

CASE STUDY

Top Clean Injection Achieves Complete Compliance and Validation with LABEL ARCHIVE and IQ/OQ/PQ Documentation

Solution: CODESOFT + LABEL ARCHIVE
with the TEKLYNX Validation Accelerator Pack

Industry: Medical Device Manufacturing

Background

Top Clean Injection specializes in the co-design and production of medical devices through the expert knowledge of plastic injection, assembly, sealing, and packaging in clean controlled environments. They are the subsidiary of Top Clean Packaging, a family-run and international group, specializing in the development and manufacturing of medical devices, packaging, and technical parts for the health, luxury, and industrial sectors.

As a medical device sub-contractor of approximately 250 products, Top Clean Injection must comply with specific standards and regulations, including:

- ✓ 21 CFR part 820, enforced by the US Food and Drug Administration (FDA), and new Medical Device Regulations (MDR) requirements on Unique Device Identification (UDI) with grade expectations.
- ✓ ISO 13485, an international standard for a quality management system for medical devices.
- ✓ ISO cleanroom standards.

Top Clean Injection leverages over 1,000 different labels for a variety of uses and in a variety of different label sizes. Primarily, labels are being used for products, samples, and shipping – some of which also need to comply with international Medical Devices shipping labeling standards.

Challenges

- ✓ Manual multi-step label approval process
- ✓ Label quality control at risk of human error
- ✓ Compliance with US and European standards and regulations regarding quality management systems, software validation, and labeling control
- ✓ Lack of validation processes (IQ/OQ/PQ)

Results

- ✓ Easy label approval workflows
- ✓ Full traceability of label creation and printing
- ✓ Deep understanding of LABEL ARCHIVE features and functionality
- ✓ Validation of labeling processes in 1.5 days instead of expected weeks of work
- ✓ Trusted validation documentation providing confidence leading up to an audit
- ✓ Trusted validation for product safety

Their labeling environment consists of six people responsible for designing and managing labels, eight people accessing and printing labels, plus their customers who approve label proofs for the products they're distributing. Prior to centralizing their labeling and establishing approval workflows, Top Clean Injection would create labels, ask their customer to review them via email or paper validation, save that label file, and quality check the label at the first print – which was manually checked by two people.

Solution

Top Clean Injection had been using TEKLYNX CODESOFT, enterprise-level barcode label creation and integration software, for over 10 years but needed to standardize their label approval process and validate their labeling processes.

Through working closely with TEKLYNX representatives, they collectively determined the best solution to fit their needs today and position them well for the future was adding LABEL ARCHIVE, label security and traceability software, to their already implemented CODESOFT software plus the TEKLYNX Validation Accelerator Pack (VAP) for certification and IQ/OQ/PQ audit preparedness.

“Traceability in labeling is an extremely important step for product conformity,” said Elisabeth Tavard, Validation Manager at Top Clean Packaging. “With LABEL ARCHIVE, there’s an electronic proof and no doubt who created or approved it. Our paperless label approval process is much more professional, and we maintain so much more control and traceability from creation, to review, to approval, to print.”

Combined, CODESOFT plus LABEL ARCHIVE supports their label traceability requirements and patient safety needs. The TEKLYNX VAP, or IQ/OQ/PQ documentation, was also key post-implementation and developed by TEKLYNX as a direct result of Top Clean Injection and other consumer demand.

Regulatory authorities have guidelines related to process validation to confirm a company's labeling processes will result in reliable outputs and meet quality standards. The TEKLYNX VAP templates are in accordance with verification and validation strategies, and working through this documentation gave Top Clean Injection a deeper look into the LABEL ARCHIVE solution and functionality.

LABEL ARCHIVE is a label management system that gives you full traceability of label design, storage, and printing to support compliance with industry regulations, including the approval of labels with electronic signatures in accordance with FDA 21 CFR Part 11.

The TEKLYNX VAP makes the validation of labeling processes quick and easy for highly regulated companies by providing IQ/OQ/PQ templates that are adaptable to specific project requirements.

[LEARN MORE](#)

[REQUEST DEMO](#)

www.teklynx.com

Results

With their newly implemented LABEL ARCHIVE solution, and IQ/OQ/PQ validation documentation, Top Clean Injection has a completely compliant labeling environment in a highly regulated industry. Quality control and accuracy with WYSIWYG (What You See Is What You Get) printing to their SQUIX barcode label printer is also vital to the success of their improved labeling software solutions.

CODESOFT plus LABEL ARCHIVE, and the TEKLYNX VAP:

- ✓ Centralized their labeling and full reports on label changes, comments, revisions, and prints.
- ✓ Expedited their compliance with industry standards in medical device manufacturing.
- ✓ Saved time and valuable resources by accelerating validation of their labeling processes.
- ✓ Made them audit-ready and compliant with FDA and European Union (EU) requirements.

Leveraging TEKLYNX Professional Services, only two Top Clean Injection employees were required in the validation of LABEL ARCHIVE from start to finish. What would have taken approximately two weeks of complete focus to prepare the validation templates and execute validation by multiple people, only took the two Top Clean Injection staff 1.5 days.

"We couldn't have accomplished this level of label management and software validation without TEKLYNX," explained Elisabeth Tavard. "It's good to know we had labeling software experts from TEKLYNX to work with our validation and IT teams to prepare the documentation. Now, we're completely confident in our label approval process and what we'll present to customers and auditors to show how our label system and printing is validated."



Validation *without*
TEKLYNX VAP:

**OVER 2
WEEKS**

Validation *with*
TEKLYNX VAP:

**ONLY
1.5 DAYS**

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.