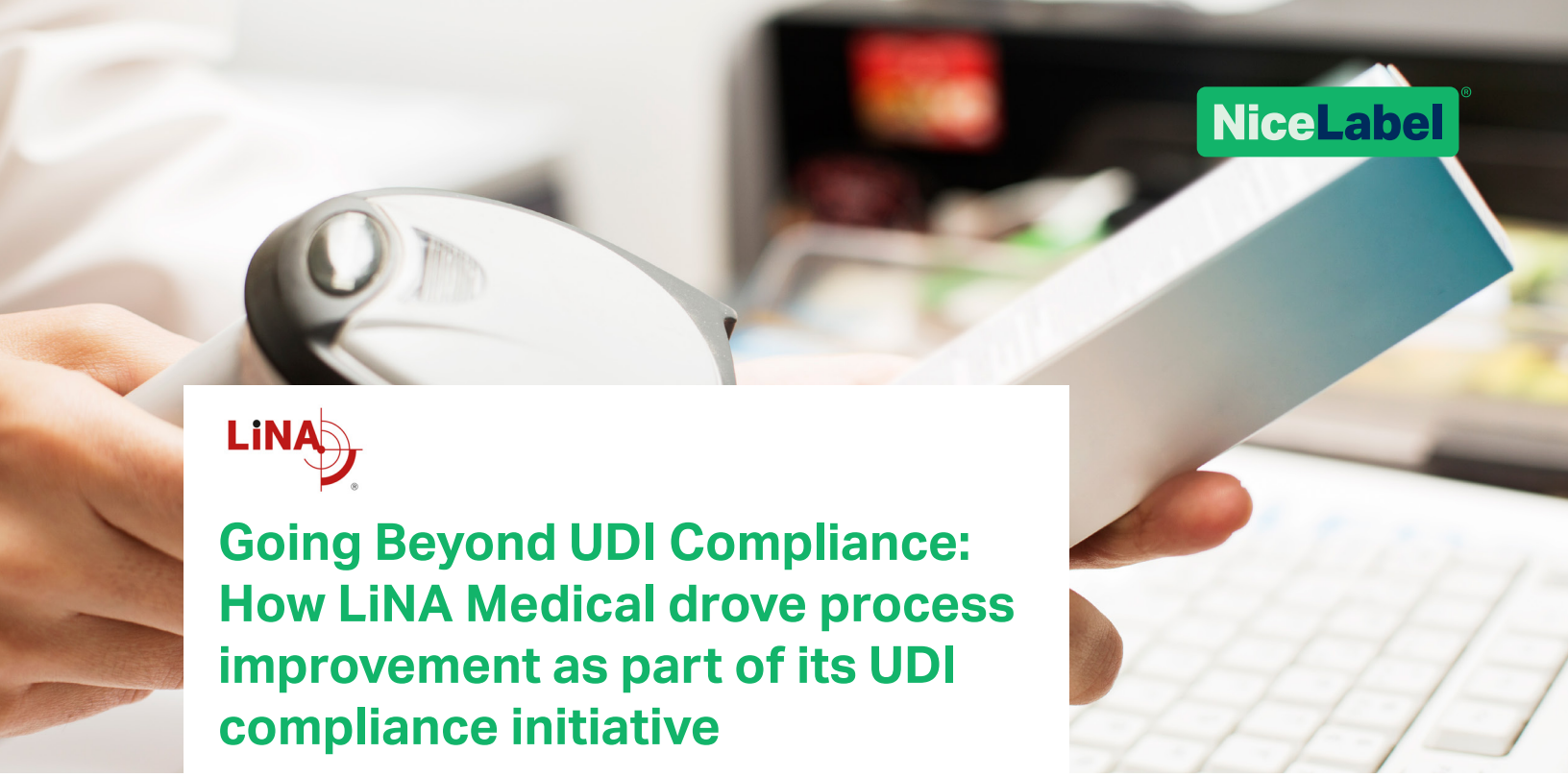


Going Beyond UDI Compliance: How LiNA Medical drove process improvement as part of its UDI compliance initiative

LiNA Medical is an international medical device company that needed to make changes to their labeling process to meet the UDI compliance deadline for Class II devices. The company capitalized on the UDI compliance initiative to cut production costs and create a more streamlined labeling process.

