

FOR IMMEDIATE RELEASE

Cognition Corporation Introduces Industry's First SaaS Solution for Guided Compliance™ in Medical Device Product Development

The new Compass™ solution provides off-the-shelf, easy to use, template-based functionality to automate the product development process in compliance with industry standards and to bring products to market faster and with less risk.

Lexington, Massachusetts, USA – June 24, 2020 – Cognition Corporation, a leader in SaaS solutions for medical device and pharmaceutical product development, today launched Compass 2020. The new SaaS solution enables medical device product teams to automate and document the entire design control process—tightly integrating risk, requirement, and test management—with built-in quality processes. Compass guides development in compliance with standards such as ISO 14971, FDA 21 CFR 820.30, and ISO 13485 to speed product development. In beta since last year, the solution is now Generally Available (GA).

“For twenty years, Cognition has been building custom software implementations based on our Cockpit® platform for the industry’s largest medical device companies. Cockpit is optimized for large, complex projects where diverse data is interconnected and implementations are highly customized because requirements/SOPs are diverse. Compass is based on the proven and powerful Cockpit technology and provides a prepackaged, templated product for medium-sized companies that do not have the time, resources, budget, or need for a fully customized solution,” explains Dale Gallaher, president of Cognition Corporation.

Compass provides template-based guided compliance through the medical device product development process and enforces quality processes across every connection. In addition, it provides a single point of truth so that when changes are made, they are made everywhere and potential effects of the change on other data are flagged. Compass enables small and midsize medical device companies to bring products to market faster while remaining in compliance with industry standards by combining automation with the most scalable trace matrices and most comprehensive risk management tools—all integrated with quality systems.

“Before introducing Cockpit/Compass, Mediso used requirement management tools, which provided little support in defining our processes. With Cockpit/Compass and Cognition, we instantly gained access to document templates, workflows, and a

knowledge base, which guided us to perform our processes in better compliance with critical standards and good engineering practices. We were able to upgrade existing processes based on what we learned from Cockpit/Compass, and at the same time these tools could be fine-tuned to areas where we already had solid foundations. We expect that this solution will help us to better manage our modular product family, and so accelerate time to market—enabling Mediso, a relatively small company, to compete with the industry giants," said Miklós Czeller, R&D Director at Mediso, a medical diagnostics company.

"Compass streamlines our product development processes, with complete confidence that we are in compliance with critical standards, by providing the needed templates to guide us in developing our LDT Software Platform. It provides a centralized environment for collaboration while ensuring that all data is correctly connected, with every activity and user action updated in real time across the process. Cognition's solution ensures teams spend significantly more time focused on productive work, rather than building and maintaining documents and complex traces. This allows us to run lean and still accelerate our time to market more than any other solution I've had experience with," said Chris W. Henry, Senior Manager, Software Quality Engineering at Epic Sciences, a medical diagnostics company.

Key features of Compass include:

- **Integrated Risk Management:** Industry-leading comprehensive risk management is tightly integrated with requirements and test management to provide real-time views of the impact of changes across the design process.
- **Automated Design Controls:** Step-by-step implementation of rigorous processes in design data and requirements management supports unlimited levels of requirements and the creation of Design History File (DHF) content.
- **Test Management:** Clearly connects testing to requirements that are linked to risk mitigation, closing the loop for risk control, and implementation.
- **Scalable Trace Matrices:** Supports the largest, most complex traces—with master trace matrices in excess of 10,000 items—and traces are automatically generated and updated when any changes are made.
- **Document Management:** Integrates predesigned workflows for easy review, approval, and release with auditable sign-off.
- **Project Management:** Real-time visibility into the status, activities, and detail of every aspect of the project.
- **Software Validation:** Validation kit includes test execution results for Compass out-of-the-box functionality, based on AAMI TIR36 and GAMP® 5 validation, and an optional validation services subscription plan to complete software validation based on specific use cases in your environment.



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Compass has multiple use cases including speeding time to market, exiting remediation, creating Design History Files (DHF), and increasing compliance with standards like ISO 14971, 21 CFR 820.30, and ISO 13485. It provides real-time dashboards and connectors to popular tools like JIRA and GitHub. Compass is hosted in a fully secure environment, accessible 24/7, with guaranteed 99.9% uptime.

For more information on Cognition's Compass Solution, click [HERE](#).

To access the Compass press kit, click [HERE](#).

About Cognition Corporation

Cognition develops, sells, and supports 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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