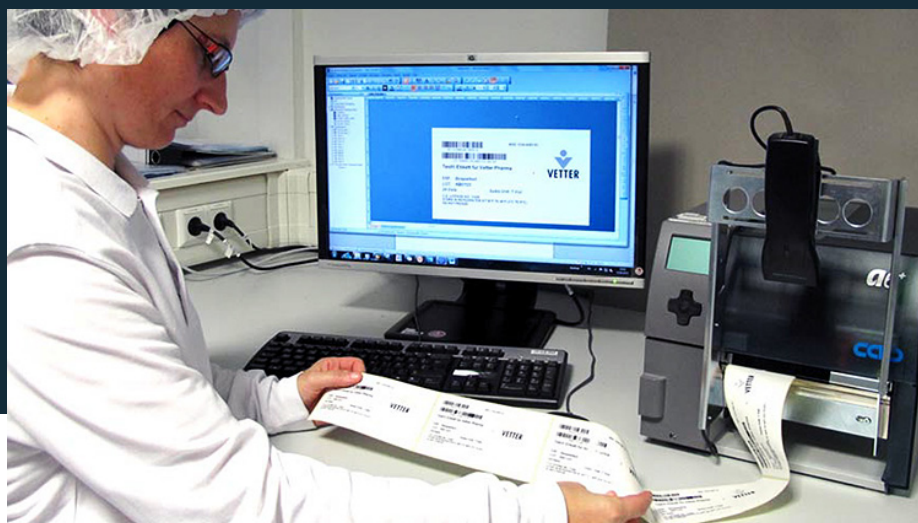


REGION
Worldwide

USE CASE
Pharmaceutical

COMPANY SIZE
Enterprise



Key Benefits

- User-friendly operation
- Stable, easy-to-use application in SAP®
- Flexible labeling processes and printer incorporation
- Quality improvements through automatic sourcing of variable data
- Scalable solution
- Incorporation of serialization

Vetter Pharma ensures patient safety with centralized, SAP-integrated BarTender® solution

Vetter Pharma integrates BarTender with SAP to create customizable GMP-compliant labels for its syringe and cartridge production—accommodating specific customer requirements, product traceability information, and serialization schemes.

Accurate, traceable labeling during the clinical development, manufacturing and packaging of syringes and cartridges is crucial to patient safety. Since 2012, Vetter Pharma has used SAP-integrated Label management software, which includes Seagull Scientific's BarTender software, from AutoID specialists OPAL. The result: Top-quality, compliant labeling processes.

Vetter Pharma-Fertigung GmbH & Co. KG is a leading global pharmaceutical service provider for clinical development and commercial production of parenteral medications. The company specializes in the aseptic filling of syringes, cartridges and vials. Vetter manages the entire product life cycle in its processes, supplying pharmaceutical and biotechnology companies throughout the global market with services including pre-clinical development and regulatory approval. Overall, the company employs about 3,300 people in Europe and the USA. Annual production of approximately 180 million units makes Vetter the global market leader in the pre-filled injection system sector.

About 2,000 cartons packed with injection products leave the facility in Ravensburg every day. Every carton is given its own shipping label, which adds up to about 450,000 shipping labels produced annually. "We are contract manufacturers, which

means that we do not provide medication directly to the market ourselves, but simply deliver the finished products to our customers, the pharmaceutical companies. Our customers determine how the labels are created — each customer needs specific information on the label for its own subsequent processing work,” said Vetter’s SAP key user production manager. The labels produced by Vetter must accommodate different layouts, logos and fonts. 1D Barcodes and Data Matrix codes contain a range of variable details, including batch number, expiration date, customer material numbers and regulation-mandated serialization schemes.

Creating label layouts using BarTender from Seagull Scientific

The company has been using BarTender label design software to create its label layouts since 2005. The BarTender Enterprise Automation edition includes powerful functions for managing Vetter’s required label design standards and for easy integration with Vetter’s existing SAP technology infrastructure. “This enterprise-level software tool enables us to quickly print perfect barcode labels. It is extremely user-friendly to work with, and for newcomers it is also easy to learn.” The software’s flexibility is also very popular at Vetter: BarTender supports all Windows fonts and printers, with system-wide support for Unicode.