Case Study

Industry: Medical device
Solution: NiceLabel LMS Enterprise

Challenges
- Risk of noncompliance
- Manual data entry
- No integration of labeling and ERP systems
- Manual label verification/approval
- Production delays
- Hard copy label catalog
- No print history

Solutions
- Standardized labeling
- Document management system for labeling
- Streamlined label changes and approvals
- Full print history
- Print operator activity tracking

Results
- Process optimization
- Reduced man hours
- Mitigated risk
- Reduced production delays
- Reduced costs
- Streamlined UDI compliance

Background

LiNA Medical is a privately held Danish corporation operating in the field of minimally invasive gynecology. Through close interaction with physicians they develop innovative products, specifically designed for gynecology, based on their vision of improving quality of life for women all over the world undergoing treatments for gynecological conditions. The company distributes products globally. LiNA's supply chain, quality, manufacturing and engineering operations are housed in Poland, while research and development is in Denmark. The company must comply with UDI guidelines when it ships products to the United States.

Existing Environment

LiNA Medical had a homegrown standalone labeling system that wasn't integrated with its ERP system. Labels were created in the labeling system, and production work orders came from the ERP system.

The company markets and sells Class I and Class II medical devices. Some products have three levels of packaging: individual pieces, inner box and outer box. Others have only one or two levels of packaging. LiNA ships product all over the world, so labels needed to be printed in multiple languages.

Challenges

High cost of label errors and non-compliance

LiNA Medical had a manual labeling process that required its print operators to have a lot of knowledge. While label templates with fixed product data were maintained in the company's homegrown labeling system, UDI production identifier (PI) data like batch number, production date and expiration date were manually entered by print operators who referenced work orders for each production line. Misspelling and other data entry errors caused problems in the production process so each batch of printed labels had to be carefully checked requiring additional quality control tasks. If errors were found, labels were discarded and products had to be reworked and relabeled. The extra quality control and manual label verification added significant labor cost and was time consuming.

Each of LiNA Medical's various levels of product packaging needed to be appropriately labeled. The labeling and ERP systems weren't integrated, and LiNA Medical needed to modernize its labeling process and connect master data (production information) with labeling to avoid the huge potential cost of a product recall caused by mislabeling.

Delays in production time

When entering production data, operators could change labels by accident, editing the wrong field or the wrong file. Re-working and relabeling would cause a significant order fulfillment delay because mislabeled products had to be quarantined before being relabeled. Fortunately, LiNA Medical did not have any product recalls due to the extra quality controls that they had in place, however they were conscious of the risk and the potential cost.

Print operators had to find the right template for each product and with almost 3,000 label variations across their product line, operators had to spend time carefully selecting the correct template. LiNA Medical needed a way to integrate label printing with work orders.

Cumbersome label change and approval process

LiNA Medical manually maintained two identical paper-based catalogs of label templates: one for the quality department, and the other for production. When label changes were made, the template was printed, verified, manually approved via a paper-based signature and then stored in the label catalogs. While LiNA Medical could see where changes were made and who made them, it was a very time consuming and cumbersome process.

Print history was manually tracked. While label designers and approvers had unique domain logins, print operators shared a single active directory login, making the process of tracking who printed what for compliance quite difficult.

Solutions

As the Class II UDI compliance deadline approached, LiNA Medical realized they had an opportunity to drive process improvement as part of their UDI compliance initiative. LiNA Medical engaged SKK, a NiceLabel partner in Poland, to create a standardized solution that would help them achieve compliance and streamline their entire labeling process.

