

Factory Labeling Migration Following Business Acquisition

Kallik + Major Global Medical Device Company



Veraciti™ has enabled not only greater control and compliance for our customer, but also allowed a rapid relabeling of 9,000 products as part of a new acquisition.



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Introduction

Headquartered in Ohio, this US based company is a leading provider of customized solutions for hospitals, health systems, pharmacies, ambulatory surgery centers, clinical laboratories and physician offices worldwide, with approximately 50,000 employees in 46 countries.

Business Drivers

Risk of non-compliance

Faced with increasing complexity of regulations, markets and languages, plus a burgeoning volume of label changes and additions, the company recognized their existing in-house labeling solution could place them at risk of non-compliance. Governed by FDA regulations, errors anywhere in the labeling process could have resulted in labeling inconsistencies causing product recalls and punitive fines.

Lack of control

The provider also wanted to ensure they had accountability to each piece of content that appeared across labels, packaging and IFU's - something their current solution was unable to provide. Largely manual and disconnected labeling processes resulted in no one version of the truth, duplicated data, labelling inconsistencies and a complexity that could not scale to match the demands of the business. Much of their quality processes were paper based, limiting corporate level visibility and making it difficult to prove compliance.

Handling a major acquisition

With a new acquisition taking place around the same time, this acted as the catalyst for procuring a solution that would replace both their existing in-house system and de-risk the integration of the newly acquired business. Over 9,000 products needed to be relabeled whilst manufacturing continued uninterrupted at the existing plant, before subsequently migrating the recently acquired company production lines to brand new facilities, all with zero downtime. This required re-branding and transitioning factory label printing to new facilities within extremely challenging timescales. Failure to achieve this would result in excessive financial penalties and potential non-compliance with FDA regulations.



During the initial phase, content changes included standardised addresses, update translations, standardised usage and warning symbols.

Why Kallik?

The medical device company chose Kallik's Veraciti™, to replace both its existing factory print supplier and artwork management system with full integration to their ERP solution. Kallik's Automated Artwork Generation (AAG) server along with its factory print capabilities were also selected as part of the solution, deployed as a SaaS and validated throughout its implementation.

Veraciti™, with its support for 21 CFR Part 11 electronic signatures, would eliminate the use of paper-based quality processes. The option to make specific fields mandatory for certain individuals meant that the information was fully audited and could be passed through the business. Using Kallik's 'Project Brief' to replace Excel and email based content collation would improve communication to artworkers, reduce effort for approval and manuscripts and enable the business to meet the following strategic goals:

- Drive cost out of the labeling process
- Reduce the time taken to review and approve artworks
- Provide flexibility and agility whilst creating a platform and process for future growth
- Enable comprehensive reporting against business KPI's
- Eliminate the need to install on-site IT infrastructure
- Provide greater accountability, process transparency and robustness

Solution

A solution was sought that would allow thousands of labels to be changed whilst production of products remained within the facility of the acquired business. They required transparency and control of the data to demonstrate that every piece of content of the new acquisition had been removed from the old labels within the timescales set to avoid penalty clauses. To do this, was necessary to first get control of the data by exporting all of labeling content from the existing internal IT systems into the Kallik solution.

The labels and IFUs of the acquired business were re-created with their new company branding and manufacturing address within the Kallik solution. Once this was completed, the production and print facilities located in the existing site were connected to Veraciti™, removing any dependency on legacy IT and printing facilities. This gave transparency of label updates and print processes with full audit trails from day one.

This was a significant step in de-risking the integration process of the acquisition, granting the executive team complete transparency as well decoupling the labeling changes from the future physical move of the production lines to the new site. Kallik's solution gave them the transparency and control they needed to make and report on label changes and provided a head start on the transition of the recent acquisition production facilities by initiating the change process within their manufacturing site.

10,000

labels changed in

8 months

ahead of the migration of the production and print facilities to the new site

Benefits

- Transition of the new business acquisition facility completed both on-time and within budget.
- Reduce stock of pre-printed templates reducing inventory costs.
- Avoided potential IT bottlenecks associated with installing their own infrastructure on the previous premises by utilizing Kallik's cloud hosted software, this enabled the new business print lines to be driven by Kallik's factory print solution whilst they were still in the old site.
- Easily relocate the recent acquisition production lines to the new facility, knowing that label content and print production had already been proven within the old site.
- Capture historical manual paperwork processes within the Kallik solution, bringing clarity and due diligence to previously approved content.

To find out how we can support label and artwork management transformation in your business, please get in touch by emailing us at enquiries@kallik.com

About Kallik

Kallik delivers trust in the label, process and brand for highly regulated industries. By connecting workflow and approval with dynamic content management, artwork assembly and printing, Kallik's cloud-based solutions bring integrity, traceability and transparency to global labeling processes.