysis from reliability analysis (FMEA), helping to meet the latest edition of ISO 14971:2019. Compass PRO understands that risk management not only requires precision but also adaptability which is why it was developed specifically to ensure compliance with changing standards.

EFFORTLESS REPORTING ON TRACEABILITY

Compass PRO supports the most complex trace matrices, accommodating tens of thousands of items and traces effortlessly. These trace matrices offer clear data visualization and evidence of alignment between inputs and outputs while also highlighting intricate connections among risk, requirements, and test data.

REUSABILITY

Compass PRO leverages centrally managed libraries for Hazards and Harms, streamlining the accessibility and consistency of this critical data. You can also generate on-the-fly libraries of reusable items, including Risk Controls, Recommended Actions, and Hazardous Situations throughout the analysis process. These items are designed to be reusable and easily interconnected, promoting efficiency and synergy in design control efforts.

INTEGRATED REPORTING AND ANALYSIS

Compass PRO comes with built-in reporting and analysis for easy custom report generation, allowing users to tailor reports to their specific needs. Moreover, it simplifies the identification of critical elements, such as a single Design Input or Output, or controlling multiple risks, while providing a comprehensive view of the most pivotal factors in your design controls process.

MANAGE USABILITY ANALYSIS

Compass PRO includes built-in templates to support the usability engineering process defined in IEC 62366-1:2015 including Use Specification, Function and Task Analysis, Use Scenario Analysis, Correct Use Analysis, and Use Error Analysis.

EASY DOCUMENT EXPORT

Compass PRO allows for straightforward and fast document export. Export in either Word or PDF, and include a cover page, headers, footers, and watermarks as required. Documents export submission-ready with no post-processing required.

CHOOSING THE RIGHT COMPASS EDITION FOR YOUR COMPANY

Whether you choose Cognition's Compass or Compass PRO, you acquire the key functionality and benefits of our industry-specific guided solution for medical device product development data.

	COMPASS	COMPASS PRO
Traceability	X	X
Asset Libraries	X	X
Simple Data Import	X	X
Document Reviews and Exports	X	X
E-Signatures Compliant with 21 CFR Part 11	X	X
Data Integrity	X	X
Industry-Leading Risk Management	X	X
Out-of-the-Box Templates Aligned to Industry Standards	X	X
Dynamic Document Authoring	X	X
Best-In-Class Customer Service	X	X
SaaS Hosted by Cognition	X	X
Limited Configurability	X	
Customization Available		X
Administration/Professional Services Required		X

HOW COMPASS PRO CAN HELP

DESIGN HISTORY FILES	Key elements of the Design History Files (DHF) are created, supported, and maintained within Compass Pro. These files are controlled from a single point of data, ensuring alignment across documents and preserving the history of the design.
REDUCE INEFFICIENCIES IN DEVELOPMENT	Disconnected, manual processes in product development are time-intensive and error-prone. Compass PRO connect data across all functional areas, automate processes, and reuse data to speed time to market while reducing the potential for error.

REMEDIATION	To successfully exit remediation, companies must establish a stable process to prevent reoccurrence. Compass PRO provide the tools to support exiting remediation via evidence from the documents, reports, and automatic creation of audit trails.
IMPROVE RISK MANAGEMENT PROCESS	Compass PRO place an emphasis on comprehensive risk analysis and integrate risk with requirement and test data supporting a thorough design controls process from the outset. Now, companies are able to easily identify and consider risks related to use (both correct use and use error) and not just failure to help bring safer products to market.

GETTING STARTED WITH COMPASS PRO

We believe in creating partnerships with our customers to ensure their success. Nothing else matters. We have a passionate team of industry knowledgeable professionals for support and will be with you every step of the way.

ONBOARDING PHASE

The onboarding phase is a “getting to know you” stage where we listen to how your current process works. This phase helps us to implement the software so that your document formats and content are integrated into Compass PRO. It explores how working within a database might encourage shifts to leverage the increased efficiency and connectedness of this system.

- Our Application Engineers meet to discuss your processes, stakeholders, product development key milestones, and critical data. These discussions cover topics such as requirements, risk, testing, trace matrices, output formats, and critical output documents to support submissions.
- Our out-of-the-box document templates, workflows, e-signatures, and stages align to medical device regulations and standards. We walk through the native process to demonstrate how we provide compliance to 21 CFR 820.30, ISO 13485, IEC 62304, ISO 14971, and design and development sections of EU MDR (aligned to ISO 13485).
- We provide training courses to general users and administrators.
- Our Application Engineers meet with lead users and administrators systematically to ensure our customer’s success with your implementation and roll-out to general usage.
- Validation support services are available for a subscription to enable rapid adoption into our customer’s QMS as accepted software supporting design control if desired.
- Professional services are available to assist in configuration work.

Once Compass PRO has been configured to our customer’s document formats and processes have been aligned, we are ready to move into implementation or production. Cognition offers training on how to use Compass PRO. Our team is available to answer any future questions, shifts in process, or integration of new features as they are made available.

Your success is our success. We look forward to collaborating with you.

NEXT STEPS

To learn more about Cognition's Compass PRO solution for medical device companies or to request a demo of Compass PRO, please visit us at www.cognition.us/solutions/compass or email us at info@cognition.us.

ABOUT COGNITION

Cognition Corporation, headquartered in Lexington, Massachusetts, develops, sells, and supports product development and compliance solutions for the life sciences industry. Its Software-as-a-Service solutions help meet regulations faster with real-time traceability, guided design controls, and change once, update everywhere functionality–turning manual and disconnected data into streamlined, structured submissions that enable them to get to market faster.

Cognition Corporation

24 Hartwell Avenue

Lexington, MA 02421

www.cognition.us