



## CASE STUDY:

### TEKLYNX CENTRAL CFR Drives Efficiency, Increases Accuracy and Simplifies UDI Compliance for Quality Tech Services

*Enterprise barcode labeling system streamlines workflow, reduces risk and provides full FDA labeling compliance*

**SOLUTION:** TEKLYNX CENTRAL CFR, TEKLYNX International's integrated label software system designed to address medical industry labeling requirements

**PARTNER:** Coridian Technologies, 952-361-9980, [www.coridian.com](http://www.coridian.com)

**INDUSTRY:** Medical device outsourcing

## SITUATION

QTS is a medical device packaging and outsourcing solutions provider based in suburban Minneapolis, MN. Founded in 2001, the company has grown to become a market leader, with clients ranging from small, single-product startup companies to multi-billion-dollar global organizations with tens of thousands of branded products. QTS provides services from small medical device assembly to complete process outsourcing, which includes a full range of medical device labeling services designed to meet clients' unique specifications, as well as industry regulations.

Since their inception, QTS leveraged LABEL MATRIX label design software from TEKLYNX to design and print their labels. With a growing customer base, QTS' label production requirements were diversifying and becoming more complex. Eventually, the QTS team found itself managing over 900 active label templates.

"We had an elaborate internal file structure accessed from various workstations," explains Todd Engelken, Value Stream Engineering Manager at QTS. "It was as centralized as needed, but it didn't allow us the level of change control that we needed to perform well as we continued to grow." The manual aspects of the company's labeling process also increased risk for labeling errors. "Incorrect key strokes can require us to go through a time-consuming corrective action process, which can have a negative impact on productivity," Engelken says.

In addition to their increasingly clear need for an enterprise barcode labeling system, the QTS team needed a solution that would allow them to continue to meet the healthcare industry's myriad and strict regulatory requirements. QTS incorporates many important data elements into clients' medical device labels, including Unique Device Identification (UDI) compliant barcodes (GS1 and HIBC) and ISO symbols, and must adhere to FDA 21 CFR Part 11 criteria for electronic signatures.

With new UDI compliance deadlines approaching, the QTS team knew they would need to implement significant changes to their existing label templates. Engelken and his team knew it was time for a new system.

"Upgrading to a new system that could handle the increasing complexities we were facing had been a topic of discussion for a couple of years," Engelken says, "but the pending UDI rule helped us decide to pull the trigger."

## AT A GLANCE

### Challenges

1. Increasingly diversified and complex labeling demands from expanding product lines beyond the current software's capabilities
2. Label design and printing not centralized and relies on significant manual input
3. Manual aspects increased potential need for corrective actions
4. Pending new compliance regulation required significant changes to label templates and database integration

### Results

1. Enterprise label management system integrates with QTS' ERP system, eliminating 100% of the need for manual entry at time of print and also reduces barcode scanning, which previously increased risk in the labeling process
2. Full compliance with regulatory standards including 2007 UDI requirements
3. Centralized, integrated software has increased efficiency by 40%, to ultimately help customers get products to market more quickly

## CLIENT SUCCESS

**"The TEKLYNX CENTRAL CFR solution ultimately enables us to serve our customers better and more efficiently. We have a very high level of confidence regarding our compliance with UDI standards. I can absolutely say we made the right choice with TEKLYNX."**

— Todd Engelken, QTS

## SOLUTION

Engelken and his team selected TEKLYNX CENTRAL CFR as their new enterprise label management system, and purchased it through TEKLYNX Strategic Partner Coridian Technologies. QTS is a longtime customer of Coridian Technologies, and the QTS team sought counsel from the solutions provider around the labeling system change.

"In the business QTS is in, companies often have to upgrade to a system-wide software solution for their labeling and data collection, because errors are most commonly seen in the label-generation part of what they do," says Rob Yanda, Senior Account Manager for Coridian Technologies.

The Coridian Technologies team and TEKLYNX collaborated to develop a proposed solution for QTS, anchored by TEKLYNX CENTRAL CFR. During implementation, TEKLYNX and Coridian Technologies consulted closely with QTS around the process of integrating the TEKLYNX software with QTS' Enterprise Resource Planning (ERP) system. "TEKLYNX was very responsive throughout the development process, and communication was always very open and easy," Engelken says. "We were able to keep moving on things and keep the process going for a smooth implementation."

The smooth implementation included the validation process, with QTS writing validation test plans and executing them internally, including software validation as well as installation, operation and performance qualifications for both TEKLYNX CENTRAL CFR and QTS' internal systems. "The documentation TEKLYNX provided during the validation process was helpful in that we were able to leverage it to help minimize overlap within our internal validations," explains Engelken. "As an example, we referenced the TEKLYNX documentation as evidence that validations were complete on the overall system, and used that as justification for not revalidating font formatting and other aspects."

