NiceLabel®

Global Healthcare Company Streamlines Labeling Processes to Meet Evolving Compliance Regulations

Case Study

Industry: Medical Devices and Pharmaceutical
Solution: NiceLabel LMS

Challenges
- Simplify label design process
- Streamline label approval process
- Simplify compliance with regulations
- Reduce label errors
- Integrate printing with SAP and MES

Solutions
- Centralized database repository
- Web based label lifecycle management
- Business Rules & Workflow Engine
- Real-time integration with SAP / MES
- Web based on-demand label printing
- Label and application designer

Results
- Significant annual savings
- Streamlined label approval process
- Thousands of less label templates
- Faster turnaround times for change requests
- Reduced line setup times by 15 minutes per job
- Less mislabeling and product recalls

Background

This NiceLabel customer is a global, broad-based health care company. Their products span the continuum of care, from nutritional products and laboratory diagnostics to medical devices and pharmaceutical therapies. With 70,000 employees in more than 100 countries and market capitalization of more than $60B, it is one of the biggest enterprises in the world.

Business Goals

The Company's business goals for this project focused on streamlining enterprise label printing across multiple sites and functional business groups while staying ahead of the constantly changing regulatory compliance landscape.

Key objectives were:
- To simplify, automate and better track the label design requests.
- Improve process efficiencies on the manufacturing floor and distribution centers.
- Standardize and unify the complete label design, printing and management with one application.

Challenges

" We wanted a solution that is scalable, web-based and allows us to easily see the differences between label versions. "

QA Manager, The Customer

Reduce Time, Automate and Establish Visibility of the Label Request Process

Updating labels was manual and tedious because the existing design tool did not leverage a centralized set of label data information. Also, the design tool did not automatically identify what other labeling components were affected by the change, so changes had to be manually cross-checked against multiple data sources to verify accuracy.

The previously used internal change order system didn't integrate with the label design software and had limited review capabilities. They did not have a way to quickly compare and comment on changes between label versions. The company needed to improve departmental collaboration and automate workflows of label design, review and validation processes.

Simplify Adherence to Regulatory Requirements

Product serialization, GTIN, UDI, FDA 21 CFR part 11 requirements and other changes in labeling standards require structured and centralized management of label related data which the company did not have. Expansion into foreign markets required a new level of adherence to regulatory requirements. Region-specific labeling is required to ensure compliance with specific geographic areas.

The burden was growing on the label design team due to the need to recreate or rework labels for regulatory submissions as well as country and language specific requests.

The team needed a more robust system to improve business processes support, regulatory compliance and customer responsiveness.

The design team also needed more flexibility in label design and a web-based solution that would instantly deploy updated templates to all locations.

Improve Process Efficiency, Automate Print Job Setup and Minimize Risk of Errors

The company saw many opportunities to increase process efficiency on the manufacturing floor across distribution centers. The shop floor needed to print directly to SAP to eliminate data duplication from one system to another.

The company performed manual setup activities for each print job. They wanted to automate the print job set up by interfacing and printing directly from the MES application. Regulations require storing a representative label after the job setup. The company wanted to replace a multi-step manual process with a streamlined electronic one.
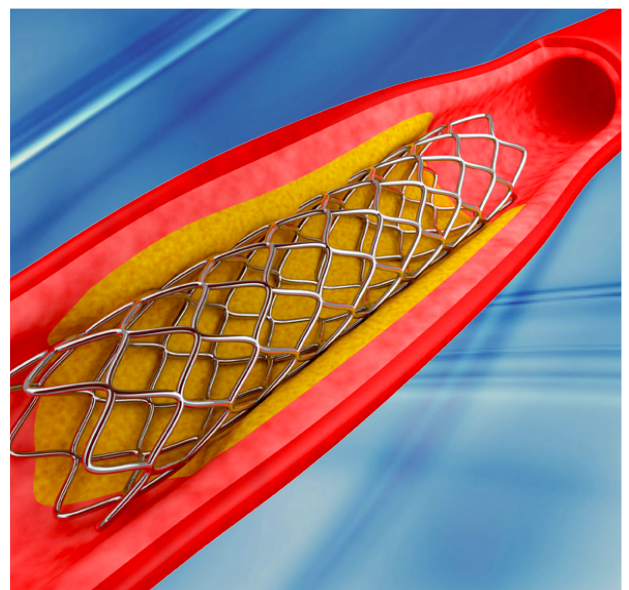
Solutions

