

Enterprise Labeling Management in Heavily-Regulated Industries: 5 Critical Success Factors

A White Paper from Kallik



Something that pharmaceutical/biotech firms, medical device manufacturers, cosmetics companies and oil/chemical processors all have in common is the need to satisfy strict safety controls, including clear product labeling and product traceability. Regulatory rigor is intensifying, and so too are the pressures to bring enterprise labeling under coordinated control. There are some common considerations with any software implementation which are critical to get right. Here, based on her years of experience of working with clients across heavily-regulated industries, Beth Peckover, VP Global Delivery at Kallik, sets out 5 proven success factors for achieving the desired benefits of an end-to-end global labeling management project.

I. Be Clear Where You're Going and Why

Typically, the way organizations manage their labeling in response to regulatory driven changes or product enhancements is far from what could be considered best practice, perhaps due to historical factors or the limitations of existing systems and processes. If they then go on to implement externally-sourced software, this may be with an expectation that the system will need to be adapted to their existing processes. This can, however, compromise the opportunity to deliver real business transformation.

Given that 80% of labelling projects are driven by time-consuming labelling changes, it's essential to look for transformation opportunities enabled by new software. Being able to easily handle mass changes should be the goal of every organization, particularly with the ever increasing volume of regulatory driven changes. Often, state-of-the-art software will have been designed in close cooperation with organizations that want to improve the way they operate - because of previous frustrations and shortcomings. By embracing opportunities for transformation at the project outset, organizations will be better placed to deliver new productivity and process gains, leading to greater profitability and reduced risk of errors and non-compliance.

An in-depth understanding of the capabilities of their solution, the vendor can also help customers exploit the new software's full potential, advising on optimal adjustments or improvements to current practice to bring these more closely into line with what works well in other industries, or peer organizations. The software is likely to have been deployed in a wide range of scenarios around the world, which means it is likely to incorporate the latest industry best practice to facilitate enterprise-wide transformation.

It's also important to keep in mind your starting point and desired destination. Establish a baseline and keep your project's business objectives in mind. Setting measurable business objectives, such as increasing speed to market for new products or reducing product recalls due to labelling errors, is an essential prerequisite for measuring project success. Plotting where you are on a labeling maturity model, and identifying steps needed to achieve target maturity, is also good practice. Often the first step is to implement some form of electronic label approvals to move away from unreliable paper-based systems. This is why we encourage our clients to map out their existing processes before embarking on any implementation. This exercise should focus on identifying pain points or bottlenecks, what works well today, and what is missing that needs to be addressed.

2. Make Change Happen

Re-thinking labeling can lead to increase sharing and greater re-use of content - reducing errors, increasing productivity, and driving consistency across global supply chains. **According to the 2019 Harvey Nash/KPMG CIO** survey, 44% of organizations expect major or radical change through business transformation projects in the next three years. Certainly, a transformational enterprise labeling project is about so much more than just the technology. To achieve your desired future state, people and processes will need to change too.

Teams in charge of deployment too often focus on the software implementation itself above any considerations around what will happen to processes, or be required of people. The assumption is often that some user training nearer the time will suffice, when actually there are likely to be stakeholders across the organization whose buy-in is crucial – but who in some cases will need considerable persuasion. Such naivety can lead to a failure of the delivery team to launch the new system, or poor acceptance or adoption by targeted users.



A successful change management project will rely on engaging all of the right people and taking them along on the journey. First, it's important to identify who all the various stakeholders might be. In the case of enterprise labeling, this could include engineers as well as regulatory and marketing resources. It is also a good idea to view potential stakeholders under two main categories: those who will be most influential in the new system's success, such as senior leaders and actual every-day users; and those who will be most affected, for example if something goes wrong.

Goals and expectations of the project should also be documented at this point by assigning Key Performance Indicators (KPIs) which can be reported on via the Business Intelligence (BI) capabilities of the new software. This insight will help to validate the business case and demonstrate the success of the project. This, in turn, will help facilitate further expansion and investment as the business and operational benefits become clear to executive sponsors.

Communication will be a significant part of the change management program – ensuring that all of the identified stakeholders have representation at key meetings and workshops, and understand the drivers behind the new system. Questions to address include: 'Why is the new software being implemented?', and 'What is it designed to achieve, and why is that important?' It's critical that the communications plan is mapped to different stakeholders' needs, and their current state of acceptance or resistance.

3. Drive Change From the Top

An executive project sponsor, who is ultimately responsible for the project's success and ideally responsible to the board, needs to be in place from the project outset. Software implementation can demand significant input from cross-functional teams and it needs to be someone with a broad understanding of the business to guide the wider team to a decision and redirect resources. An IT, Labeling, or Marketing Executive would be a good fit. The sponsor can also play an invaluable role in breaking down or transcending departmental silos – getting Regulatory stakeholders to understand Marketing's perspective and in turn that of Product groups.

