Cognition Corporation Launches Compass MED: A Revolutionary Solution to Simplify and Accelerate Medical Device Development

As medical devices become increasingly more complex, the need to enhance development efficiency, quality by design, integrated risk management, and regulatory compliance has never been greater

Lexington, MA, September 10, 2024 – Cognition Corporation®, a leading provider of product development and compliance solutions for the life sciences industry, today announced a groundbreaking solution set to streamline and enhance the medical device development process: Compass MED. The company, whose customers include Boston Scientific, Smith+Nephew, Zimmer Biomet, and Cook Medical, developed Compass MED in direct response to the market's need to address the increasing complexity associated with medical device development.

The complexity is growing due to multiple factors, but one of the most impactful is the fact that medical device manufacturers are navigating evolving industry standards and regulations, such as ISO 14971 and ISO 13485. Though these standards and regulations are critical to ensuring quality and safety, implementing appropriate compliance workflows, testing, and documentation can elongate development timelines.

"Compass MED is a revolutionary solution for medical device development. Its advanced capabilities enhance collaboration, efficiency, data integrity, and risk management, helping companies reduce time to market while ensuring compliance with the highest quality and regulatory standards," says Nathan Brown, R&D Fellow, Boston Scientific. "With its robust risk management features, Compass MED provides unprecedented visibility and control, enabling organizations to proactively identify and address potential issues before they escalate. Compass MED has transformed product development. This product doesn't raise the bar, it sets a new bar for the industry."

Specifically engineered for medical device manufacturers, Compass MED combines core features from Cognition's previous solutions including guided design controls, real-time traceability, submission-ready documents, and change once, update everywhere functionality—with new additional efficiency and quality enhancing capabilities including:

- Flexible workspaces for both design controls and risk management
- User-defined landing pages
- Interactive dashboards
- Integrated comprehensive risk management
- Collaborative document reviews
- Submission-ready documents
- Better integration of libraries across projects

With Compass MED, Engineering and R&D teams accelerate innovation by using a fully connected data model with enhanced collaboration. Meanwhile, Quality and Regulatory teams save time and ensure compliance by automating complete and accurate documentation and leveraging real-time analytics, essential for meeting regulatory

standards. Compass MED fosters seamless collaboration and optimizes workflows across product development functions.

“One of the biggest benefits of using Compass MED is the traceability within the design documentation,” says Julie Whalen, Global Quality Senior Leader, Design Controls, Kimberly-Clark. “When you're using Excel files and Word documents, the linkage is not clearly evident to the designer and the development team or the sustaining team supporting the product while in market. Having that clear linkage helps to ensure that appropriate verification and validation are completed during the design and development phase of the product.”

Industry research also underscores the value of Compass MED’s efficiency and quality-enhancing capabilities.

- According to the McKinsey Center for Government, a single warranty or recall process can cost manufacturers up to $600 million. More broadly, non-routine quality events, such as recalls and associated warranties and lawsuits, cost the medical device industry up to $5 billion per year.
- According to the FDA, over 2 million reports of suspected medical device-associated deaths, serious injuries, and malfunctions occur each year.
- According to recent research from Harvard Business School, enabling patients to benefit from new and effective devices sooner can mean the difference between “life and death” for some patients.
- According to a recent independent survey of 75 medical device manufacturing executives and engineers, most organizations are highly focused on accelerating time to market, with half citing it as their top priority. That same survey found that only about half of respondents are “very satisfied” with their current documentation management, test management, and risk management practices. The survey managed by Sage Growth Partners was commissioned by Cognition Corporation.

“Bringing innovative, safe, and effective devices to market as quickly as possible is absolutely critical—not just for medical device manufacturers, but for patients as well, which is why we are committed to empowering medical device manufacturers with the tools they need to succeed,” says Ben Higgitt, Compass MED Product Line Manager. “With Compass MED, manufacturers experience more efficient processes and workflows and more ease in complying with evolving quality and regulatory requirements.”

“The increasing burden on medical device manufacturers to meet standards and regulations is a challenge without a tool such as Compass MED,” says Natalie McRoberts, Co-founder, Amstermed Group. “Having a centralized system improves the efficiency of data management, allowing users to build and challenge their data and assumptions more effectively. Compass MED is the only way to go for device development.”

Compass MED was designed and developed after thorough research into the challenges faced by medical device manufacturers, including extensive in-depth

interviews with numerous executives, development engineers, and quality and regulatory leaders. The solution was piloted with organizations including Boston Scientific, Kimberly Clark, Senseonics, Teva Pharmaceutical, Think Surgical, and Werfen, and is GA (General Availability).

For more information about Compass MED, visit https://cognition.us/solutions/compass-med/.

About Cognition Corporation®
Cognition Corporation specializes in product development and compliance solutions for the life sciences industries. Our solutions focus on enhancing efficiency, quality, and compliance throughout the development process.

For medical device companies, Cognition offers a design controls software platform, Compass MED, 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 solutions that simply replicate traditional documents and spreadsheets, Cognition takes a structured data approach so you can easily build relevant connections between data items, automatically create complex trace matrices and data tables, and export formatted documents instantly – offering a more efficient and integrated solution. We are shifting the data management landscape for life sciences 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.

For More Information
John Gonda
616-309-4888
jgonda@sage-growth.com