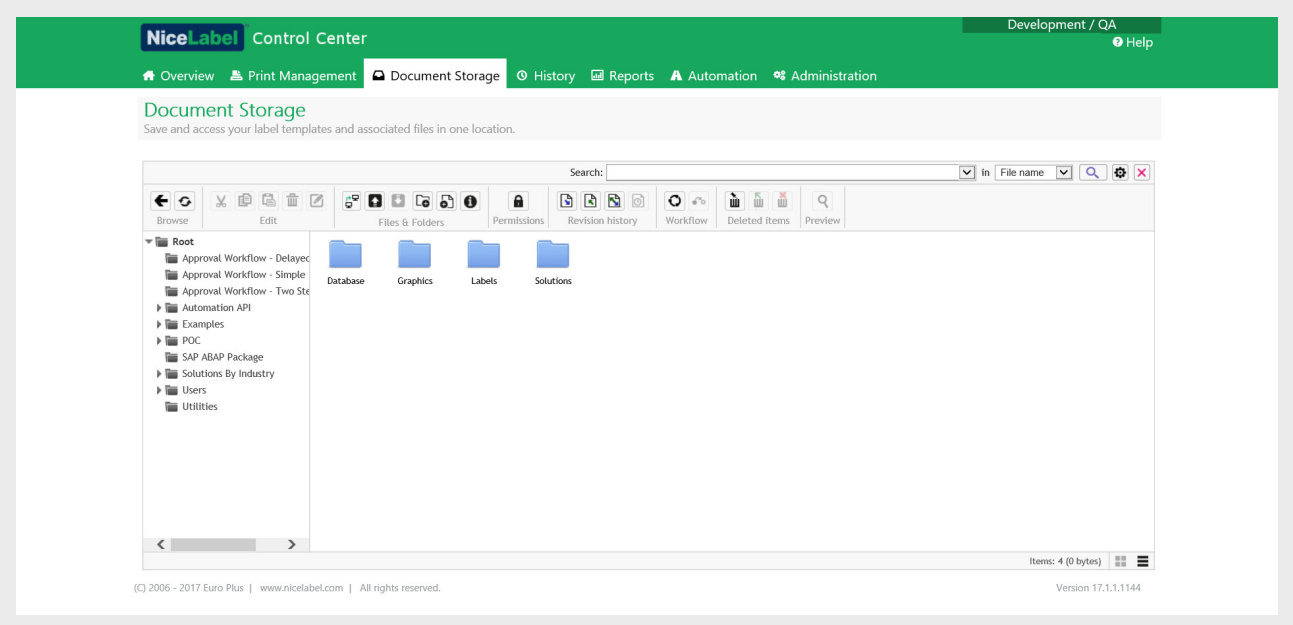
Standardized labeling

LiNA Medical's work orders are now integrated with its labeling processes. A separate database houses packaging unit information and a streamlined user interface connects to label printing to reflect the appropriate piece and box information for each product. A database management form maintains the number of units and labels for each level of packaging. Print operators can easily choose a work order and label quantities are calculated based on the information stored in the packaging database. The system also selects the appropriate printer according to the label size.

With the new system, print operators make minimal edits to the form. The only editable field is "quantity". This information is populated from the work order and print operators can edit if necessary. In the case of an issue with the default printer, operators can choose the printer from the dropdown. The remaining production identifier (PI) values are fixed and can't be changed.

Document management system built for labeling

LiNA Medical now has a centralized document management system for UDI compliant labeling. A digital label catalog has replaced the paper based binders of approved, hard copy labels. Label design and approval workflows are streamlined and happen within the system. Labeling is now transparent and the company can keep track of labels printed with production orders, including label versions, which print operator initiated the print job, detailed traceability and quantities. In addition, they can reprint labels.



Print operators still share an active directory login however an additional login screen within the print form allows LiNA Medical to track the activity of individual operators.

Results

> *Our goal is to have a zero-error environment, and NiceLabel's label management system plays a big role in that. We can already see the positive impact the system has had on our productivity and transparency, and we expect that those benefits will only increase over time.*
>
> Michał Mydlikowski, Logistics Manager

Process optimization and cost reduction

LiNA Medical's improved labeling process is significantly reducing labor costs and saving the company countless man hours in streamlining the label creation and approval process, and reducing the need for excessive quality control tasks.

Mitigated risk of product recalls

As LiNA Medical moves toward its goal of a zero-error environment, they have become much more agile and responsive. Label changes and approvals happen in a fraction of the time they used to take, saving the company time and money. They have a completely transparent label approval process and have visibility to who changed a label, when it was changed and where it was printed. The risk of a product recall due to mislabeling has significantly dropped.

Reduced quarantined product and shipping delays

Mislabeling has all but disappeared, meaning the company no longer needs to delay shipping while product is held in quarantine. Product no longer needs to be re-worked or relabeled.

To learn more about NiceLabel's solutions for the medical device industry, visit www.nicelabel.com/udi

NiceLabel®

About the NiceLabel label management system

The NiceLabel label management system provides businesses with everything they need to standardize, centralize and control their entire labeling process to achieve maximum print productivity. The NiceLabel label management system includes a label designer, application builder, document management system, web printing system, integrated printing system, a non-production environment and a change and transport system. It is scalable from five users to many thousands of users and can be extended to remote locations, suppliers or contract manufacturers. NiceLabel's core technology is proven with hundreds of thousands of customers, making it the most robust label management solution.

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