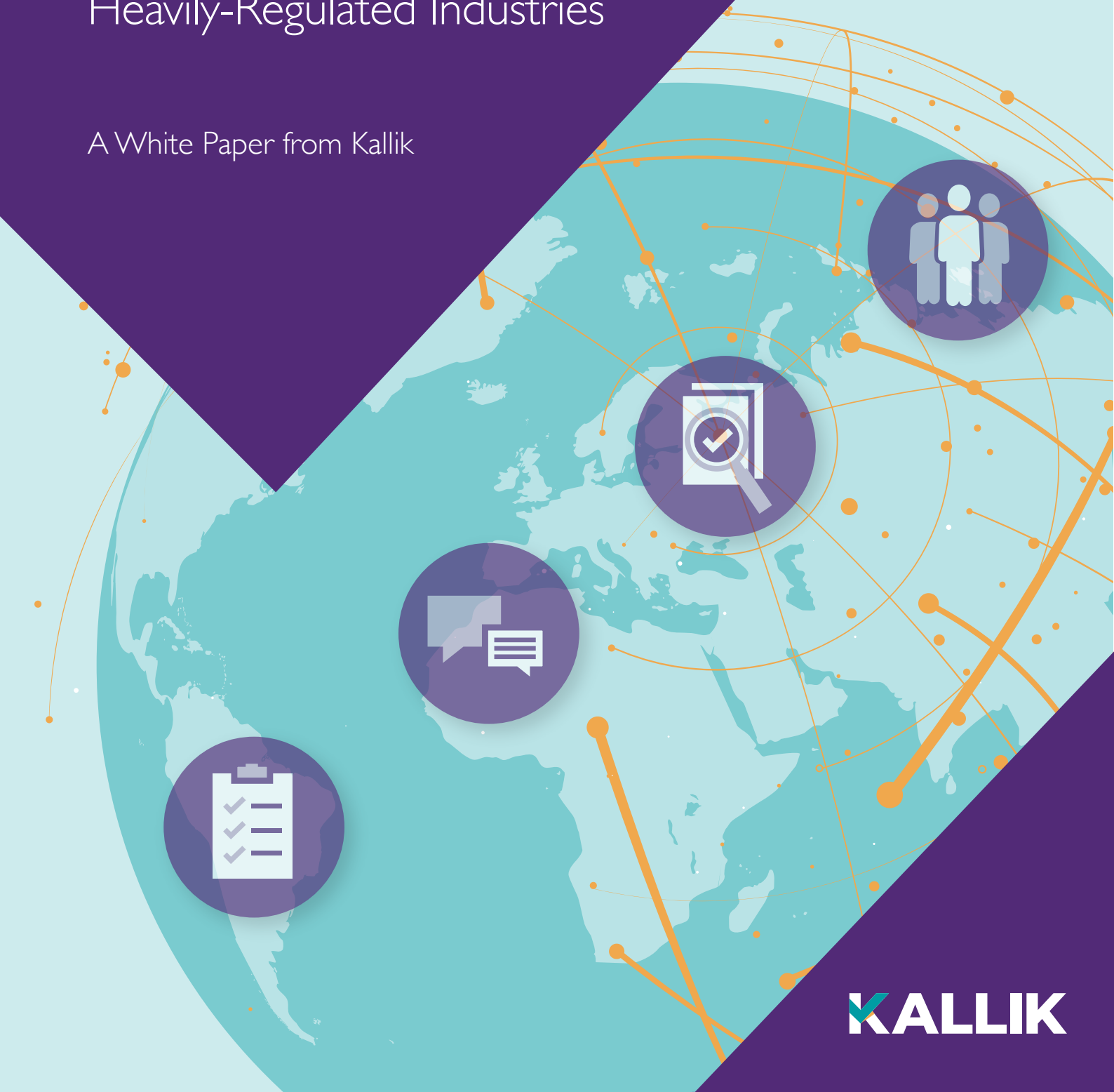
Establishing End-To-End Control Of Product Labeling & Customer-Facing Materials: 5 Focal Points For Improvement For The Year Ahead

A 2020 Guide For Cxos Of Global Businesses In Heavily-Regulated Industries

A White Paper from Kallik



KALLIK

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In heavily regulated industries including medical device manufacture, pharmaceuticals, chemicals and cosmetics, demand is intensifying for accurate, compliant and contextually-relevant labeling and customer-facing materials. Labeling has become a board-level topic now, given its strategic importance in reducing barriers to entry into new markets. At the same time, product transparency and process traceability are rising rapidly up regulators' agenda, which is putting renewed pressure on global organizations to ensure they can provide the right product information and safety advice, for each market and customer group. This must be available however and wherever healthcare providers and consumers need to access it. Companies must be able to ensure this consistently, confidently and efficiently.

The rise in e-Labeling and electronic publishing of information is another major driver for change. Some organizations are already embracing electronic formats, and the new EU Medical Device Regulations (MDR) encourage greater use of electronic information-for-use (IFU) materials, booklets and labeling. This makes strategic business sense too, due to the obvious cost-efficiencies of reducing physical print copies, and the ability respond more dynamically to ongoing regulatory changes.

It is no coincidence that respected market analysts such as Gartner and IDC are predicting significant growth in spending on solutions for managing all of this, collectively categorized as enterprise labeling solutions, or labeling and artwork management solutions.

So what are the drivers that will prompt new urgency around investment in such software in 2020; what are the challenges and issues that manufacturers and brands need to bring under control; and what does good look like?

Below we set out five important drivers for building a global labeling strategy over the year ahead.

