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Cognition® Corporation Announces Compass® PRO: A Flexible SaaS Solution Purpose-Built for Medical Device Product Development

Compass PRO is the latest addition to Cognition's Compass family, empowering medical device manufacturers to efficiently and effectively manage their design controls data by providing a solution to grow with their business.

Lexington, MA - September 20, 2023 - Cognition Corporation, a leader in Software-as-a-Service (SaaS) solutions for medical device and pharmaceutical product development, today announces Compass PRO, the latest in their product portfolio designed specifically for medical device companies. Compass PRO provides trusted guided compliance functionality with flexible customization to meet business needs and processes. Compass PRO is a SaaS solution that streamlines the design control process for medical device product development. It is purpose-built to interconnect large amounts of diverse data, including risk, requirement, and test data, while automatically applying quality processes across all company functions and user actions. The solution will be available for demonstrations starting in October.

Leveraging a structured data model, 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 business needs and processes.

"We have taken 20+ years of best practices and industry knowledge and poured them into our Compass product family. This gives us the ability to provide medical device companies a 'quick start' in managing their product development data using our guided compliance solutions with built-in templates. The release of Compass PRO is the next step in empowering medical device companies to deliver safer products to market faster by enabling them to align precisely with their business needs and processes," said Ben Higgitt, Product Line Manager, Compass/Compass PRO. "What truly sets Compass PRO apart is its ability to provide seamless and robust connectivity between risk, requirement, and test data. In the fast-evolving world of medical device product development, staying ahead is essential, and Compass PRO is designed to guide companies toward success."

Compass PRO provides a single solution for managing design controls data. Its key features include:

- A unified environment: integrating risks, requirements, and tests to maintain consistency and linkages within the product development environment.
- Design and development: step-by-step implementation of rigorous processes to support design control with a strong emphasis on requirement management to comply with 21 CFR 820.30 and ISO 13485/EU MDR.
- Flexible risk environment: risk management not only requires precision but also adaptability; Compass PRO was developed specifically to ensure compliance with changing standards.
- Usability analysis: 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.
- Reusability: leveraging centrally managed libraries for Hazards and Harms, streamlining the accessibility and consistency of this critical data.
- Integrated reporting and analysis: built-in reporting and analysis for easy custom report generation, allowing users to tailor reports to their specific needs—giving companies a comprehensive view of the most pivotal factors in their design controls process.
- Effortless reporting on traceability: supporting 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.
- Easy document export: exporting documents is straightforward and fast in Compass PRO. Documents export submission-ready with no post-processing required.

“The entire Cognition team is thrilled to announce Compass PRO, a real game-changer for the medical device industry. With Compass PRO, we've put customization at the forefront, allowing our customers to tailor the software to meet their unique business needs and processes while maintaining all the functionality our medical device customers rely on,” said Gerald Wesel, Chairman & CEO, Cognition Corporation. “We believe Compass PRO will empower medical device companies to take their product development data to new heights, and we can't wait to see the positive impact it will have on the industry."

Compass PRO has multiple use cases to help medical device companies bring safer products to market faster. These include speeding time to market, addressing remediation, creating Design History Files (DHF), and supporting compliance with standards and regulations like ISO 14971, 21 CFR 820.30, IEC 62366-1, and ISO 13485/EUMDR. It provides unmatched connectivity between risk, requirement, and test data with a 360-degree view of a company’s product development project and with real-time and historic traceability for the most informed planning, development, and impact analysis.

For more information on Cognition’s Compass PRO solution, click here.

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About Cognition
Cognition Corporation specializes in product development and compliance solutions for the life sciences industries. For medical device professionals, Cognition offers a design controls software platform that helps meet regulations faster with real-time traceability, guided design controls, and “change once, update everywhere” functionality, turning manual and disconnected data into structured submissions that enable them to get to market faster.

Unlike other design controls solutions that simply replicate traditional documents and spreadsheets, Cognition takes a structured data approach, combining risk with test and requirements data so you can easily build relevant connections between data items, automatically create complex trace matrices, and export formatted documents instantly—offering a more efficient and integrated solution.

We are shifting the data management landscape for medical device and pharmaceutical product development from a static, document-based approach to a dynamic, information-driven approach, helping to streamline and alleviate the administrative burden of product development documentation. Further information about Cognition Corporation can be found at www.cognition.us.

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