

## Case Study:

# TEKLYNX CENTRAL CFR Improves Labeling Accuracy, Reduces Label Approval Time & Simplifies Labeling Compliance for Aspen Medical Products

Solution: TEKLYNX CENTRAL CFR

Industry: Medical Device Manufacturing

Partner: VantagelD

## Background

Aspen Medical Products is the leading designer, developer and marketer of upper and lower spinal orthotics in the healthcare industry. Headquartered in Irvine, California, the company sells its products throughout the US and around the world. Aspen Medical Products has grown year after year as it continues to provide breakthrough spinal bracing designs that improve patient recovery and outcomes. As the company anticipates this growth well into the future, it continuously evaluates processes and systems to ensure it can support expected growth as efficiently as possible.

One area determined to be falling short of meeting both current and future business needs was the company's labeling system. "We had a lot of manual entry in our labeling process," explains Aspen Medical Products Planning Manager Israel Lopez. "We were looking to implement a standalone labeling system that would eliminate manual entry and integrate with our existing IQMS ERP system."

In short, Aspen Medical Products was looking for a labeling system that could better manage labels, not just design and print them. This was particularly important as much of its recent growth was coming from expanded distribution in international markets. "We needed a labeling system that could handle language translation demands," notes Lopez.

Aspen Medical Products was also interested in finding a solution that could improve its ability to meet the vast and ever changing medical device compliance standards such as the FDA's standard 21 CFR Part 11 which requires approvals via electronic signature.

## Challenges

- ✓ Improve labeling control and support for global user base
- ✓ Need to reduce manual label data entry to improve accuracy
- ✓ Compliance with medical device manufacturer labeling regulations
- ✓ Need to integrate labeling with existing ERP system

## Results

- ✓ Centralized label system seamlessly manages labels globally
- ✓ Label automation improved labeling accuracy
- ✓ Regulatory compliance software improves ability to comply with labeling regulations
- ✓ ERP labeling integration creates responsive, scalable labeling environment

Aspen Medical Products contacted supply chain automation specialist VantageID to discuss its options. VantageID partnered with Aspen Medical Product's existing barcode software solutions provider, TEKLYNX, to determine that an enterprise label management (ELM) solution would position Aspen Medical Products to address its current labeling issues while meeting these additional business needs:

- ✓ Provide support for a global, multi-user labeling environment: over 40 different employees in locations including the US, China, Europe and Mexico needed to access and print desired labels.
- ✓ Efficiently serve a leanly staffed label design environment: four employees are responsible for managing labels for over 350 different products.
- ✓ Integrate with the company's ERP system now and into future: Aspen Medical Products wanted to implement a standalone labeling solution that could integrate with its existing ERP, but also easily integrate with a new ERP system in the future.
- ✓ Facilitate labeling compliance: Aspen Medical Products needed to ensure its labeling environment was equipped to comply with medical device manufacturer labeling regulations such as those required by the FDA's standard 21 CFR Part 11.

The TEKLYNX Enterprise Team was eager to help Aspen Medical Products because it was confident an ELM barcode labeling software solution would create a better labeling environment for Aspen Medical Products.

## Solution

Aspen Medical Products collaborated with the TEKLYNX Enterprise Team and VantageID to determine that browser-based, integrated label management system TEKLYNX CENTRAL CFR would meet Aspen Medical Products' labeling requirements while delivering on the company's desire to have a standalone labeling system that could be integrated with its current ERP system as well as any ERP system the company might transition to in the future.

"Enterprise label management was hands-down the best option for Aspen Medical Products," explains TEKLYNX Channel Partner Manager, Casey Sciano. "As the company continues to expand distribution internationally and face complicated regulatory compliance standards, TEKLYNX CENTRAL CFR can streamline labeling globally, simplify compliance, and provide the bandwidth for future growth."

TEKLYNX partnered closely with Aspen Medical Products throughout the implementation process to ensure all existing label templates were transitioned from its current labeling system, TEKLYNX LABEL MATRIX, to TEKLYNX CENTRAL CFR. In addition to transitioning label templates, Aspen Medical Products relied on technical support from TEKLYNX to automate its critical "country of origin" designation on product labels.

