NiceLabel®

How creating a standardized, global labeling strategy benefits pharmaceutical companies

Index

Introduction

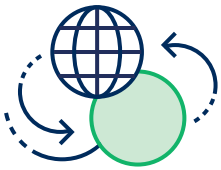
For pharmaceutical manufacturers, quality is paramount. And this high level of quality has to be present in all phases of the manufacturing process, from production to shipping and from product to label. Let's take labels as an example. Labeling errors can lead to costly product reworking, quarantine or, as in the **case of Mirtazapine**, recalls. Why, so far into the 21st century, are we still having to talk about labeling errors? In our experience, the answer lies in a lack of standardization, centralization and system integration.

Labeling errors can lead to costly product reworking, quarantine or, as in the case of Mirtazapine, recalls. Why, so far into the **21st century**, are we still having to talk about labeling errors?

The road to system fragmentation

There can be a variety of reasons that lead to a de-centralized approach to labeling. Perhaps a pharmaceutical manufacturer has gone through a number of mergers and acquisitions, inheriting a series of homegrown, independent labeling solutions along the way. Or perhaps a company has taken a one-off approach to regulatory compliance, purchasing independent systems to address each compliance need, such as serialization or aggregation. While this approach addresses the immediate compliance need, it results in a series of silos – disparate systems that don't interact with one another. Whatever the road taken, the destination is the same. Decoupled labeling processes that make it difficult to ensure an accurate, efficient labeling process.

In this paper, we address four of the most common labeling challenges that arise from a decentralized approach to labeling, and how you can address these.



www.fda.gov/safety

50%

of pharmaceutical recalls are due to errors in product labeling or packaging artwork.

Source: Xtalks

$8m

The average cost to distribute a recall notice is $8 million.

Source: GS1

20x

Pharmaceutical product recalls occur about 20 times per week in the U.S. alone.

Source: McKinsey

4 common labeling challenges **and how to tackle them**

1

Challenge #1: Complex label design and change process

The first challenge has to do with designing and updating labels. With many homegrown systems, IT staff have to hard-code label templates.

2

Challenge #2: Manual quality assurance

The second challenge is also an extension of the first. Pharmaceutical manufacturers using legacy approaches to label design inevitably have manual quality checks in place.

3

Challenge #3: Lack of integration

For pharmaceutical manufacturers errors are something to be avoided at all costs. So, they usually take the siloed or the standardized approach to prevent them.

4

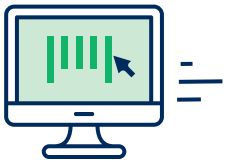
Challenge #4: Accurate supplier labeling

Guaranteeing the accuracy of the labels printed in-house is challenging enough. However, most pharmaceutical manufacturers today have to deal with a complex array of third-party suppliers, contract manufacturers, repackagers and relabelers, many with country-specific labeling requirements, and all of whom need to print accurate labels as well.

1

Challenge #1: Complex label design and change process

Pharmaceutical manufacturers that have implemented **track and trace solutions** for primary pack serialization often end up using the same system to design **complex case and pallet labels**.



The first challenge has to do with designing and updating labels. With many homegrown systems, IT staff have to hard-code label templates.

They often need to create separate label templates to match different printers, which increases the number of templates that have to be maintained and updated when label information changes. The same is true when companies use a software not built for labeling. Some of our pharmaceutical customers have used programs such as Microsoft Word or PowerPoint to create labels. They've then had to implement a number of manual quality checks and workarounds to ensure label information was accurate and labels were printed correctly.

Other manufacturers use legacy approaches like SAPScript or Smart Forms to create their labels. Yet, this also requires hard-coding and a considerable amount of IT involvement. Change requests take weeks or months – hardly the recipe for an agile labeling process.

Pharmaceutical manufacturers that have implemented track and trace solutions for primary pack serialization often end up using the same system to design complex case and pallet labels. This creates inefficiencies as the software isn't optimized for label design. This means companies have to use valuable line time for label design and configuration rather than production.

