Hologic Inc. is a leading developer, manufacturer, and supplier of diagnostic products, medical imaging systems, and surgical products.

Hologic’s assays and automation platforms work together to give laboratories the power to quickly and accurately screen donated human blood to detect disease. Its imaging solutions improve visibility into breast and bone health, giving every patient the best possible chance to overcome life-threatening diseases.

Hologic’s intervention and treatment solutions span several key areas of women’s health, from breast biopsy and treatment to minimally invasive gynecologic surgical solutions. Hologic also provides a full range of best-in-class testing solutions for cervical cancer, sexually transmitted infections, cystic fibrosis, prostate cancer, and pre-term birth risk assessment.
The Challenge

Most of Hologic’s products utilize both hardware and software that are developed by different sets of people and need to come together into a cohesive product prior to the launch date. In addition, the company’s many different product lines and projects utilize different development processes (e.g., some groups use a waterfall process).

Hologic is in the midst of moving to a disciplined, yet agile development process, and faces the challenge of providing people who are new to agile processes with tools that will help ensure compliance with corporate standards and best practices. Documenting compliance with the product development process is essential to comply with ISO 13485, which sets out the requirements for quality management of medical devices.

Aligning Hologic’s functionally and distributed engineering teams is a key objective and recurring challenge. “Our organizational challenge is to bring all of these highly creative, but also very individualistic, people together in such a way that hardware and software work together flawlessly, products meet all of their requirements, documentation has been produced to prove the compliance of our product development process, and data and metrics are consistent across the organization to inform decision-making,” Eric DePaul, Senior Principal Systems Engineer and Technology Specialist for Hologic, says.

Before centralizing on PTC Integrity Lifecycle Manager, the company struggled with the burden to demonstrate compliance with its development process, resulting in increased risk and higher costs of compliance.

“\nIn the past, each team used their own set of disconnected point tools to manage and document the development process,” DePaul explains. “Coordinating the work of different teams relied upon the various team members to stay in touch with meetings and email, which was difficult during busy periods. Using Microsoft® Word®
and Excel® to document our development process, there was no way to ensure the consistency and completeness of documentation until review time, at which point it was very costly to go back and reconstruct the process.”

The Solution

“We wanted to be connected, fast, mobile, and provide management with visibility into the product development process,” DePaul says. “We asked ourselves, ‘How could we consolidate our broad product portfolio into a single platform? Could we get all of this data into one system and make its interdependencies and relationships transparent?”

After evaluating potential vendors, Hologic decided that the PTC Integrity Lifecycle Manager platform would offer the solution to automating its software engineering lifecycle.

“PTC Integrity Lifecycle Manager stood out because it provides a common data model that links requirements, design, code, and test results,” DePaul explains. “The platform helps keep different teams in sync, documents the process, provides visibility as to the status of each task, and highlights any steps that might have been skipped. Another factor in our decision was that we believe PTC will be around for the long run to support PTC Integrity Lifecycle Manager.”

PTC Integrity Lifecycle Manager helps apply structure and repeatability to Hologic’s processes, enabling the creation of repeatable rules, triggers, and workflows that help keep the various contributors aligned and moving in the same direction. Information is seamlessly shared between teams, which increases productivity by reducing the amount of time spent in inter-team communications.

The platform also tracks the relationships between discrete systems engineering processes, so when something changes it’s easy to see the upstream and downstream impacts. Visibility is provided to design information throughout the project team, making it possible to identify errors at the earliest possible stage of the process.
“PTC Integrity Lifecycle Manager is ideally suited for safety critical development because it delivers a traceability model that captures the chain of custody of a decision,” DePaul adds. “So when we find a problem, we can immediately determine where it originated, how it affects our entire product line and what we need to do to correct it.”

Another advantage of PTC Integrity Lifecycle Manager is that it provides the flexibility needed to support the full range of Hologic’s projects and processes. “Our projects come in many different colors and sizes,” DePaul says. “PTC Integrity Lifecycle Manager supports the individuality of projects by allowing us to modify data models and workflows as needed. These customizations allow all of our projects to exist in a homogeneous environment while maintaining their individuality.”

DePaul added that PTC Integrity Lifecycle Manager also provides the ability to set up views that provide team members with all of the information and only the information that is relevant to them. “If you are involved in requirements management, we will set up a view that shows you only the requirements. If you need to see more, there’s a way to get it but you don’t have to drink the fire hose.”

The Results

Automating the company’s software engineering lifecycle has freed up cycles to focus on product innovation. “With the PTC Integrity Lifecycle Manager platform, I see the activity of the people that I work with in real time and gain understanding of how they are thinking and what they are doing and how it affects me,” DePaul says. “The result is collaboration and synergy that helps us develop a better product.”

Reuse is another key benefit of the new solution. “It’s excellent at the identification, control, and centralization of information,” DePaul says. “When I bring a project to close, I baseline it, shut it down, we go into production. The people who worked on the project move onto other projects or even to other companies, but the data is there. So when we need to do the next generation of the product or create a new product in the same family, I can use the data as a starting point rather than starting with blank paper which provides huge cost benefits.”

In the fast-paced medical devices market, the ability to meet market windows is a key engineering competency. DePaul credits the new PTC Integrity Lifecycle Manager solution with improving team productivity and agility.

Once we traversed the learning curve, we at least doubled—and in many cases tripled—our productivity, which far more than paid back our initial investment.”

For more information, visit: PTC.com/go/Integrity

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