CASE STUDY

Enabling compliance and accelerating go-to-market with cloud-based labeling

Migration to Loftware achieved 100% label accuracy

Founded in 1958, W. L. Gore & Associates is a privately held company with over 12,000 Associates worldwide. The company has made its name by creating innovative, technology-driven solutions, from medical devices that treat aneurysms to high-performance GORE-TEX® fabric. Gore has more than 3,500 unique inventions worldwide and manufacturing sites in the United States, the United Kingdom, the Netherlands, Germany, Japan, and China. A world leader in membrane technology and biomaterials, the company's medical device manufacturing division has more than 40 million devices implanted worldwide – including vascular Enabling compliance and accelerating go-to-market with cloud-based labeling grafts, endovascular and interventional devices, surgical meshes, sutures, and staple lin reinforcement materials.

W.L. Gore's relationship with Loftware dates back over a decade when it used Loftware's printing applications to manage labeling for its medical device manufacturing business. By implementing Loftware Print Server (LPS) in 2014, the company increased the efficiency of its labeling operations. However, challenges remained. In 2018, W.L. Gore decided to migrate from LPS to Loftware with a specific goal in mind: To create an electronic image capture (DHR) of each label it printed, so it could respond to audit requests more efficiently.

Challenges & solutions

Maintaining compliance by reducing audit response time

During audits, W.L. Gore would get numerous requests to produce or reproduce a label that was previously printed. Prior to migrating to Loftware, accommodating these requests took time, as there was no straightforward way of reproducing a printed label in the system. Thus, the main driver for migrating to Loftware was the ability to create a DHR image that would support audit requests. Gore wanted to remove the need to print and manage a separate label and make it easier to archive and retrieve previously printed labels.

Now, each time a label is printed, Loftware generates a PDF copy of each label, and saves it in an archive. The W.L. Gore team has created an internal user interface that enables any user to easily retrieve printed labels from a cloud database during an audit.

Improving speed-to-market
Before implementing Loftware, W.L. Gore typically needed four to six months to design, approve and implement new labels, with half of that time being spent on the regulatory review process. This long processing time could delay bringing products to market.

By moving to Loftware, the company was able to enhance and expand the integration between its labeling, Product Life Management (PLM), and Enterprise Resource Planning (ERP) systems. Loftware stores the format and image files for each label, as well as the printers. The PLM identifies the label type and production format and image files for a given SKU. And the ERP maintains specific GS1, UDI (Unique Device Identification) and production run data. W.L. Gore can now take a more modular approach to label design and change management that has helped to decrease processing time. By using Loftware's out-of-the-box functionality, such as variable text fields, formulas for building UDI-compliant barcodes and avoiding overlapping information in label designs, the W.L. Gore team has streamlined the label creation process and improved label consistency.

Using automation to eliminate errors
Integrating Loftware with its PLM and ERP systems has also helped W.L. Gore to address another key challenge: automating its change management process. The entire process – from label creation to barcode testing, to distributing approved files to the print server for production – consisted of a series of manual handoffs. Each handoff increased the likelihood of errors.

With the PLM integration, W.L. Gore can ensure that all label updates comply with its Quality Management System (QMS) and that all files are reviewed and approved prior to use. Now, the team can create sample labels using system data from the PLM and label files from Loftware, and, if needed, submit them for regulatory approval. Once a change is approved, the team can deploy it to the regions for use on a specific time and date. During the entire review and approval process, the Loftware file structure enables the team to isolate the in-process and in-design files from production files, which prevents labels from being printed prior to approval.

We were able to go from a 30-minute conversation with an auditor about how we can produce a label, to a couple of minutes to log into the system and provide the actual label image to the auditor. This was well received by all our auditors during our audits."

Michael R. Kinnett
Product Labeling,
Medical Products Division

Increasing customer responsiveness
W.L. Gore aimed to enhance its adaptability and responsiveness to customer requests. Generally, accommodating unique customer-specific requirements often led to creating one-off, specialized solutions, which increased operational complexity.

A new modular approach to label creation has helped address this challenge as well. Rather than relying on a single format and image combination for an SKU to produce a label, the Product Labeling team can now use a single format with more than 500 images to support multiple SKUs – in some cases 100-200 SKUs within the same family. Thus, they can support over 3,800 SKUs with only 75 label designs and 7000 image files. The team can easily swap format files and images based on customer needs, quickly adjusting languages, product brand name, size details, information, and instructions on the labels to comply with regional customer or regulatory requirements.

Expand label printing across the globe
W.L. Gore's final objective with the migration was to equip its regional teams, partners, and third-party logistics to easily handle labeling operations. This would enable them to process returns more quickly, eliminating inefficiencies in their processes and reducing processing costs.

Loftware Cloud removes the need for storing label format and image files on premise. Now, all users can use the same files without needing to replicate data or create local file versions. And IT teams no longer need to manage label design and deployment.
The US-based Product Labeling team designs, manages, and approves the labels and uploads them to the cloud, where regional partners can use and print them as soon as the changes are published. All the labels are designed and managed in the same manner, which ensures consistency across markets and languages.
The team supports 24/7 label printing in the United States, the Netherlands and China.
For finished goods labeling alone, this involves managing 15,000 daily print events to 85 printers in all supported regions.

We went into this migration with the idea that we would only be migrating our current data to Loftware to gain the DHR file print event. But after evaluating the system, we discovered many more features we could leverage to advance our labeling and printing capabilities. These have been instrumental in changing the way we provide labeling across the globe."

Results

Increased speed-to-market by 50%

After the migration, W.L. Gore reduced the processing time for designing, approving,
and implementing new labels from four to six months to two to three months. Depending on the update, the Product Labeling team can support changes in days rather than months. And if there is a necessary, required change to a regional label, the team can make the change within days.

100% accurate labeling

Pulling the data from the company's business systems has enabled W.L. Gore to create the proper channels for pulling data into the labels and build error-proofing into the label creation process. Now, the system will only print a label when accurate information is provided. If there are any data or information inconsistencies, the built-in error handling mechanisms will stop the label from printing. These measures have helped W.L. Gore achieve 100% label accuracy.

Increased processing volume by 50%

Originally, W.L. Gore was constrained to only 52 labeling updates annually, hindered by the complex manual review and approval process. With Loftware implemented, they now efficiently handle 100 label changes each year.

Greater flexibility across the board

The ability to service specific customer needs is now a part of W.L. Gore's core capabilities. By integrating labeling with key business systems, automating manual processes, and expanding label printing to regional offices, the company can now adapt quickly to changing requirements. Whether it's input from customers or updates to regulations, the team can understand the update that's necessary, and review, approve, and deploy it to the regions, or across the entire organization, if necessary. In the future, W.L. Gore hopes to increase its regional labeling footprint and expand printing capabilities in other countries.

By migrating to Loftware, W.L. Gore & Associates has modernized and future-proofed labeling, and benefited from the following results:

+ Improved speed-to-market by 50%

+ Achieved 100% label accuracy

+ Increased processing volume by 50%

+ Reduced label creation and update times from months to days

+ Automated label design and management to easily meet complex regulatory requirements

+ Simplified auditing processes to enable compliance

+ Enabled regional offices and external partners to print consistent labels