Cytonome

Centralized and Automated Development Processes Get Accolades from ISO Auditor

Customer

Cytonome develops, manufactures and markets the most advanced, highest quality cell purification systems available worldwide for BioMedicine, BioIndustry, and BioScience.

The company's innovative and proprietary technology is combined with optical detection for the precise and safe selection of discrete cell subpopulations. Their BioMedicine products are aimed at cGMP-compliant cell purification using a closed, sterile and disposable cartridge to guarantee operator safety and sample isolation.

Challenge

Manual Entry of Data among Disparate Design and Enterprise Systems

Cytonome's engineering department has an innovative focus to developing new products. Engineering works quickly to develop concepts and manufacturing works in parallel during the prototype phase. Efficient communication among engineering, manufacturing and purchasing is critical and Cytonome needed to create a product development environment to ensure this.

The company managed product development with tools that did not communicate with each other (SolidWorks Workgroup PDM, CAMA Software QCBD (Quality Collaboration by Design), and Expandable ERP). Product information was converted from SolidWorks to Excel spreadsheets. Cytonome was having a difficult time with this environment because information had to be manually entered into each system which took up valuable employee time, introduced costly human data entry errors and resulted in systems containing incorrect or out-of-date information.

"The process was rather cumbersome and prone to errors," stated John Bragg, Mechanical CAD Designer for Cytonome. "We needed a solution that could automate engineering change order workflows, ensure steps are not skipped, and could provide a one stop location for all of our documentation."

Cytonome was also preparing for their International Organization for Standardization (ISO) certification and needed to have formal processes in place to demonstrate proper management, tracking and reporting of product development and manufacturing procedures and information.

Quick Facts:

Company

- Cytonome

Industry

- Cell Purification Systems

Key Benefits

- Eliminate errors associated with manual processes
- Direct integration with **SOLIDWORKS**
- Direct integration with **Expandable ERP**
- Faster and more efficient product development processes
- Real time information sharing among engineering, purchasing and manufacturing
- Manage product, quality and training in a central system
- Ease of use facilitated adoption across the company
- First ISO audit achieved accolades from auditor

Cytonome Viva™-G1 system. The world's first cell sorter dedicated to purifying GFP-expressing cells.

Cytonome

> "The success of our preparation for our first ISO audit as demonstrated by having the first two days having no findings is a direct result of having (and using) Omnify Software."
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> -*Heather Kiessling, Chief Financial Officer, Cytonome*

Solution

In order to achieve a cohesive environment, Cytonome needed to address their manual product development processes. They searched for a solution that provided a central location to manage product information and quality processes and could communicate directly with SolidWorks and Expandable ERP. Past experience with Product Lifecycle Management (PLM) technology and Omnify Software prompted them to look at Omnify's Empower PLM solution. "After seeing a product demo, we were impressed with the capabilities and simple web interface of Empower," noted Mr. Bragg.

Adopting Empower helped Cytonome to create automated signoff workflows for new Part Requests (NPRs) and Engineering Change Orders (ECOs) as well as establish an automated data transfer with SOLIDWORKS and Expandable. To support their ISO compliance and goal to obtain full cGMP compliance, Cytonome also uses the Omnify Empower Quality Management and Training Management modules. All Non-Conforming Material Reports (NCMRs), Corrective and Preventive Actions (CAPAs), process deviations and customer service repair processes are managed within the Quality module and directly connected to the product record in Omnify Empower. Cytonome uses the Training Management module to manage and track employee training documentation, calibration processes and calibration records. General business documents such as product development reports and Non-Disclosure Agreements, are also maintained and controlled in Omnify Empower.

Customer Success

Omnify Empower serves as a central location to securely access accurate product data and documentation for all Cytonome team members. "Over eighty five percent of the company uses Omnify Empower at Cytonome including engineering, quality, manufacturing and purchasing," stated Heather Kiessling, Chief Financial Officer for Cytonome. "The most significant business benefit of using Empower is the real time global updates among engineering, purchasing and manufacturing that we did not have before."

Quality information is now shared in real time across the organization. When an ECO is under review, engineering, purchasing and production know this information immediately. Decisions on buying parts or build plans for assemblies under ECO are made in real time. Purchasing can access the system to pull the most up-to-date drawings that need to go to vendors for fabricated parts. Manufacturing has access to the most accurate and current BOM with automated updates from Omnify Empower to Expandable ERP. "Our overall product development processes are faster and more efficient due to the time savings and improved data accuracy we have realized by implementing Omnify Empower as our central product information management system," said Miss Kiessling.

First ISO Audit Gets an A+

With the new centralized and automated product development processes in place, Cytonome had the proper signoff, history tracking and reporting to meet ISO compliance guidelines. During their first ISO audit the auditor gave accolades to Cytonome's tracking and management of calibration records, training on quality documents, and procedures associated to groups. The auditor noted that they were very impressed with the capabilities of Omnify Software and the extent to which Cytonome uses it to control information, documents, changes, training, project data, manufacturing processes and engineering data and was particularly pleased with their automated workflows and signoff stages with history tracking for NCMRs and ECOs.

"The success of our preparation for our first ISO audit as demonstrated by having the first two days having no findings is a direct result of having (and using) Omnify Software," commented Miss Kiessling. Adopting Omnify Empower validates Cytonome's commitment to manufacture their products under the strictest quality control guidelines and to deliver the most advanced, high quality cell purification systems to the market.

Omnify Software