

## HOLOGIC®

Hologic Inc.  
Bedford, MA  
www.hologic.com

### Industry:

Life Sciences

### Annual Revenue:

US\$1.6 billion

### Employees:

3,500

### Oracle Products & Services:

Agile Product Collaboration  
Agile Engineering Collaboration

**“Oracle’s Agile platform provides us with a single source of truth and enables us to demonstrate the necessary internal controls over our product records that we need to ensure regulatory compliance.”**

– Dave Rudzinsky, Senior Vice President, Information Systems, and Chief Information Officer, Hologic Inc.

### Hologic Inc. Accelerates Engineering Change Order Cycle Times from 40 Days to 4 Days

Hologic Inc. is a leading developer, manufacturer, and supplier of premium diagnostics, medical imaging systems, and surgical products dedicated to serving the healthcare needs of women.

#### Challenges

- Reduce engineering change order (ECO) cycle times to introduce products faster and more efficiently
- Automate the ECO system to reduce overhead costs
- Ensure compliance with FDA regulation 21 CFR Part 11, while improving visibility into product records
- Support the company’s acquisition strategy designed to diversify product lines and promote growth
- Integrate the ECO system with the company’s Oracle manufacturing resource planning (MRP) and enterprise resource planning (ERP) systems to facilitate product transition from engineering to manufacturing

#### Solution

- Implemented Oracle’s Agile Product Collaboration and Agile Engineering Collaboration for cross-divisional cooperation ,accelerating product enhancements and design changes
- Increased visibility and control of product record information and ensured compliance with industry and financial regulations by providing demonstrable internal controls
- Reduced the ECO cycle time from 40 days to 4 days with Agile’s improved workflow capabilities
- Reduced overhead costs by eliminating paper-based processes with the automated product lifecycle management solution
- Introduced new products faster, while expanding Hologic’s product portfolio and facilitating entry into new markets
- Achieved compliance with FDA 21 CFR Part 11 for electronic records and signatures quickly, with access to validation protocol pack templates
- Enabled Hologic to roll out Oracle’s Agile solution to newly acquired companies in just a few months
- Integrated with Hologic’s manufacturing resources planning and enterprise resource planning systems to leverage synergies and optimize use of existing parts and suppliers
- Saved time with electronic workflow and signature capabilities—enabling redeployments to value adding roles