Project representatives (some of whom are expected to be change agents, leading by example) are likely to be anyone involved in managing labelling projects - spanning Marketing, Regulatory, Product Management, Factory Print (ideally one person per site) – as well as the project sponsor, and a project manager to note and chase any follow-up actions. If the new software implementation is likely to have implications for any other third-party systems, in the context of integration and content sharing, relevant stakeholders here too should ideally be

present. Essentially, someone from any team that contributes information to labeling, is involved in labeling change approvals, or has a role further downstream in the printing process, should have a place at the table.

Once these people have been identified, the next step is to engage them and find out where they are in their attitude to the changes that are coming. Which are strongly in favor, and could be made 'change champions', for example? Which may be starting out as dissenters or resistors of change, and who might de-rail the project without careful handling? If there is considerable resistance, or if an impasse has been reached, it can help to bring in independent consultants who can help to voice any awkward questions, read the room, and propose a positive way forward.

4. Actively Engage the Right Stakeholders

It can feel like expecting a big commitment from busy people, to try to get all parties adequately represented at each meeting, this is the only way to both ensure your final solution is right for your business and to get stakeholder buy-in for the changes being made. Emphasis on the benefits for each stakeholder will help overcome resistance to change, and speed up adoption. It is also a valuable opportunity for each stakeholder group to hear from peers in other departments, so building up a rounded view of what's happening, why, and where any issues are arising.

The importance of involving the right spectrum of stakeholders, in the overall change management required to transfer to a new system, and associated way of working, cannot be understated. Usually, in the build-up to a new system rollout, there will be a series of workshops and it's important that all stakeholder groups are represented at each - not everyone impacted by the new system attend; just someone representing each perspective who can reflect the current mood and any concerns, questions, requests or other feedback. If each stakeholder group has someone who is reporting back to them on the latest developments, this will save a lot of repetition too.

In these meetings, everyone should feel that they have a voice and that they can put across their views or concerns without fear of looking foolish or seeming obstructive – so that the outcome is an ideal system configuration that works optimally for the majority.

It is essential to invite input from all stakeholders, all of this feedback needs to be assessed, considered and filtered to arrive at workable decisions. The disadvantage of being thorough and inclusive can be that it becomes hard to reach consensus, or to do so without diluting the impact of any transformation. Designating someone to challenge the status quo, consider and reject some requests, and make the final decision is advisable; otherwise project teams can become blinded by too many possibilities. It is rare for everyone to agree and this is where the executive sponsor should drive the discussion forward to a positive conclusion that the majority will accept, to enable continued progress.



5. Maintain Focus on the Business Objectives

In an ambitious project, it is all too easy for stakeholders or project teams to become hung up on the small details, such as particular features the existing software product doesn't have (which may have mapped onto old or existing processes, for instance). The more important consideration here should be whether any perceived omission is a barrier to delivering the improvements that are needed. If the small, missing details do turn out to be important, could they be addressed or added in later? Can you realize your business objectives without them?

To keep everyone focused on progress, the project sponsor should keep bringing teams back to why the change is being introduced; why an enterprise labeling management solution is needed, and the business objectives it is designed to fulfil. Typically, transforming global labeling management is geared to introducing coordinated control to formerly disjointed and highly manual processes, for the purposes of regulatory compliance, quality control, reliable auditing, and improved public safety – not to mention operational efficiency and cost control. The point of focus might be achieving the ability to see the current status of all labels, and a full audit trail of any changes and approvals, all in one place. This will mean that if a safety symbol has been wrongly applied, or needs to be updated, it is possible to manage that change holistically across the global organization within a matter of days. This mitigates risk, and is highly cost-efficient for the company, and is a level of control that is very appealing to regulators.

People Are the Biggest Determinants of Success

The overriding message to organizations reviewing their global approach to label management is not to underestimate the people element of the planned transformation. Rather, this should be a central consideration and facet to the project. It is something that the company itself must take ownership of too; it should not be left to the software provider to orchestrate.

The goal must be to prepare people for the transformation that's coming, and make them feel good about it - identifying change champions, and getting the word out there. Remember, especially when it is out-of-the-box software that's being implemented, the product itself is the known quantity – the element of the project that can be relied upon. It's the other elements that are less predictable.

A final point of advice, make sure that the change management strategy and communication plan are adjusted along the way, as the main project unfolds and evolves. Clear guidelines are vital, nothing should be set in stone as even the best laid plans can change over time.

Kallik: The Enterprise Labeling Company

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

Its cloud-based labeling platform, Veraciti™, enables compliance and delivers supply chain efficiency for all the artwork and content assets that make up product packaging, labeling and instructions for use (IFUs). 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, pharmaceutical, chemical and cosmetics companies use Kallik to deliver trust in their labeling, integrity in their process and confidence in their brand.