Integrating labeling process with SAP

Vetter’s continuous quality improvement strategy led the company to seek a new labeling solution that would enable the company’s existing SAP system to print BarTender labels. “We’d had an excellent experience with BarTender label design software, and we wanted to import our label formats from our existing stand-alone implementation of BarTender,” said the manager of Vetter’s IT applications division. Vetter also required version creation, secure access to the label formats and direct control of the printers, and complete GMP labeling standard compliance.

AutoID-specialist with SAP-expertise

After researching available labeling technologies, Vetter chose to implement the OPAL SAP-integrated Labelmanagement system. OPAL’s extensive experience in over 500 large, complex SAP – BarTender labeling system integrations, factored in the decision.

Installation of a 3-system environment

OPAL installed a three-system environment (development, testing and production) according to Vetter’s requirements, enabling the creation, printing and administration of the labels directly via the SAP system —many parameters are available as standard options in the OPAL Labelmanagement software. Label formats, label printers and location specifications are administered directly through the OPAL SAP-integrated system.

According to Vetter, label formats can be set up quickly, with no software development skills required. The Labelmanagement system is user-friendly and was easy-to-use right from the start. The Vetter team is also pleased with the built-in security throughout the label creation process. Every layout modification is logged by the OPAL software, as required by GMP. Any hardware malfunction generates an immediate notification, so the system operator can intervene right away.

“OPAL supported us not only in the system’s implementation, but also with its validation documentation, and troubleshooting. We’re very satisfied with the services we received, and with the training provided to our employees.”

Conversion and Go-Live

The complete system conversion took place over the course of six months. Label formats were configured during this phase, facilitating a smooth transition to the new, integrated data sourcing process. Upgraded software was installed. The new system went live during the second quarter of 2013.

“Our new system has realized an enormous increase in quality. The OPAL and BarTender solution ensures correct GMP version creation for automated label printing processes, with a transparent audit trail captured along the entire processing chain. We plan further integration in these processes as part of our ongoing serialization projects.”

—
Manager Responsible for SAP Key
User Production for Vetter

Transparent label printing process

Today, Vetter packs, palletizes and prepares units for shipment using its state-of-the-art packaging lines. Customized label layouts are saved for every item. An electronic catalog of the label class data required for each customer and product was assembled, and enables functions like conditional printing or other languages to be automatically integrated in the label design process. Specific information, such as the customer material number, order and batch numbers, is pulled directly from SAP with each order.

Label printing using industrial printers

Approximately 30 industrial label printers from several different manufacturers are used at the Vetter facilities. Printing commands are initiated in SAP, providing data recording and printing of the batch protocol. Direct control of labeling can also be set up using the new system: "Since a new label does not have to be created for every print job, we can now load the correct label media in the printer in advance, and with the click of a button select the right label to print.

Quality improvement thanks to automated data provision

According to Vetter, the automated management of data within the labeling process has resulted in further quality improvements. "Populating the variable data on the label directly from the database completely eliminates the need for manual input. This guarantees that we provide the correct data on the correct label. We now operate a complete SAP-integrated, automated Label management solution," said both of Vetter's IT experts. The system provides GMP-compliant versioning and a complete audit trail of label formats. "Now we always know by whom, for what product and when a format was changed, and who initiated the blocking or the release. This enables us to meet all of our obligations for documenting the labeling processes."

Expansion through serialization

Serialization capabilities have been added, expanding the scope of the system for compliance with global pharmaceutical traceability regulations. Each product now is marked with an individual serial number, which is registered with the appropriate regulatory agencies, where necessary. "Another advantage of the OPAL Label management solution is that it makes this process scalable."

Vetter is currently considering a change from batch-level printed stock to printing the individual labels on demand, when the package is created. "Every batch is currently prepared using the batch protocol. The number of labels corresponds with the order quantity. They can be printed as stock and affixed manually. We are now considering decentralized printing, which means that whenever a package is created, the printer will print out the label. The label could be printed on-site at various locations once the package has been created and it has been registered in SAP."