Centralized data management will increase the global visibility and control of labeling data, allowing us to align with constantly changing labeling regulations.

IT Manager, The Customer

NiceLabel provided a complete label lifecycle management solution built on the NiceLabel Label Management System. This next generation labeling platform provides the ability and agility to rapidly react to the changing environment and lower the total direct and indirect costs of ownership.

Centralized management increased global visibility and control of label templates and data.

Label consolidation reduced thousands of individual product labels into templates and groups of common label information. This dramatically improves management of label data and label change request turnaround times. The new system improves agility as new labels are created with greater ease and instantly shared across the organization. Controlled access to the system eliminates paperwork, improves visibility and improves cross-team collaboration.

After the implementation the Company experienced improved label accuracy through consolidated information and process improvements. These improvements also reduced the risk of field actions, production downtime and product recall concerns.

NiceLabel's LMS Enterprise helps identify differences between labels making even the smallest variations clearly visible. The comparison, as seen in Figure 1, helped the company achieve a previously unattainable level of quality control and label data accuracy.

Compliance with industry regulations

Centralized management of label data allowed the company to meet FDA 21 CFR part 11 requirements as well as produce region-specific labeling to comply with requirements from specific geographic areas.

Process efficiency and label accuracy

The label printing process is improved by consolidating templates and using master data as the single source of truth. The amount of time needed to setup up the production line has been significantly reduced.

NiceLabel's 64-bit Automation Labeling Service Bus provides real-time integration with the Company's MES and SAP environments. In addition, integration with SAP allows the Company to deploy label formats and workflow configurations in a development environment, move them to QA for testing and validation, and ultimately shift to production based on a controlled schedule.

Figure 1: Label comparison example.

Results

Consolidating three separate labeling applications into one reduced our support costs, eliminated hardware constraints and aligned with the global strategy of IT portfolio reduction.

IT Manager, The Customer

The browser based labeling productivity solution improved operational efficiency, responsiveness and agility while decreasing costs.

Results and benefits:

- Streamlined label approval process saved hundreds of man-hours per year
- Thousands of labels reduced to templates
- Streamlined label request process and faster turnaround times
- Unified platform for design, printing and management
- Streamlined cross-team collaboration
- Print job setup times are reduced by 15-20 minutes
- Local and global regulatory requirements are easily met
- Process improvement and less errors due to eliminated data duplication
- Compliance with FDA 21 CFR part 11 requirements
- Fewer product recalls

Unique label consolidation technology

The unique label consolidation technology reduces the need for label variations. It significantly reduces labeling system complexity and simplifies label creation, management and validation processes.

The configure-don't-code approach empowers business users to manage label templates. It dramatically reduces response times and lowers costs of label creation and maintenance.

Secure Web access enables the Customer to centralize label management, globally synchronize changes in real time, collaborate across all their locations and extend labeling to business partners.

To learn more about NiceLabel's solutions for the pharmaceutical industry visit www.nicelabel.com/pharma

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NiceLabel®

About the NiceLabel LMS
The NiceLabel LMS is the only 64-bit true-next-generation modular solution designed to address the complex labeling requirements of large and highly regulated organizations. The NiceLabel LMS and its unique "configure, don't code" approach delivers a new level of "print productivity". NiceLabel core technology is proven with hundreds of thousands of customers, making it the most robust enterprise labeling solution.