Case Study: Life Sciences

Streamlining quality management to improve patient care

Medical device maker committed to improving its operations and products with a total quality management solution.

In the medical devices sector, innovation moves with astonishing speed. Quality management is essential to improve device design, streamline operations and promote optimal patient care.

Cognizant Digital Business spearheaded a quality management initiative for a global designer and manufacturer of sophisticated medical devices to transform manufacturing and promote operational efficiency while addressing compliance risk.

Keeping pace with rapid change

In the last decade, advances in engineering, robotics and software design have led to remarkable growth in the medical device industry. Companies continually introduce innovative products to diagnose, treat and assist patients.

But with technological advances come challenges. The U.S. Food and Drug Administration (FDA) has noted that the increase in adverse events due to product quality that result in hospitalization, disability or death is about twice the rate of the increase of the medical device market overall.

At a Glance

Cognizant Digital Business reimagined how our client could leverage digital information to better manage data insights about product use and transform its process for monitoring, documenting and responding to adverse events.

Outcomes

Using PTC's ThingWorx Navigate platform and integrating with Windchill suite, we helped our client centralize data systems, streamline information flows and reduce response times from 20 days to less than a week. We built a dashboard for the client to:

- Monitor device information to drive efficiency with first-time right information, for the right people, at the right time.
- Reduce compliance and risk events and drive reports for compliance audits.
- Provide feedback to product design for improvements.

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Responding to adverse events attributable to device use is a paramount concern. Companies must maintain quality, comply with evolving regulations, control costs and improve efficiency. They must track the source and cost of all quality events, understand their urgency and address them. Lack of visibility hinders investigations, slows product improvements and can lead to unnecessary recalls. All these factors contribute to increased costs.

Addressing quality with centralized information management

Our client provides specialized medical products and related services in facilities across the U.S. As part of a total quality management initiative, it sought ways to better manage its business process for addressing adverse events to comply with requirements for Corrective Action and Preventive Action (CAPA) and control product quality.

The company had multiple applications for handling information on products, processes, and patient treatments and outcomes—including information for regulatory compliance. Much of its event monitoring was kept in Microsoft Excel or Word, on local databases or on isolated desktop applications, which slowed response times, led to errors in data handling and added costs. Moreover, the company had different and inconsistent approaches to implementing standards, processes and systems to manage information.

This situation increased operational risk, cost and production downtime. Vital information was often missing, duplicative or inaccurate; with data scattered across multiple applications and processes, information was often not available to those who needed it.

Digital making the difference

To be confident it could continue to deliver safe, reliable products while responding to quality events quickly, our client needed a strong, centralized analytical platform for decision support, along with the means to ensure accurate data to address its various compliance needs.

We focused on developing a single data management system with a corresponding centralized governance program to provide a single source for verifiable data. Our solution allows the company to validate data, monitor data ownership and create an audit trail, quickly address adverse events, track key performance indicators and manage user access privileges to reduce data handling violations and information security risk.

Reducing its reliance on point solutions and paper-based processes, our client now runs a single decision support and analytics system that meets its operational and compliance needs, with faster response times, more accurate data for decision-making, lower costs and increased efficiency.

Our solution also addresses users' frustration by providing readily available common access to data and reports on quality events. Users specify the type of report they need and the solution displays key information graphically. It also provides detailed drill-downs on any data point for further analysis.

Cognizant's work for this global medical device company is a model for how rethinking the digital enterprise can impact operations in a favorable way—and have a direct, tangible and positive impact on efficiency, profitability and most importantly patients.

Learn more at **cognizant.com/enterprise-iot-solutions.**

About Cognizant

Cognizant (Nasdaq-100: CTSH) is one of the world's leading professional services companies, transforming clients' business, operating and technology models for the digital era. Our unique industry-based, consultative approach helps clients envision, build and run more innovative and efficient businesses. Headquartered in the U.S., Cognizant is ranked 193 on the Fortune 500 and is consistently listed among the most admired companies in the world. Learn how Cognizant helps clients lead with digital at **www.cognizant.com** or follow us **@Cognizant**.

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