



Pharmaceutical company Krka streamlines compliance and label management

Case Study

Industry Pharmaceutical
Solution NiceLabel LMS

Challenges

- Complex regulatory compliance
- Various technologies and fragmented label creation
- Complex master data management
- Too many label variations
- Long cycle times for changes

Solutions

- Electronic label lifecycle management system
- A single, unified platform to design, integrate and manage labeling
- Electronic and centralized label catalog
- Graphical label design interface for business users
- Real-time integration with SAP® and Werum
- Label preview within SAP

Results

- Increased efficiency and streamlined compliance
- Label consistency and customer responsiveness
- Label template consolidation
- Business ownership and governance for label content and layouts
- Label system consolidation and scalability

Unifying labeling with the NiceLabel Label Management Solution (LMS) improves master data management, streamlines compliance and builds a next-generation system to support future growth.

Background

We had outgrown our existing system and wanted to put a next-generation solution in place to achieve sustainable long-term growth.

Anton Skof, IT Department Manager, Krka

Krka is one of the top generic pharmaceutical companies in Europe. The company produces and sells prescription pharmaceuticals, non-prescription products and animal health products. With headquarters in central Europe, production sites in five countries and multiple distribution centers, Krka delivers medications to more than 70 countries worldwide.

Krka was in the process of building a new state-of-the-art production facility. The team at Krka knew that their existing labeling processes would not support future growth. The construction of the new facility presented an opportunity to modernize legacy systems and implement new technologies, which would be used in other facilities if proven successful.

Krka's goals were to unify labeling to a single platform, have better oversight of label variations and streamline regulatory compliance processes.

Challenges



Failing an audit would have a devastating effect on the company's revenue.

Anton Skof, IT Department Manager, Krka

Complex regulatory compliance

One of Krka's challenges was adhering to the stringent regulations in each of their key markets. Failing an inspection in a specific country could jeopardize sales in that country and consequentially in others. Among other things, the regulations require documenting every change in the system including new and updated label templates. All printed labels also need to be archived for a year after the end of the product lifetime. Krka has strict internal governance procedures that ensure compliance. However, these paper-based procedures were labor intensive and required a lot of documentation. Krka needed to establish an electronic label compliance process that would improve quality assurance while reducing manual operations.

Various technologies and fragmented label creation

Krka has multiple systems that touch the labeling process including SAP and Werum, its MES platform. They uploaded barcode printer programming language (coded templates) into SAP and also at local production sites on the Werum system. Results varied between each system, so labeling lacked consistency. To address this, Krka's labeling staff had to create label formats to accommodate each system. While this helped to address label inconsistencies, Krka ended up with hundreds of hard coded label templates and long cycle times for label creation and change requests. They also relied heavily on their IT department. Recreating labels for disparate systems cost Krka valuable man hours and negatively impacted customer response times. Krka needed to consolidate its label printing process and systems.

Complex master data management

In heavily regulated markets like the pharmaceutical industry, the label is an essential master data record. Master data management is a very complex and mission-critical component of the business. Krka had high standards for its master data and wanted to bring label data to the same quality level as its other master data. In order to do this they needed to find a way to integrate label lifecycle management with their master data management system.

Too many label variations

Krka had a label catalog which was used to maintain oversight to all of the company's labels. The catalog was fragmented and management of label template revisions across Krka's various systems was extremely complex and consumed valuable IT resources and time. Krka needed to reduce the number of label templates to a more manageable number and to use a single centralized platform for label design, change control, printing, integration and management.



Solutions

// *With NiceLabel, we made a significant improvement in the quality and management of the label catalog. We continue to reduce the number of label templates as we roll out changes to our other systems.*
Anton Skof, IT Department Manager, Krka

Electronic label lifecycle management system

NiceLabel enables Krka to streamline compliance with FDA and GMP requirements. The electronic label design and approval processes ensure data accuracy, reduce paperwork and increase customer responsiveness. Krka uses an HTML5 based Web application to preview and inspect label content against specifications. Built-in approval and validation rules and role-based access prevent users from completing more than one step at a time in the validation process, which ensures compliance. Copies of all printed labels are automatically archived in a PDF format instead of printed documentation, which significantly reduces paperwork and lowers archiving costs.