Solution:
Simplify label design and centralize label storage

The solution to the above challenges is to simplify label design and reduce IT dependence and workload. Implementing an easy-to-use label designer that is built for labeling gives you flexibility in your labeling process. You can train business users to create labels, or you can greatly simplify the process your IT staff have to go through in order to update label templates. Users can design labels from the comfort of the office, as opposed to on the production line. This label designer should include universal label templates that are printer agnostic, which will save your IT staff valuable time spent on hard-coding printer-specific templates.

By centralizing label storage, business users can access a company's entire label library from one, web-based interface. They can quickly locate and compare labels across all of their operational locations, searching based on label names or content, and get instant query results. Business users can also more easily compare and identify differences between label variations and revisions, thus improving accuracy and preventing duplications. And when it comes to best-practice within label printing, think automation. By automating the label selection process, you relieve operators from the manual process of accessing and picking the right labels. Implement a label management system that does this for you by automatically executing pre-defined business rules.

Centralized label storage also enables you to grant contract manufacturers and other suppliers access to your secure label database, for example, via a secure web browser. You get the peace of mind knowing that suppliers are always accessing the most up-to-date version of your label template, and suppliers get a simple method for printing approved labels.

By **centralizing label storage**, business users can access a company's entire label library from **one**, **web-based interface**.

Case study: How a pharmaceutical customer met the challenge

1 Challenge #1: Complex label design and change process

Bilthoven Biologicals
Cyrus Poonawalla Group

Bilthoven Biologicals BV (BBio) is a pharmaceutical company based in the Netherlands. It is their ambition to protect the world's infant population with affordable vaccines. Prior to implementing NiceLabel, BBio struggled with a lack of consistency in their label templates. "We were in a situation where we no longer had an overview of all of the templates and label systems we were using," relates Martijn Huijbreghs, IT Application Manager with BBio. "Label design and production were spread out over a number of employees, so we lacked consistency in our label templates."

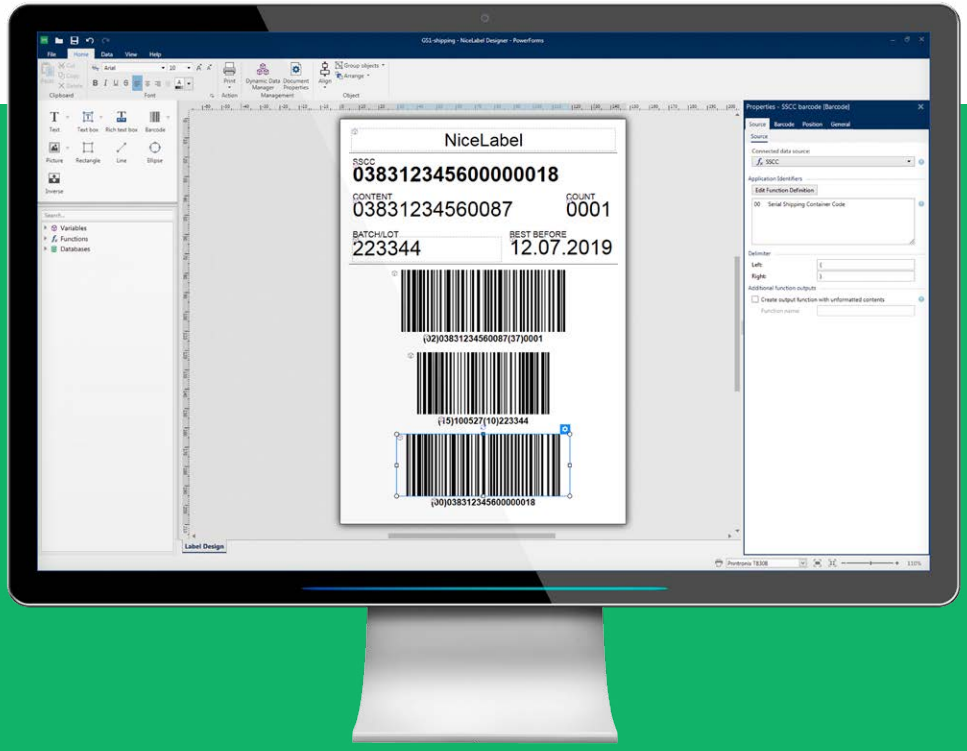
By implementing a standardized labeling solution, BBio was able to reduce costs, increase efficiency and transform procurement. "The gain in template management is in itself a win. Having fewer templates and one designer guarantees less maintenance and a uniform label design. But we gain even more by being able to standardize our label materials and even our printer hardware. This guarantees easy IT support, reduces material costs and ensures less downtime because you have everything in stock," Martijn Huijbreghs states.

