Maintaining Labeling Compliance In Highly Regulated Industries (GxP Validation)

A White Paper from Kallik

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Computerized systems validation is essential for medical device and pharmaceutical manufacturers. Here, Beth Peckover, VP Global Delivery at Kallik, pinpoints the three areas businesses need to get right to ensure computerized systems used for labeling meet all GxP requirements set out by industry regulators.

Validation of computerized systems is a non-negotiable requirement enforced by regulators such as the FDA in the U.S., EMA in Europe, TGA in Australia, and HS-SC in Canada. The ability to demonstrate adherence to appropriate practice and processes that underpin a quality driven, risk-based approach to computerized systems validation is a pre-requisite to being able to operate in any highly regulated market, including medical device and pharmaceutical manufacturing.

As part of GxP regulations, manufacturers involved in these highly regulated industries must adhere to good manufacturing practices (GMP) defined as "a system of processes, procedures, and documentation that help ensure that products are consistently produced and controlled according to quality standards." It's necessary to zero in on GAMP 5 guidance for GxP computerized system compliance and validation – this is the standard regulators work to.

Outdated labeling systems are in need of overhaul

Enterprise labeling is a classic area where computerized systems play a vital role in providing the highest quality and most accurate description and branding of products, such as medical devices and pharmaceuticals. Meeting these regulations requires applying the best quality management systems and standard operating procedures (SOPs) to the design, development and delivery of labeling software.

Medical device and pharmaceutical labeling is ripe for modernization, but many manufacturers are still using outdated systems for product labeling because they are not willing to bear the validation burden of implementing a new system. Validation of newly built computerized systems is an involved task. It can take several months to complete successfully. Usually, it entails performance, operational and infrastructure qualification of regulated systems used to manufacture medical devices and pharmaceuticals.

Product recalls carry a heavy cost

Correct labeling is a key requirement for manufacturers of medical devices and pharmaceuticals. Analysis of FDA drug recalls shows that, between 2017 and 2019, 14.9% of recalls occurred due to labeling issues. Recent statistics also highlight that 9% of global medical device recalls were due to label errors, equating to over one million items.

The FDA explains that medical device manufacturers must incorporate several elements in their quality assurance (QA) program that relate to labeling in order to meet the GMP requirements of Quality System regulation. The potential damage to consumers and company reputation due to a recall from not meeting these standards is extreme – patient safety can be put at risk and businesses shut down because of incorrect labeling.

Putting in place a bespoke computerized system for labeling requires significant effort

But validating a new computerized system is an involved task. Many medical device or pharmaceutical manufacturers find themselves in a catch-22 situation when assessing their labeling system options. On the one hand they may have a legacy labeling system, which is in need of updating but is validated – on the other, developing a new system requires full validation from scratch.

Developing a system in-house puts the entire validation burden on the medical device or pharmaceutical manufacturer themselves. If a manufacturer cannot trace the driving factors behind why a computerized system was built or selected, or how to satisfy and test them, then it becomes challenging to establish whether the system is fit for purpose.

The lack of a proper definition of why a particular system is in place can lead to inconsistent and incomplete computerized systems, as well as feature creep gaps when deploying the system. If a manufacturer does not document their requirements and testing process clearly, it becomes impossible to claim to have a compliant system in place.

Ongoing compliance adds further cost and process headaches

Manufacturers are likely to incur high costs and spend more effort in the validation of their own bespoke on-premise applications when labeling processes update or develop – because the responsibility of performing the qualifications after each release is on the organization themselves.

And constant rule assessment doesn't stop there. Requirements must be kept up to date throughout a software system's lifecycle. To ensure all regulations are followed through on a regular basis, manufacturers are required to establish standard operating procedures and a lean governance structure to interpret all regulations and requirements on the organizational level, and ensure action is taken where appropriate.

Validation-ready alternatives

Thankfully, there are pre-validated third-party solutions which can ease the compliance pressure of having a modernized, best practice labeling system. Such a solution should build and demonstrate GxP compliant processes across the creation, review, print and publication of all product and package labeling, in particular, software and processes that align to GAMP 5 quality guidelines and 21CFR Part 11 regulations.

With this in mind, there are three critical areas to consider when setting criteria for a validated enterprise labeling system.

1. Validation straight out of the box

An alternative option to developing a bespoke solution in-house is to leverage existing software on the market. This can be locally installed 'on premise', but having the software delivered in a software as a service (SaaS) model can offer significant benefits when it comes to efficient validation, both during the initial implementation and as part of the ongoing maintenance of the system.

By using software which is hosted in the cloud, the software provider takes responsibility for the IQ/OQ validation activities with each software release, meaning the manufacturer minimizes their own validation efforts and cost with a 'validation-ready' software system.

2. Transfer the validation burden to your supplier

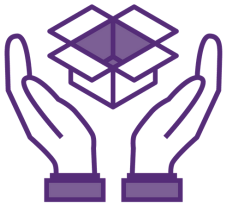
Beyond delivering a validation-ready system, a software supplier who is experienced in delivering validated software to regulated customers will have the capabilities be able to further relieve the burden by taking responsibility for other aspects of the validation if requested, such as creating a traceability matrix or writing the test scripts to be using during user acceptance testing (UAT).

It's possible to 'outsource' the majority of these activities to the supplier, leaving only the execution of the UAT to the manufacturer.

3. Regulated industry alignment brings compliance expertise and collaboration

Working with a trusted software partner brings industry-wide compliance expertise and knowledge. While every medical device or pharmaceutical manufacturer will have their own unique processes and business requirements, there are common industry challenges and scenarios which medical device and pharmaceutical labeling software providers will have encountered before. An industry-specific partner should speak the language of GxP and GAMP 5, with in-house experts dedicated to continuous education and training to stay up to date with latest guidelines and best practices.

This enables that partner to collaborate directly with a manufacturer, consulting with them on how changes to labeling may impact compliance going forward and discussing steps required to make sure new processes adhere to current best practices.



Guarantee a validated platform

The speed of change in information technology, combined with constantly evolving manufacturing processes makes adhering to GxP and GAMP 5 regulations in highly regulated industries a continuous task. This quickly becomes unsustainable when a manufacturer weighs up the compliance pros and cons of deploying a bespoke on-premise system for enterprise labeling.

Partnering with a reliable software provider becomes a critical factor in guaranteeing computerized systems validation, creating a platform for compliance with industry mandates now and into the future. The result is a collaborative and efficient process that satisfies compliance and eliminates risks and delivers huge value to your manufacturing processes.

About Kallik

Kallik, the enterprise labeling company, provides regulated industries with a responsive, end-to-end label management platform they can trust.

Its cloud-based labeling platform, Veraciti™, delivers definitive compliance and supply chain efficiency for all the content assets that make up product packaging, labeling and customer information documents. From barcodes to safety symbols and text, Veraciti manages any format, in any territory, on any material and via any channel - with complete reliability and traceability.

Medical device manufacturers, pharmaceutical firms, chemical and cosmetics companies use Kallik to deliver trust in their labeling, confidence in their brand and integrity in their process.

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.