A single, unified platform to design, integrate and manage labeling

With NiceLabel, Krka now uses a single platform to manage all aspects of labeling. The same universal template is used for label printing regardless of the printer model or system that initiates the task (Werum for manufacturing execution and SAP for other business operations).

Electronic and centralized label catalog

Krka has the ability to quickly search through all label data across the enterprise. Instead of designing a new template and increasing complexity, the team at Krka can quickly find and compare existing label

variations and avoid template duplications. Users now have the ability to compare and graphically highlight the differences between labels on their screen. Even the smallest variations are clearly visible. This helps Krka achieve a previously unavailable level of quality control, label data accuracy and template consolidation.

Graphical label design interface for business users

Labels are now designed by business users who best understand the requirements. They no longer depend on IT to program printer specific code and can quickly design accurate labels that meet customer and regulatory requirements.

Real-time integration with SAP and Werum

With NiceLabel's high speed 64-bit automation labeling service bus, Krka is able to integrate with SAP and Werum using pre-built certified connectors, without custom programming. The real-time label preview inside the SAP form streamlines the validation in the change management process, offers another quality check for the operator before printing and simplifies regulatory agency audits. Additionally, the seamless integration has another benefit – the operator user-interface remained the same so no additional training was needed for print operators.

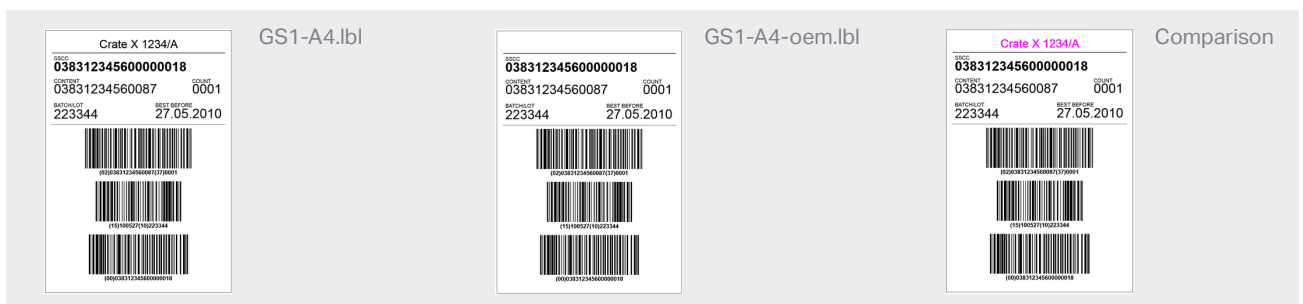


Figure 1: Label comparison example. NiceLabel LMS.

Results



With NiceLabel, we made a significant improvement in the quality and management of the label catalog. We continue to reduce the number of label templates as we roll out changes to our other systems.

Anton Skof, IT Department Manager, Krka

Streamlined compliance

The electronic label lifecycle management system that replaced the paper-based compliance system is saving Krka countless man hours, which translates into significant cost reduction. With the new system in place Krka's agencies and customers can rest assured that Krka is following best-in-class practices for quality.

Label Consistency and customer responsiveness

The consolidation of label systems and processes has resulted in better customer response times and eliminated label inconsistencies. Regardless of the system being used, or the location, the right label template is printed and the output is consistent across all systems.

Label template consolidation

The ability to search the label catalog and compare the differences between similar templates has helped Krka eliminate duplicate labels and also reduce the number of label templates that they need to maintain.

Business ownership and governance for label content and layouts

Business users at Krka can now design and manage labels without the help of IT. This dramatically improves cycle times and reduces the overall time spent on labeling.

Label system consolidation and scalability

All systems are now integrated on the same centralized platform. This means less knowledge management costs, seamless connectivity, consistency and dramatically simplified change management. The simplified, integrated and unified labeling system can be scaled and extended to stimulate instead of limit future growth.

Future outlook

Krka plans to extend their unified labeling system to suppliers and sub-contractors so that they can use the label template that is used internally. This will help them optimize inbound logistics and most importantly to improve master data management.

To learn more about NiceLabel's solutions for the pharmaceutical industry visit

www.nicelabel.com/pharma



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.



Americas
+1 262 784 2456
sales.americas@nicelabel.com

EMEA
+386 4280 5000
sales@nicelabel.com

Germany
+49 6104 68 99 80
sales@nicelabel.de

China
+86 21 6249 0371
sales@nicelabel.cn