Find out more about how Bilthoven Biologicals BV simplified label design

www.nicelabel.com/solutions

Bilthoven Biologicals
Cyrus Poonawalla Group

1 Challenge #1: Complex label design and change process



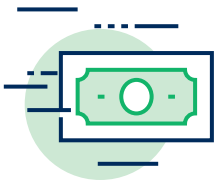
"The gain in template management is in itself a win. Having fewer templates and one designer guarantees less maintenance and a uniform label design. But we gain even more by being able to standardize our label materials and even our printer hardware. This guarantees easy IT support, reduces material costs and ensures less downtime because you have everything in stock."

Martijn Huijbreghs, IT Application Manager, BBio

2

Challenge #2:
Manual quality assurance

Just think of the **man-hours it takes** to dedicate three people to checking one label if you have a database of 50, 500 or 5,000 labels.



The second challenge is also an extension of the first. Pharmaceutical manufacturers using legacy approaches to label design inevitably have manual quality checks in place.

We've worked with companies where employees had to print out copies of each label and walk them over to the Quality department to be checked. We've also had pharmaceutical customers who required each label to be checked by three different Quality employees before signing off on any changes. While these quality checks can catch most errors, they are incredibly resource-intensive and time-consuming.

Just think of the man-hours it takes to dedicate three people to checking one label if you have a database of 50, 500 or 5,000 labels. And if the QA process is manual, the label catalog is as well. Which means it's very difficult to maintain a version history of each label. This manual approach also makes it difficult to approve exact finished labels for a specific SKU.

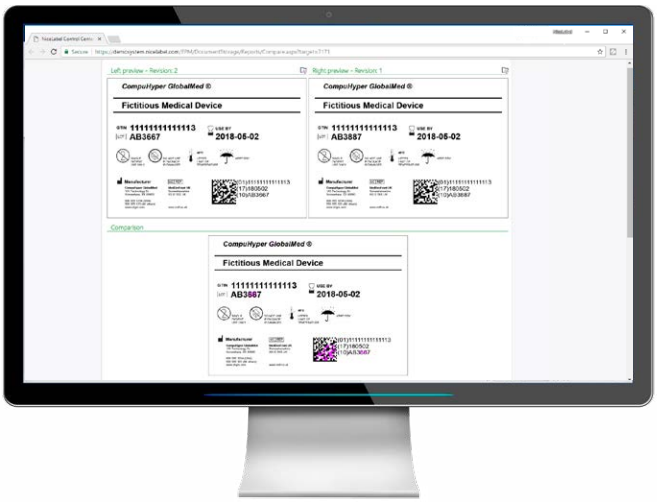
Companies have the choice of either forgoing this last quality check (which increases risk) or doing it manually by creating separate templates for each SKU (which increases complexity).

Solution: Digitize the quality assurance workflow

2 Challenge #2: Manual quality assurance

The only solution to this challenge is digitizing the quality approval workflow. By creating a centralized, digital label catalog, you get a full version history of each label in your organization. Every change and approval are documented in the label management system. You can use role-based access to control the level of access each user has, which eliminates the possibility of unauthorized label changes. Creating a digital, visual workflow for quality will also help QA staff more quickly recognize label changes, thus expediting the approval process.

