



Case Study:

MicroVention Improves Total Production Efficiency by 50% with TEKLYNX CENTRAL CFR

SOLUTION: TEKLYNX CENTRAL CFR, TEKLYNX International's Browser-Based Integrated Enterprise Label Management System

INDUSTRY: Medical Device Manufacturing



Background

MicroVention, a wholly owned subsidiary of Terumo Corporation, is a leading medical device company headquartered in Aliso Viejo, California. A world-renowned developer, manufacturer and marketer of innovative neuroendovascular technologies, MicroVention operates facilities in California, Costa Rica and China. Recently, the company has experienced rapid growth, fueled by growing product demand and expanded distribution in key international markets.

To date, MicroVention leveraged TEKLYNX' barcode label design solution, LABELVIEW, to design and print labels. However, recent growth has caused MicroVention to re-evaluate its labeling operations in favor of gaining efficiencies across all facilities. "We reached a point in our growth where we needed a labeling solution that was available over our network, not stored on each individual computer," explains Frank Carranza, MicroVention Associate Label Engineer. "I immediately thought of TEKLYNX, given my past experience with TEKLYNX' enterprise-level barcode labeling solution, TEKLYNX CENTRAL CFR, at a previous employer."

For MicroVention, the upgrade to an enterprise-level labeling solution – that integrates with its Enterprise Resource Planning (ERP) System – would position MicroVention to streamline labeling operations globally while addressing the need to:

- ✓ Adequately support a global and secure, multi-user environment: over 50 different employees in 4 different facilities needed to access and print desired labels.
- ✓ Efficiently support a leanly staffed label design environment: 2 employees were responsible for designing and managing labels for over 2,000 different SKUs.

Challenges

- ✓ Need to integrate with its JD Edwards ERP System
- ✓ Need to improve labeling efficiency, control and support for its global, multi-user labeling environment
- ✓ Provide data center security throughout its global network
- ✓ Compliance with medical device manufacturer labeling regulations such as UDI

Results

- ✓ Integration with its ERP system minimized room for human error by providing database-driven templates
- ✓ Streamlined entire labeling process, resulting in a 50% improvement in total production efficiency
- ✓ Ability to control user privileges, record audit trails, and ensure electronic signatures are linked to relevant records improved security
- ✓ Improved ability to comply with regulations such as UDI

- ✓ Provide bandwidth for future growth: operating in a rapidly growing industry meant MicroVention needed a labeling solution that could grow with them over time.
- ✓ Comply with medical device manufacturer labeling regulations such as those required by the FDA's Unique Device Identification (UDI) requirements.

In addition to these unique labeling challenges, MicroVention's global presence required it to be particularly mindful of security and accessibility issues related to the company's data center. "We have thousands of global installations and know that security and access is top of mind for companies," explains Cory Catterall, TEKLYNX Enterprise Sales Executive. "We were confident our enterprise-level barcode labeling solution could meet MicroVention's labeling requirements while providing secure access and sophisticated user profile control."

Solution

The TEKLYNX Enterprise Team collaborated with MicroVention to determine that browser-based, integrated enterprise label management system, TEKLYNX CENTRAL CFR, would be a scalable and efficient solution for managing its facilities, including those beyond US borders, while providing the bandwidth for future growth.

"We were excited to work with MicroVention on its upgrade from LABELVIEW to an enterprise-level barcode label solution. As companies grow and business requirements change, so do labeling requirements," explains Catterall. "Upgrading to TEKLYNX CENTRAL CFR was an opportunity for MicroVention to streamline labeling operations globally."

TEKLYNX worked in close partnership with the MicroVention team throughout the implementation, including providing MicroVention with a significant amount of advanced label creation services. These services proved invaluable as MicroVention relied on TEKLYNX to create extensive logical date stamp formulas to ensure accurate printing of expiration/manufacturing dates on MicroVention's products.

These formulas allowed MicroVention the flexibility to manually override dates when special circumstances required MicroVention to do so (i.e. a product label reprint from a previous production day). This intelligent label design reduced the chance of manual error globally while allowing for granular date control when necessary.

MicroVention also relied on TEKLYNX to develop a Structured Query Language (SQL) script that synchronizes work orders, products, labels, and variables from over 50 tables in MicroVention's database. Developing the SQL script eliminated manual processes, allowing MicroVention to create thousands of printable products with the single press of a button while improving the company's database speed and efficiency – a move that made it easier for network users in Costa Rica and China to utilize the system.

