Digital Transformation

As preparations are made for the age of serialisation, readying operations for full-scale track-and-trace throughout the supply chain, manufacturers can seize the opportunity to digitally transform their entire manufacturing operations

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As one of the most regulated industries on the planet, the pharmaceutical industry is accustomed to compliance exercises. With regulations governing practically every step in the manufacturing process, one can understand the temptation to view serialisation as just another in a long line of cost-incurring mandates. However, serialisation presents a unique opportunity for pharma companies to do more than simply comply with the letter of the law. Serialisation can be a springboard to a digital transformation.

If you have attended an industry conference in the past year and a half, chances are digital transformation was on the agenda. The basic idea of this transformation is leveraging advances in technology to digitise each stage of the manufacturing process. Rather than embark on a grand discussion of digital transformation as a whole, this article will focus on how it relates to one of the principal areas of serialisation: factory label printing.

Digitising the Label Database

In a recent survey of 100 key decision makers in the pharma and biopharma industries, almost one-third of the companies surveyed still relied on a paper-based label catalogue and approval process. See **www.nicelabel.com/pharma-survey**

Meeting serialisation requirements while relying on manual label processes is a recipe for disaster. The first step in digitally transforming labelling is replacing paper-based catalogues with a centralised, electronic label database. By digitising the label database, information can be accessed and updated in real time. This will allow manufacturers to track and trace products in the event of an issue, and they can correct errant information more quickly and efficiently.

Single Source of Truth

A discussion of digital transformation would be incomplete without talking about integrating labelling with internal business systems, be they enterprise resource planning (ERP) systems, manufacturing execution systems, or track-and-trace systems (TTS). The benefits of integrating labelling within these systems cannot be understated. Pulling label information from one source not only ensures the accuracy of that information, but it also increases the efficiency of the entire label production process.

For example, integrating the label management system with the ERP system makes it possible to print and report aggregation information. Additionally, integrating a label management system with a TTS makes it easy to manage and control label templates for direct marking printers.

Securing Label Information

As the amount of data that needs to be displayed on a label increases, so does the risk of errors in that information, especially if it has to be manually entered or modified. Locking down label templates is virtually impossible if they are manually maintained. With a digitised label creation process, pharma manufacturers can have a centrally-stored master label template and can control which templates are available for editing and by whom.

Handling Compliance

In the aforementioned survey, 62% of respondents stated they needed to print labels across multiple locations. In addition to this, manufacturers also have to handle the variations that result from having to comply with label requirements in multiple markets and languages. Many pharma manufacturers also have to deal with legacy printers and systems that need specific label formats to be created, resulting in hundreds of hard-coded label templates that make processing label change requests a time-consuming nightmare. Furthermore, with manufacturers having to assign unique numbers and barcodes to the smallest saleable unit and display these in the transaction history, full-scale digitisation is the only path to compliance.

Through digitisation, manufacturers can create universal templates that work across printers and systems. By using dynamic fields to customise the template to various markets and languages, manufacturers can drastically reduce the number of label templates they have to maintain and process label change requests more quickly across markets and languages. The end result is less time spent on updating and maintaining templates, a quicker reaction time to changes in regulations, and a generally more agile manufacturing operation.

Having a printer-agnostic template also ensures that the standardised labelling process can be extended to suppliers, regardless of the printers they have installed on their end. This guarantees that label formats will be

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correct and consistent no matter where they are printed in the supply chain.

Next Stop: Full Automation

The final element within this digital transformation is automation. By digitising the label production process, manufacturers can programme business rules into the management system, so logic-based decisions are made automatically.

Instead of having operators perform a certain task related to a specific market or supplier, this can be automated and handled by the system. This again saves time and enables manufacturers to process products more quickly.

Transforming Quality Control

Think of what this transformation will mean for quality assurance. Label information is updated in one place. Visibility and control regarding label template changes are clear. Every label ever created, every change ever made, and every label ever printed is saved and tracked in the database and can be re-created on-demand in response to audits and other queries.

Maintenance is completely digitised, version history is digitised, and quality checks and approvals are digitised and documented; in other

words, it signifies the complete digital transformation of quality control. Not only will manufacturers now be able to meet serialisation requirements in every country where they do business, they will also be in the best position to adapt to new regulations as they come along.

True Process Improvement

This transformation also means pharma manufacturers have a standardised, consistent label production and printing process across their entire supply chain. Once the process is consistent, they can identify areas where it can be improved. Rolling out those initiatives will be a lot easier as everyone is working from the same process.

Going digital has another tantalising side effect: manufacturers get data on all of the processes they digitise. They can gain a better understanding of printer performance, utilisation, and print media usage, which information manufacturers can use to optimise purchasing decisions and improve system performance. These insights can also be shared with other suppliers, thereby improving business methods in the entire supply chain. The result will be end-to-end manufacturing process improvement.

Pharma manufacturers who seize the day using serialisation as a catalyst for true digital transformation will find that what started out as a compliance exercise ended with becoming the key to transforming the way they do business.

About the author

Ken Moir is Vice President of Marketing at NiceLabel. With over 25 years of experience as an international technology sales and marketing leader, he was a partner in two high-tech start-ups, as well as a member of the management team at Zebra Technologies. Ken has extensive international technology sales and marketing experience, specifically in the fields of product, channel, vertical, and alliance sales and marketing. He is an automatic identification and data capture industry veteran with diverse market and technology knowledge, including barcode, radio-frequency identification, mobility, and label management solutions.
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