For example, the **NiceLabel label management system** includes a graphical label comparison tool. This tool provides reviewers with a visual comparison of label versions, so they can quickly spot and understand what's changed from one version to another.



The NiceLabel label management system includes a graphical label comparison tool. This tool provides reviewers with **a visual comparison of label versions**, so they can quickly spot and understand what's changed from one version to another.

2 Challenge #2: Manual quality assurance

Digitizing the quality workflow also enables you to have electronic signatures and a complete digital label archive, with full label and print history, providing a full digital audit trail. In terms of best practice within label quality management, you should select a system that enables you to digitally approve the label template and the final output, the label with the corresponding data, before you print it. This will add an extra layer of quality assurance, as you can approve the final version of each label, and it provides an efficient way of automating and approving mass label changes.

These steps will also make it easier for you to validate your system, in accord with US and EU regulations, such as FDA CFR 21 part 11 and EU Annex 11. If you have a fragmented process with many different systems, this complicates the validation process. However, by standardizing on a single labeling system and digitizing quality control, you make the validation process easier as you only have to validate one, unified system. Of course, validating one system is only an advantage if that system is designed in a way that supports validation. Look for a label management system with built-in functionality designed to ease validation, and that provides the necessary supporting documentation.

Learn more about NiceLabel's Validation Acceleration Pack

www.nicelabel.com/vap

See how our variant technology helps Chr. Hansen, a global bioscience company, guarantee accurate, compliant labels

www.nicelabel.com/solutions

Case study: How a pharmaceutical customer met the challenge

2 Challenge #2: Manual quality assurance

Boehringer Ingelheim

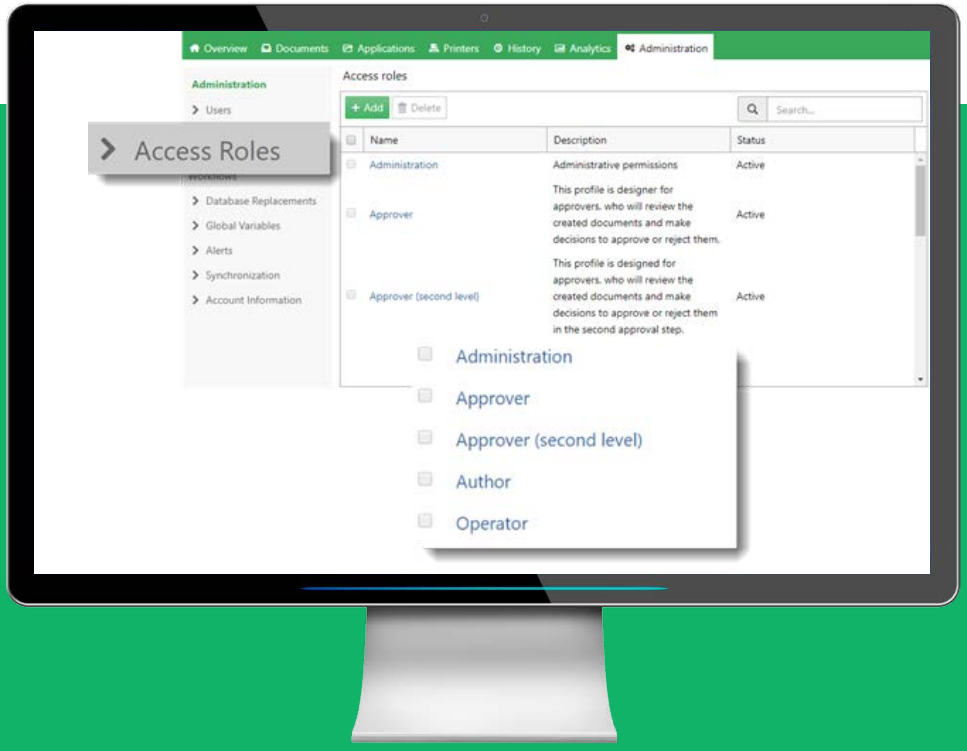
Boehringer Ingelheim is one of the pharmaceutical industry's top 20 companies with over 80 production sites and some 50,000 employees. By implementing the NiceLabel label management system, they were able to digitally transform their manual quality assurance process.

