

FOR IMMEDIATE RELEASE

Cognition Corporation Boosts Performance and Security in Latest Release of Compass® for Medical Device Product Development

The Compass SaaS solution for structured and highly organized risk, requirements, and test management data, now with single sign-on, guides users through compliant device development

Lexington, Massachusetts, USA – March 8, 2022 – Cognition Corporation, a leader in SaaS solutions for medical device and pharmaceutical product development, has released a new version of its Compass solution. Compass is purpose built for medical device companies, provides four-dimensional data capacities and enables medical device product teams to connect and document the design control process—tightly integrating risk, requirement, and test management data—with built-in guided compliance and quality processes. With out-of-the-box functionality, Compass guides development to support best practices and compliance with standards and regulations such as ISO 14971, FDA 21 CFR 820.30, and ISO 13485 to speed product development. The newest release includes significant improvements in performance, single sign-on functionality, and more.

“When requirements, test, and risk data are managed separately – in spreadsheets, documents, or general-purpose databases – there are no connections between the data. The information contained in isolated cells is not connected or traceable to information in other cells. Consequently, when changes are made, they must be manually updated which results in errors upon errors and a very slow and complicated verification process. Compass provides a solution for managing all of that data in one place with built-in quality processes,” said Ben Higgitt, Compass Product Line Manager.

Compass provides template-based guided compliance through the medical device product development process and enforces embedded quality processes across every connection. In addition, it provides a single source of truth so that when changes are made, they are made everywhere and potential effects of the change on other data can be identified. Compass enables medical device companies to bring products to market faster by reducing data verification time by 60% while supporting compliance with industry standards and regulations. It combines automation with the most scalable trace matrices and most comprehensive risk management tools—all integrated with quality systems.

Key features of Compass include:

- **Built-in Deep Integration of Risk Management:** Industry-leading risk-first management techniques, optimized for medical device design, are tightly integrated with requirements and test management. By integrating tightly, real time analysis is possible to identify critical inputs and outputs, residual risks, and areas to further mitigate hazards. It clearly connects testing to requirements that are linked to risk mitigation, closing the loop for risk control, and implementation.
- **Structured Data:** Structured data contains specific information, each with a unique identifier. For structured data to be valuable, it may be used in multiple locations, exist over time, be reusable, be connected to child/parent/peers, and enable action at a

distance. Given the unique ID setup, if you need to update the central property, the update will be pulled or pushed through to all locations that use it. This is exactly how Compass treats your product development data.

- **Scalable Trace Matrices:** Supports large, complex traces across multiple levels of inputs, outputs, risk, and test that are built as content is added, enabling efficient and effective analysis that all elements are covered and connected. Updates are automatically propagated so that data is always in sync with no manual updates required.
- **Document Review:** Integrates predesigned workflows for easy review, approval, and release with auditable sign-off.

About Cognition Corporation

Cognition develops, sells, and supports risk-first product development and compliance solutions for the medical device and pharmaceutical industries and is trusted by the world's leading life sciences companies. Its Software-as-a-Service platform enables customers to structure their data and automate processes with built-in quality to save time and money and bring products to market faster. For more information, visit www.cognition.us.

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