Automated pharmaceutical label production increases accuracy and compliance while reducing risk

The labeling systems deployed by pharmaceutical manufacturers must include a rigorous set of controls to protect the integrity of the pharmaceutical supply chain. A major pharmaceutical company deployed ROBAR, an integrated label management system that features BarTender® labeling software, to transform its labeling processes. The company experienced streamlined workflows, reduced potential for error, and improved regulatory compliance capabilities.

"We evaluated several competing solutions, and found BarTender to be the best choice because of its advanced programming interface, solid reliability, exceptional support and unmatched flexibility for label design and printing. Integrating BarTender into Innovatum's ROBAR system enables the world's best label software to be used in compliance with all US and international labeling regulations."

Ardi Batmanghelidj
President, Innovatum, maker of ROBAR

The challenge: Secure, compliant pharmaceutical labeling

Pharmaceutical manufacturing is among the most highly regulated global industries, and justifiably so. With its complex, multi-nodal supply chain, the integrity of that supply chain—and in turn, patient safety—can be at risk at each link.

In the US, for example, Part 11 of the Code of Federal Regulations (CFR) 21 stipulates a company must capture and record activity of any electronic system used to identify and track pharmaceutical products throughout the supply chain. And drug serialization, e-pedigree and other traceability requirements soon to take effect in Europe, the US, China and Brazil mean that almost 2,500 million consumers worldwide will be protected by new, stringent standards.

These efforts are driven by concern for drug quality and patient safety. They aim to protect the global drug supply from adulteration occurring via manufacturer error, counterfeiting or acts of terror. Violation of these regulations, which are enforced by periodic, detailed audits of pharmaceutical processes and facilities, may subject a company to penalties, fines and worse: a pharmaceutical company lacking in proper controls potentially exposes its customers to the risk of illness or death. And the commercial costs of an adverse event, including the loss of sales, reputation and market value, can devastate a business.

By shoring up the supply chain and employing rigorous processes that increase levels of control, pharmaceutical companies can enable regulatory compliance across the enterprise, protect the products they manufacture and distribute—and generate cost savings through increased efficiencies.

Transforming the labeling process at a pharmaceutical facility

Recognizing that their label generation process was inefficient and creating opportunities for error, a multinational pharmaceutical manufacturer sought to streamline its operations by deploying a fully automated labeling system.

The company administered, shared and printed over 5,000 individual label files using a highly manual process.

To print a product label, line operators browsed through server files and folders, accessing the correct label format by file name. The operator opened the label design file in maintenance mode, and then manually entered values for manufacturing data such

as lot and production numbers and expiration date directly on the label template, creating a new file for every label generated. The label was then printed and saved to a file folder on the local server.

The process was similar for printing labels at the company's remote plants. Administrators at the main facility navigated to the correct label format on their central server, and sent it to the remote plant as an email attachment. There, the data on the label was edited by the user to reflect the appropriate production variables, printed, and saved on that facility's server.

The system relied substantially on individual user expertise and accuracy, and its lack of controls presented multiple windows for error. It depended on the latest version of a label file being stored in its proper place in the production folder, and on the labeling operator remembering its correct location. Auditability was compromised by sharing files via email, with label files stored on local servers rather than in a central repository. There was no protocol to ensure proper file backups were performed.

And the system wasn't scalable to future needs. With each new label, the number of individual files increased, and the manual nature of the label administration processes precluded compliance with anticipated global e-pedigree and serialization requirements.

The solution: ROBAR and BarTender

After evaluating available options, the pharmaceutical manufacturer chose to deploy the ROBAR enterprise label management system from Innovatum, Inc. ROBAR includes BarTender label software from Seagull Scientific as an integrated component of its system, providing the label template, barcoding and design interfaces and unparalleled printer support via a browser based printing solution.

Now, through the automation capabilities provided by this integrated management system, the entire labeling process is managed without the user ever touching an individual label file. All label templates and content are maintained in a secure, version-controlled database. Variable data such as lot number, expiration date and serial number are shared from external, validated ERP, PLM and serialization systems at print time.

The operator initiates the label printing process through a browser-based print screen, submitting a work order. The system then automatically, accurately and reliably merges the variable data with the appropriate, approved version of the label template, prints the label, and captures a comprehensive audit trail.

Instead of personnel hours spent individually managing 5,000 label files and their content manually, the company now centrally administers just 60 label templates, which are automatically populated with a secure, auditable, central database of label content.

ROBAR's web-based design enables granular security access and incorporates layered security features, including role-based permissions. Automated, multi-user, browser-based review and approval workflows provide system controls. And BarTender provides ROBAR with incrementing serialization capabilities with the flexibility to serialize per-page, per-job, or by data source or database field change, with additional support for host-driven, randomized serialization.

Benefits

By placing controls on workflows, data entry and printing, BarTender and ROBAR have reduced the potential for user error in labeling processes, while securing and improving the company's ability to comply with global regulations. The system now provides complete audit trail capability and 21 CFR Part 11 electronic signature compliance.

ROBAR allows the pharmaceutical company to be agile in the face of changing business needs—central file management means that label changes are now implemented across the enterprise in a matter of seconds, applied to all relevant records and label templates. The new, streamlined and efficient processes are realizing cost savings for the company, and the built-in regulatory compliance structures are reducing corporate risk.

The new labeling processes are scalable across the enterprise, and adaptable to meet the gamut of serialization, e-pedigree, and other traceability requirements as they are implemented.

To learn how BarTender and ROBAR can help your pharmaceutical or medical device company meet compliance initiatives while streamlining your supply chain, visit seagullscientific.com, or contact us by phone:

SEAGULL SCIENTIFIC

Americas	+1 800 758 2001
EMEA	+34 91 435 25 25
APAC	+886 2 3765 2440
Japan	+81 3 5847 5780

Synopsis

- A major pharmaceutical company used a manual, operator-managed system to administer over 5,000 individual label files, each stored and accessed by file name.
- Data changes were entered by the user directly into the label format, and then shared across the enterprise via email.
- The system was unauditable, and out of compliance with 21 CFR Part 11—its lack of automation increased potential for user error.
- The company selected the ROBAR enterprise label management system, which uses BarTender for label design and printing.
- Now, label formats are stored centrally via a browser-based print screen—the user never opens or changes a label file.
- The multi-user, enterprise-wide workflow system provides review and approval of label designs and data.
- Variable manufacturing data are pulled from validated interfaced systems, merged with an approved BarTender template, and then the label is printed.
- The company is protected through reduced error potential, full audit trail capabilities, and compliance with electronic signature requirements.
- The system is fully scalable to meet the serialization and traceability provisions of DQSA and other global regulations as they come into force.

Innovatum

+1-770-945-4595