

Coloplast Achieves New Benchmarks for Compliance, Efficiency and Consistency



We originally thought the issues we were trying to solve were limited to labeling, but we quickly realized that we had invested in a solution that enabled us to satisfy even the most stringent regulatory requirements.



Jette Byg,
Head of Global Labeling, GQA,
Coloplast

Coloplast A/S is a Danish multinational company that develops, manufactures and markets medical devices and services related to ostomy, urology, continence, and wound care. Kallik's Veraciti solution has achieved benefits for Coloplast in terms of speed of adoption and productivity gains and so enabling the business to minimize time to market for new product launches.

Challenges

In terms of its label and artwork management, prior to Kallik having a non-task driven PDF workflow underpinned by approvals sent via email was making it almost impossible to prove compliance. The entire process was time-consuming and making it difficult to track audit changes due to the large volume of artwork amends being processed. Coloplast also needed to react quickly and effectively to new legislation and regulation requirements. UDI was fast approaching and stakeholders knew their current processes would not fulfill business requirements and could potentially delay meeting key compliance targets.

"We simply didn't have the time or resources to meet required levels of quality without causing major delays," confirms Jette Byg, Head of Global Labeling, GQA, Coloplast, who is responsible for the end-to-end artwork process.

"This resulted in us being constantly behind and not able to prove compliance in acceptable time frames," she adds. "Ultimately, this led to delayed product launches."

As a result, Byg and her team started to look for a single solution capable of managing all the company's global labeling processes, from data collation to final print at the factory. A core requirement was that all content had to be manageable from within a single platform, including content shared with external production and print partners.

"We looked at many options, but Kallik's Veraciti was the only product that could offer this," she states.

How Kallik helped

Having satisfied themselves that Veraciti was the best fit, Kallik worked closely with Byg and her team to help rationalize label templates and artwork content to minimize the number of unique assets needing to be managed.

Since adopting the Kallik solution in May 2012, Coloplast have completed

80,000 projects and hold over

1.6 million files in the system.

This led to greater levels of standardization, while reducing the risk of duplication, she notes, adding that Kallik's unique Automated Artwork Generator has also been invaluable to the artwork production, enabling Coloplast to keep labels compliant within evolving markets.

Results

Having all the artwork data in Veraciti has also allowed Coloplast to automate the creation of a large proportion of artwork labels with one simple process. In practical terms, what once took a conventional artwork studio days/weeks to produce, now takes minutes — if not seconds.

"The results were obvious and very clear to us," says Byg. "We can now achieve global artwork consistency across all our brands, from multiple packaging formats and complex Information for Use leaflets."

Identifying and updating all labels impacted by regulatory and/or local market changes is also now much less of a challenge, she adds, as all impacted labels can be quickly identified, changed and automatically regenerated for approval using Veraciti's unique 'Where Used' function. "UDI compliance has also been made easier by simplifying the capture of labeling content required for submission to the Global UDI Database (GUDID)," she points out.

Due to the flexibility of Kallik's cloud-based platform and its ease of use, Coloplast has also been able to engage external business units to assist on large scale projects. Veraciti has also simplified entry into new markets such as South America, where countries such as Columbia require market specific labeling and packaging, says this delighted customer.





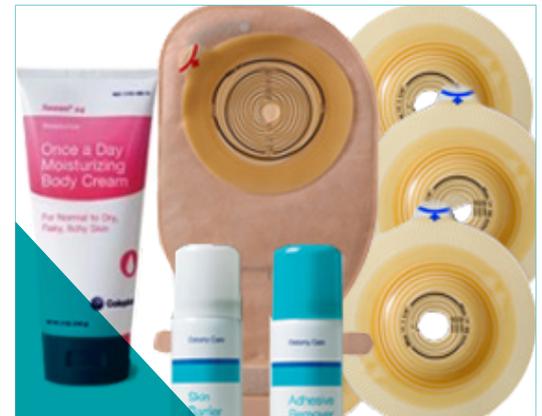
Our IT President stated that this was the first time he had not encountered any resistance to the introduction of a new system. Instead, users were asking for Veraciti implementation to be given priority over other projects.



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Head of Global Labeling, GQA,
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Business benefits at a glance

- Thousands of hours have been eliminated across review cycles since deploying Veraciti
- Full compliance adherence can now be proven in seconds as opposed to weeks or months
- Quick and easy access to latest approved assets including all phrases (content), imagery and cutter guides now guaranteed
- Unprecedented levels of process transparency, with the regulatory function becoming the greatest advocate of the solution
- Data can be safely and securely shared globally, internally and with Third Party Designer Studios, Printers and Manufacturers
- Accurate business insight not guesswork to enable management by truth now deliverable.



About Kallik

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