TEKLYNX also created interface patches to further customize MicroVention's user interface. This customization simplified MicroVention's interface, allowing for greater ease-of-use and faster network speed. All told, these custom development services were key to helping MicroVention not only label better, but also work better as a company.

In addition, MicroVention's implementation of enterprise-level solution TEKLYNX CENTRAL CFR would position it to

TEKLYNX CENTRAL CFR

is a browser-based, integrated enterprise label management system that combines the proven technology of TEKLYNX label design, printing and tracking software into a single regulatory solution that helps companies fall in line with FDA compliance standards such as 21 CFR Part 11 and UDI.

integrate labeling operations with the company's existing JD Edwards ERP system. Integrating the two systems meant that all label files could now be created using database-driven templates, minimizing the room for human error.

Yet another benefit of MicroVention's upgrade to TEKLYNX CENTRAL CFR related to a very critical aspect of its business operations – compliance with medical device manufacturing industry regulations. Because TEKLYNX CENTRAL CFR was specifically designed to help manufacturers fall in line with FDA compliance standards such as 21 CFR Part 11 and UDI, MicroVention would be in the best position possible to meet these requirements.

"The TEKLYNX team's guidance throughout the implementation process was remarkable," states Carranza. "They were knowledgeable, responsive and successfully guided us through our internal issues as they arose."

Results

MicroVention Associate Label Engineer, Frank Carranza, and his team set out to improve labeling efficiency, control and support for its global, multi-user labeling environment. "From design to approval, production, and print, our goal was to make our labeling process more lean overall," states Carranza. "By implementing TEKLYNX CENTRAL CFR, we were able to streamline our entire labeling process, on a global level, resulting in a 50 percent improvement in total production efficiency."

Hear from MicroVention's Associate Labeling Engineer, Frank Carranza, detailing their labeling success in [this video](#) with TEKLYNX

In addition to a 50% improvement in total production efficiency, MicroVention's successful implementation of TEKLYNX CENTRAL CFR led to the following labeling environment enhancements:

- ✓ Improved ability to support its global multi-user, multi-facility environment:
 - ✓ Access to true internet printing allows MicroVention to print labels from anywhere in the world.
 - ✓ Ability to print labels to a virtually unlimited number of printers provides the necessary bandwidth to support future growth.
- ✓ Improved ability to support its leanly staffed labeling environment:
 - ✓ The automated network printing module can manage hundreds of printers in multiple locations from a single server.
 - ✓ The regulatory compliance software ensures that electronic signatures are linked to relevant electronic records by requiring user ID and password sign-in to perform all functions.
- ✓ Provided the desired level of data center security throughout its global network:
 - ✓ User privileges are controlled with customizable user groups so only authorized individuals can use its system and/or electronically sign a record.
 - ✓ The system records audit trails throughout label life cycles, making MicroVention audit ready.
- ✓ Improved ability to comply with medical device manufacturer labeling regulations:
 - ✓ Can easily create complex bar codes, such as HIBC or GS1 Databar, to meet FDA compliance and healthcare industry standards.
 - ✓ Access to a label approval module that allows for electronic approval while providing the required security and traceability in accordance with FDA 21 CFR Part 11.
 - ✓ A single regulatory compliance software Command Center that coordinates its enterprise labeling process while providing secure access and sophisticated user profile control.

In addition to addressing all of MicroVention's immediate labeling challenges, the TEKLYNX CENTRAL CFR implementation has also put MicroVention in a solid position to address future labeling challenges. This couldn't be more critical for MicroVention as it looks to continue growth in a highly competitive, fast-growing and ever-changing industry.

"Our enterprise-level barcode labeling solutions have proved invaluable for medical device manufacturers time and time again," comments Catterall. "Companies like MicroVention can rest easy knowing their labeling environments are equipped to handle whatever labeling challenges the marketplace or industry throws their way."

For TEKLYNX General Manager Doug Niemeyer, this notion of future preparedness speaks to how TEKLYNX approaches each and every one of its installations, "We're not looking to simply install software at companies, we're looking to partner with companies to ensure our labeling solutions integrate well into the supply chain to help those companies work better over time."



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TEKLYNX International helps supply chains work better. Today, more than 750,000 companies in over 170 countries trust TEKLYNX integrated barcode and RFID label design products and the people behind its solutions to make barcode labeling operations efficient, accurate, secure and industry compliant. With over 30 years of experience, TEKLYNX is the global leader because of its reliable software and superior customer support. To learn more about how the TEKLYNX community helps companies across industries worldwide, visit teklynx.com or call TEKLYNX in your region. Barcode Better™ with TEKLYNX.

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