Find out how Boehringer Ingelheim digitized quality assurance

www.nicelabel.com/solutions

Boehringer Ingelheim

2 Challenge #2: Manual quality assurance



“The biggest advantage is that we no longer have that extensive change procedure with documentation. With NiceLabel, we have complete label management in the document management system.”

Pierre Rahm, IT Operations Services in Boehringer Ingelheim

3

Challenge #3:
Lack of integration

However, companies are realizing that for true supply chain visibility and **track-and-trace** capabilities, they need **aggregation**, a process which calls for far more detail and flexibility in terms of label templates.

For pharmaceutical manufacturers errors are something to be avoided at all costs. So, they usually take one of two approaches to preventing them.

They either take a legacy approach to integration by hard-coding labels inside their MES and ERP systems – a process which is both rigid and IT-intensive; or they don't integrate at all and end up with dozens of manual quality checks in order to catch errors. Both of these approaches are time- and labor-intensive for IT and quality assurance staff.

Another integration-related labeling challenge stems from the "siloed" approach many pharmaceutical manufacturers have taken to serialization. Because the labels needed for serialization are quite simple in nature, many companies handle primary packaging labeling on the line level. While this approach enables the data integration necessary to meet serialization requirements, it doesn't provide for label template integration. It's only a workable solution as long as the labels remain relatively simple.

However, companies are realizing that for true supply chain visibility and track-and-trace capabilities, they need aggregation, a process which calls for far more detail and flexibility in terms of label templates. And designing labels for cases and pallets at the line level is an operational nightmare. Without a proper label designer and template centralization, companies face a long series of manual workarounds which hamper productivity.

Solution: Integrate labeling with your master data

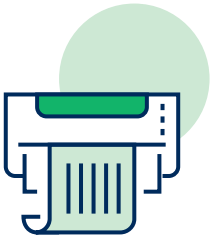
3 Challenge #3: Lack of integration

It should come as no surprise that the solution to a lack of integration is: integration. However, not just any integration. Integration that standardizes on one labeling system, which then integrates with all of your other systems: ERP, WMS, PLM and track-and-trace.

This affords you several advantages:

- You unite all printers on one label management system, including the thermal inkjet and thermal transfer printers used in serialization and aggregation.
- You decouple the label layout from the production line set-up (where it normally resides when you design aggregation labels using serialization systems) and handle the design and verification process offline. You can then send the approved label template to the packaging line dynamically with each production order. This helps you avoid the production downtime necessary when running verification on the production line itself.
- You can automate business rules and workflows for increased efficiency and productivity.

Integration that standardizes on one labeling system, which then **integrates with all of your other systems**: ERP, WMS, PLM and track-and-trace.



Case study: How a pharmaceutical customer met the challenge

3 Challenge #3: Lack of integration

KRKA

KRKA is one of the top generic pharmaceutical companies in Europe. They produce and sell prescription pharmaceuticals, non-prescription products and animal health products. In order to have label data quality which was on par with their other master data, Krka were looking for a way to integrate label lifecycle management with their master data management system.

Using NiceLabel's integration system, Krka now has real-time integration with SAP (their ERP system) and Werum (their MES), without having to do any custom programming. They have real-time label print preview inside of the SAP form that streamlines validation in the change management process, offers another quality check before printing and simplifies regulatory agency audits.

Find out more about how Krka solved the integration challenge

www.nicelabel.com/solutions

KRKA

3 Challenge #3: Lack of integration

“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

4

Challenge #4: Accurate supplier labeling

For example, if you deliver a drawing of a label to 10 different contract manufacturers, chances are you will get 10 different labels back.