A key advantage of TEKLYNX CENTRAL CFR for QTS was the fact that it enabled efficient label conversion from LABEL MATRIX. "We were looking for as much interchangeability with our old software as we could find," Engelken says. "We really wanted to minimize the amount of work we had to do to convert all of our existing files to a new software, to save time and also minimize the potential for corrective actions."

Beyond the streamlined conversion opportunities, TEKLYNX CENTRAL CFR beat the competition on a number of other fronts. Similarly priced solutions did not offer the full suite of tools QTS needed or the ease of integration with their ERP system, and a much more expensive software led with key functionalities QTS didn't need. TEKLYNX CENTRAL CFR, sold by Coridian Technologies, Engelken affirms, offered QTS the best value.

## RESULTS

With TEKLYNX CENTRAL CFR, the QTS team is experiencing the benefits of a centralized and streamlined label management process that includes full regulatory compliance capabilities, thanks to TEKLYNX and Coridian Technologies.

Efficiencies began with the conversion process. Engelken estimates that the label converter functionality that streamlined QTS' migration from LABEL MATRIX to TEKLYNX CENTRAL CFR offered a significant time savings versus building and copying a label from scratch. "We're running on average 40% less time to convert an entire product line from LABEL MATRIX to TEKLYNX CENTRAL than it would take to re-build," Engelken says, "so that time savings starts to add up quickly." In fact, across the hundreds of product lines in QTS' client portfolio, the label conversion tool saved the QTS team over 400 hours.

The robust and versatile interaction between QTS' ERP system and TEKLYNX CENTRAL CFR is another key benefit, as information for the labels is pulled directly from their ERP system. "We are having to do a lot less manual entry as we are starting a new print job," Engelken says. "That reduces the possibility for errors, which is a huge consideration. If we were to manually enter the wrong thing, that could potentially cost us a lot of time."

The ERP integration also significantly reduces corrective action potential, by eliminating 100% of the need for manufacturing staff to make decisions about label template selection. The engineers who convert or design the labels now make this decision. "We've drastically reduced the probability of error by moving that decision up to the customer-specific engineer," Engelken says.

## KEY RESULT

The ability to integrate with the ERP system significantly reduces the possibility of labeling errors through 100% elimination of the need for manual entry per Coridian through reducing the need for barcode scanning.

Engelken adds that his staff's experience with the browser-based interface of TELKYNX CENTRAL CFR has been very positive, and says that with the new system, "Our ability to interact with the TEKLYNX database and predefine the association between a part number and a specific label file has significantly streamlined the process."

In terms of regulation compliance, TEKLYNX CENTRAL CFR offers substantial benefits to the QTS team. The ability to pull data from their ERP system has simplified the printing of UDI-compliant barcodes. "With more than 100 active medical device customers, we have basically every variety of barcode that you could print: 2-D, linear, stacked, HIBC and GS1; a little bit of everything," Engelken says. "Having one program with dedicated tools to build the barcodes just makes our process that much quicker. We have a very high level of confidence regarding our compliance with UDI standards."

Improved change control, security and documentation have helped QTS increase compliance and increase efficiencies to what was previously "a very manual process," Engelken says.

With print users and engineers assigned unique logins and passcodes, QTS is now able to access the time, user and quantity printed, as well as any variable information printed on the label, which is key for compliance as well as transparency to clients.

For QTS, the bottom line is the enhanced value TEKLYNX CENTRAL CFR enables them to deliver to their customers. With the fast, accurate and reliable ERP integration, the QTS team feels confident about label accuracy, is no longer concerned about downtime-induced delays and offers its clients greater efficiency in new label development.

"Not only have we seen immediate improvements to our process, but the TEKLYNX solution ultimately enables us to serve our customers better and more efficiently," Engelken says. "We can give sample labels to our customers more quickly, make tweaks and adjustments faster, and get their products ready for market sooner. This offers us a competitive advantage that will help us retain and grow our business. I can absolutely say we made the right choice with TEKLYNX."

## About TEKLYNX:

TEKLYNX International is the world's leading developer of barcode labeling software solutions. More than 620,000 companies in 120 countries rely on TEKLYNX integrated software solutions for supply chain automation, regulation compliance, warehouse management, shipping and receiving, inventory control, and asset management. TEKLYNX is a Microsoft Gold Certified Partner, Oracle Gold Partner, has internal GS1 Certified Barcode Professionals and invests to develop SAP Certified solutions. TEKLYNX barcode labeling software is CFR Part 11 compliant, and is capable of printing GS1 and HIBC required to generate the AIDC technology labels for UDI compliance, as well as GHS compliance, with support for thermal and thermal transfer printers. TEKLYNX is headquartered in France with operations in the United States, Europe, Japan, China, and Singapore. For more information on how TEKLYNX can help organizations in the medical device and healthcare industry, visit <http://www.teklynx.com>.



**With over 30 years of experience, TEKLYNX International is the world's leading developer of barcode labeling software solutions.**