Delivering World-Class Compliance Solutions Since 1993

CASE STUDY: Enterprise Compliance Labeling Software for the Life Sciences

Overview

Country/Region:

United States and Europe

Industry:

Life Sciences – Medical Device/*In Vitro* Diagnostics Manufacturer.

Customer Profile:

Customer, based in Europe, is a global leader in tissue-based diagnostics. Customer employs more than 1000 people and operates in more than 70 countries.

Business Challenge:

Customer sites in the U.S. and Europe used four different custom software systems for regulated labeling; resulting in regulatory risk, inefficient & redundant processes; and a costly burden on internal IT and RA/QA staff for ongoing system support, maintenance and validation.

Solution:

Using Innovatum's ROBAR Enterprise Label Management System and Innovatum Consulting Services, Customer consolidated labeling under a single global platform with unified data, images and SOPs.

Benefits:

- 30% reduction in label stocks
- Increased productivity.
- Reduced operating expenses
- Unified label data & SOPs
- Reduced regulatory risk.
- 24/7/365 Vendor Support

Labelicious – A Tale of Globalization

Leading Manufacturer of *In Vitro* Diagnostics Ensures Global Labeling Compliance with ROBAR Enterprise Label Management System

Executive Summary

As a leading manufacturer of consumer medical products with global distribution, this customer's finished goods must be labeled in accordance with a variety of regulations imposed by the FDA (*e.g.* 21 CFR Part 11, Part 820, *etc.*), as well as the EMEA and other international regulatory agencies. Until recently, the customer managed regulated labeling with a total of four different label software systems between its two production facilities located in the U.S. and Europe.

All four systems were significantly older, highly-customized and operated independent of one another. Moreover, 3rd-party support/maintenance was virtually non-existent given the advanced age and custom nature of the various systems. Consequently, the customer's global labeling operations were fraught with compliance risks, redundant & laborious procedures, and an ever-growing burden on internal IT and Quality resources for ongoing support, maintenance and system validation requirements.

Recognizing these risks and inefficiencies, the customer partnered with Innovatum – a leading provider of enterprise compliance software and services for Life Science manufacturers – to replace all four applications with Innovatum's ROBAR Enterprise Label Management System. ROBAR's client-server architecture, enterprise-class back-end database and XML integration interface, enabled the customer to consolidate and standardize its label templates, images and data under a single, global platform with role-based access rights, electronic signatures, comprehensive audit trails and vendor-supplied 24-7-365 support & maintenance.

As a result, the customer eliminated regulatory exposure, streamlined labor-intensive SOPs and removed the costly burden of ongoing system support and validation from internal IT and Quality resources by globalizing regulated labeling operations with ROBAR.

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"The software being used at both sites was problematic at best. The main software solution in USA had been developed by a 3rd party no longer interested in supporting a one-off labeling system."

- Regulatory Affairs Labeling, Customer.

Business Situation

The systems, procedures and data employed in the labeling of consumer medical products for U.S. distribution are governed primarily by FDA 21 CFR Part 11, Part 801 and Part 820. For distribution outside the U.S., Life Science manufacturers face additional compliance requirements from international regulatory agencies, such as the EMEA in the European Union.

While details vary, the basic goal of these regulations with regard to labeling is to ensure the adequacy of label systems, procedures and printed content to prevent errors that could jeopardize patient safety. The operational implications for Life Science manufacturers center mainly on system security, data security, change control, transactional data retention (*i.e.* audit trails) and documented validation of label systems and SOPs. Until recently, however, there were no commercial off-the-shelf (COTS) label applications available that could effectively meet these regulatory requirements "out-of-the-box."

Like most Life Science manufacturers, the customer initially addressed label compliance requirements with "home-grown" systems built from a combination of commercial software and custom programming, and validated by internal Quality/Regulatory staff. As the customer's needs evolved, additional requirements were met with new systems, manual SOPs, or a combination thereof.

Ultimately, this resulted in four different custom systems for regulated labeling at the customer's U.S. and European manufacturing facilities. Thus, while many of the customer's products are manufactured at both locations, labels printed at one facility often used different layouts and/or content than those printed at the other facility for similar products. Labeling SOPs also varied significantly between the sites.

This not only put the customer at risk for non-compliance, but it also hindered the ability to improve productivity and operational efficiency via unified system resources and SOPs. Moreover, the low level of 3rd-party support placed a heavy toll on internal IT and Quality staff for ongoing support, maintenance and validation of four different label systems; resulting in substantial long-term operating costs.

Solution

Recognizing the risks, limitations and costs of its multiple custom label systems, the customer assembled a project team of IT, Quality, Regulatory and Production staff from the U.S. and European facilities to evaluate potential solutions. One of the primary goals of the team was to globalize not only the labeling solution, but also the look of all the labels and the label stocks that they're printed on.

After reviewing the available commercial systems for regulated labeling in the Life Sciences, the team selected Innovatum's ROBAR Enterprise Label Management System to replace all four of the existing custom label systems between the U.S. and Europe. The

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customer also utilized Innovatum Consultants to aid in project planning, implementation, integration and validation of the system at its production facilities.

Among the key factors in their decision were Innovatum's extensive experience in – and focus on – regulated Life Science production environments, as well as ROBAR's proven capability to manage regulated labeling operations for other leading Life Science manufacturers in a multi-site, international implementation.

Benefits

Since going live with ROBAR at its U.S. and European manufacturing facilities, the customer has realized the following benefits:

- 30% reduction in the number of label stocks, creating better volume discount opportunities, and availability across sites.
- Reduced system maintenance associated with upkeep on four separate systems
- Increased productivity and reduced errors in production via simplified user interface.
- Improved regulatory compliance, all but eliminating the risk of costly label-related CAPAs.
- All labels now conform to a corporate-wide visual branding standard regardless of the site at which they were manufactured.
- The label system is now global, with 24/7/365 support from a vendor with 17 years experience in the Life Sciences.
- Product builds are now managed under a single platform without the need to create new labels in different systems, or new label stocks at different sites.
- Expertise on the labeling system is no longer centered on a single individual, but is shared across sites and positions.

"All in all, I think that the Global Labeling Project was an outstanding success for everyone involved."

- Regulatory Affairs Labeling, Customer.

For More Information

For more information about the ROBAR Enterprise Label Management System and Innovatum Professional Services for the Life Sciences, call (877) 277-3016 or visit Innovatum's Web site at: www.innovatum.com