With its former labeling system, Aspen Medical Products had to rely on manual lookups and operator entry to designate "country of origin" on each product label. This process was time consuming and error prone. The company relied on TEKLYNX' technical expertise throughout the TEKLYNX CENTRAL CFR implementation process to develop coding, formulas and database integrations that would automate "country of origin" on labels based on lot numbers. This new system would eliminate the room for human error on a very critical labeling component.

### **TEKLYNX CENTRAL CFR**

is a browser-based, integrated 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 Unique Device Identification (UDI)

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In addition to increased label automation, upgrading to TEKLYNX CENTRAL CFR meant Aspen Medical Products' labeling system would now be integrated with its ERP system. Doing so would allow team members globally to print labels from a browser-based printing interface, a benefit that would better position Aspen Medical Products to support international growth.

"We wanted to provide global users the ability to print from a central source using standard templates housed and centrally controlled from our company's document control department," explains Lopez. "This would give us the ability to control revisions and push changes to templates seamlessly without disruptions to global users."

TEKLYNX CENTRAL CFR would also help Aspen Medical Products comply with increasingly complex medical device manufacturing industry regulations because the included label design software was specifically designed to help manufacturers fall in line with FDA compliance standards such as 21 CFR Part 11 and UDI.

## Results

Aspen Medical Products was intent on transitioning its labeling environment from "design and print" to "label management", and TEKLYNX CENTRAL CFR proved to be the solution to do it. "With our former labeling process, we had a lot of production stoppages," comments Lopez. "Our IT labeling infrastructure simply wasn't able to cooperate with our ERP system."

With TEKLYNX CENTRAL CFR, Aspen Medical Products now has a centralized labeling solution that manages labeling from start to finish. One noticeable labeling improvement resulting from the implementation is increased labeling accuracy. With its former labeling process, the company's production operators relied on manual entry, leaving room for labeling errors in cases where operators selected the wrong lot or item number.

The company's goal was to eliminate manual input and replace as many labeling data entry tasks as possible with barcode scanning. "Five years ago, we averaged three corrective actions a week due to labeling errors," notes Lopez. "Now that our operators simply have to scan barcodes, I haven't seen a corrective labeling action all year."

In addition to improved labeling accuracy, the company's implementation of TEKLYNX CENTRAL CFR has eliminated weeks from its label approval process when dealing with global contractors. "In the past, when our contractors in China would make a label, we would send out label copy and ask them to generate a label using their own system and send it back to us," explains Lopez. "This back and forth label creation and approval process could take weeks."

With TEKLYNX CENTRAL CFR, the company can centrally control labels and make changes without disruption to global print users.

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- Israel Lopez, Planning Manager, Aspen Medical Products

## Key Result

With TEKLYNX CENTRAL CFR, Aspen Medical Products can centrally control labels and make changes without disruption to print users globally, eliminating weeks from its label approval process with global contractors.

"Our contractors simply log in to our TEKLYNX labeling system, access and print the latest version of the label without the need for back and forth approvals," states Lopez.

In addition to improved labeling accuracy and reduced label approval time, Aspen Medical Products' successful implementation of TEKLYNX CENTRAL CFR provides the following labeling environment enhancements:

- ✓ Improved ability to support its growing, global multi-user labeling environment:
  - Access to True Internet Printing allows users to print labels from anywhere in the world.
  - Ability to print labels from up to 1,000 printers provides the necessary bandwidth to support future growth.
- ✓ Improved ability to comply with medical device manufacturer labeling regulations:
  - Aspen Medical Products now has 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.
  - Added ability to create complex, UDI-compliant barcodes, such as HIBC or GS1 Databar, to meet FDA compliance and healthcare industry standards.
- ✓ 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.

With its newly implemented TEKLYNX CENTRAL CFR labeling solution, Aspen Medical Products is equipped to meet its current labeling challenges and is prepared for growth because the software is designed to scale up as the company grows. "Aspen Medical Products provides life-changing medical products in one of the fastest growing industries," comments TEKLYNX General Manager Doug Niemeyer. "We take great pride knowing that our enterprise-level barcode labeling solution positions them to label accurately and expand rapidly into new markets so they can impact more patients in need."



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