Guaranteeing the accuracy of the labels printed in-house is challenging enough. However, most pharmaceutical manufacturers today have to deal with a complex array of third-party suppliers, contract manufacturers, repackagers and relabelers, many with country-specific labeling requirements, and all of whom need to print accurate labels as well.

This complexity is compounded by the fact that this collaboration often happens across borders and markets. Each supplier has its own IT infrastructure and printers, all of which further complicates the process of printing consistent labels across the entire supply chain. The method of delivery is an added wrinkle. For example, if you deliver a drawing of a label to 10 different contract manufacturers, chances are you will get 10 different labels back.

Then there's the question of agility and speed-to-market. We've seen cases where it can take weeks, or even months, to take new labels from design to approval to print. That's a timeframe that can dramatically impede a company's time-to-market.

Solution: Deploy a cloud-based labeling solution for suppliers

4 Challenge #4: Accurate supplier labeling

We believe that the key to consistent, standardized supplier labeling lies in the Cloud. With Cloud-based labeling, you can use the same label asset you've designed for your own internal use, distribute it to third parties, and get the same, fully-compliant, accurate label back.

Cloud technology makes it possible for you to store your label information centrally, control the entire label management process and extend that standardized label process to your suppliers through a secure, web-based interface.

Using Cloud technology, you can:

- Guarantee the same label output regardless of the supplier's printer brand or technology.
- Reduce your IT burden and security risks. With cloud-based supplier labeling, your IT staff don't have to spend time granting suppliers access to your internal labeling infrastructure. This saves time and IT resources, and it protects your systems and key data from unauthorized access.
- Onboard new suppliers quickly. The Cloud offers instant deployment and a quick on-boarding process.

With Cloud-based labeling, you can use the **same label** asset you've designed for your own internal use, distribute it to third parties, and get the same, **fully-compliant, accurate label back**.

Case study: How a pharmaceutical customer met the challenge

4 Challenge #4: Accurate supplier labeling

One of our customers is a large biotechnology company in Canada. After using the NiceLabel label management system to standardize in-house labeling and digitize quality assurance, they saw the benefits of extending their labeling to contract manufacturers. As their IT Project Manager stated, "We have some contract manufacturers, and right now, we send them blank labels and we have a manual auditing process. We have zero visibility into their labeling software, and we need to change that. So, we're going to be leveraging NiceLabel's cloud solution to have a standard template across the board, whether it's new facilities coming on line in Europe and Asia, or it's our partners who are printing labels on our behalf. They'll all be using NiceLabel for their label templates."

Find out how labeling in the Cloud can solve the supplier labeling challenge

www.nicelabel.com/label-cloud

Conclusion

As we've discussed, by implementing a standardized, global labeling solution, you can:

1. Simplify label design and centralize label storage.
2. Digitize the quality assurance workflow.
3. Integrate labeling with master data.
4. Deploy cloud-based labeling for suppliers.

The result is the digital transformation of your labeling, which helps you simplify compliance with industry regulations, increase operational efficiency and, ultimately, get products to market faster.

We're here to help you standardize labeling

For over 25 years, NiceLabel has been working with the world's leading pharmaceutical companies to help them digitally transform their labeling and meet industry regulations. In fact, 57% of the pharmaceutical companies on the Forbes 2000 list use our technology. We know that labeling is a business-critical function in the pharmaceutical industry. Your labeling system needs to meet the unique regulatory requirements and market demands in every country where you do business. By implementing our label management system, either on-premise or in the Cloud, you can respond more quickly to new industry regulations, ensure accurate, consistent labels and get products to market faster. We work with you to ensure your system is configured and implemented according to best practices, and that it is validated according to pharmaceutical industry standards. Let us help you standardize your labeling.

Contact our Pharmaceutical Specialists

www.nicelabel.com