Continued merger & acquisition activity

Increasing regulation & the soaring cost of product recall

Balancing global/ local/custom requirements

Increased use of outsourcing

The growing influence of customers & healthcare providers

1. Continued merger & acquisition activity

Uncertainty in international economies, rising global competition, talent shortages, and the need to keep pace with the latest innovation, continues to prompt market consolidation across many industries. Large international brands which can't move quickly enough to seize an advantage are looking to smaller, more agile peers or startups to accelerate their entry into attractive markets.

In life sciences, for instance, large pharmaceutical companies are buying their way into medical device manufacture, nutraceuticals/'wellness' products, or advanced technologies, to propel them into the future. Another driver surrounds growth in 'combination products' – for instance, drug or vaccine vials packaged with a delivery device such as a syringe. In the cosmetics industry, acquisitions are helping brands to bolster their presence in growing markets, such as those for natural/organic or cruelty-free/vegan products. Acquisitions can also offer a shortcut to expansion into additional territories, or be a defensive move to take out the competition.

Whether the merging brands are consolidated or remain distinct, changes in ownership or regulatory jurisdiction are enough to send shockwaves of impact across global labeling and customer advice - which must all be brought into line at speed, to avoid delays in product supply in affected markets.

In 2020, M&A activity shows no signs of abating, so provisions for harmonizing and streamlining the management of packaging, labels, instructions for use (IFU) and other customer-facing materials will need to be on CxOs' agenda.

2. Increasing regulation & the soaring cost of product recall

Around the world, regulatory demands are growing and becoming ever stricter. That's as authorities strive to improve consumer safety and transparency, and make manufacturers and their supply chain partners more accountable for the impact of their products and production processes. And the more specifications and requirements there are, the greater the chance that something could slip through the cracks, with the risk of punitive product recalls and a lot of bad publicity. All of which means that global companies, especially those operating in heavily regulated industries, need to be ahead of changes to rules, and have processes in place to manage necessary changes to product labeling and the information and instructions provided to customers. This is where publishing labeling content electronically allows for greater agility.

One of the hardest challenges for global organizations is maintaining clear visibility of where products are, and the status of current materials. Coordinating changes is a mammoth task and without systematic quality control and process vigilance, there is a real danger that the wrong information or out-of-date instructions will go out in a market, or to a target customer group - at which point everything quickly begins to unravel.

For markets such as medical device manufacture which are less advanced compared to adjacent markets in terms of discrete product transparency requirements, new measures to assure consumer safety could easily catch companies out. This is especially the case where manufacturers still rely heavily on manual processes to create factory-level labeling, and/or where different teams - or even different companies - are responsible, respectively, for handling packaging-based labels and customer instructions-for-use leaflets.

In 2020, these companies should look to consolidate the creation and lifecycle management of labeling and other customer-facing materials around a definitive master set of content assets for both print and electronic media. The ability to check the status of current artwork all in one place, and make a set of master updates that can then be cascaded down to affected products and markets once approved, promises to reduce compliance-related risks and costs considerably.

3. Balancing global/local/custom requirements

As ambitious businesses expand strategically into additional markets internationally, they will need to strike the right balance of maintaining consistent quality standards while fulfilling specific local regulatory requirements. This includes ensuring accurate translations, correct safety statements and icon/logo use, and culturally-appropriate language and references. Leaving this to local operating companies or affiliates to manage could leave corporate quality teams out of the loop, without visibility of the assets that are currently in play leading to increased risk of non-compliance. The more separation and fragmentation of processes and controls there are, the greater the risk of something going awry.

Granularity of content management will become increasingly important in industries where product personalization is climbing up the strategic agenda. In life sciences, for instance, drug batches are likely to become smaller in many cases, as treatments are more finely tuned to the needs of individuals – and product messaging must be adapted to reflect that.

4. Increased use of outsourcing

From greater reliance on contract manufacturing, to growing use of business process outsourcing, many industries are seeing increased reliance on external partners to look after large elements of what they do. Whether someone else is making or packaging products, or looking after regulatory submissions activity, any disconnect with or blind spot between operations could prove a weak link and source of risk.

Outsourcing can be an excellent option for all sorts of activities, as long as there is continuity between systems, checks and controls, and assuming that corporate teams retain the oversight they need. In a labeling/artwork management context, a coordinated cloud-based system, with all the right security and access controls, offers a practical option for collaboration across distance/between diverse parties, supported by the same core set of approved assets and real-time status visibility.

Managing everything in the cloud also makes it easier to switch contract manufacturing organizations or local print providers, or appoint and use additional outsourcing services, if process requirements change or grow.

5. The growing influence of customers & healthcare providers

Demand for greater process transparency, and product information and traceability, is not coming solely from regulators. Public awareness of safety issues, environmental sustainability factors, and ethical sourcing considerations, is placing its own pressures on manufacturers to be open and transparent about what they do, how, with whom, and with what impact.

In life sciences and medical device sectors, as in healthcare more broadly, patients now expect to have more insight into what's being offered and recommended to them, and why, and to be able to scrutinize products and their provenance directly, for themselves. As well as forcing manufacturers to be more accessible and consumer-friendly in the language they use and explanations they give, this is also driving more consumer information online where it easier for the public to look up and search, to satisfy their own queries. Regulators are responding to this too, specifying the need for manufacturers and suppliers to manage online materials as part of their broader responsibilities around the product information they publish.

Healthcare providers are a further driving force in all of this, as they seek to optimize procurement process, healthcare supply chains and inventory management. The NHS is a strong advocate of UDI for example, as it sees this is providing a much better way for managing its suppliers in terms of stock levels, negotiating bulk purchasing discounts, and so on.

Keeping ahead of customer expectations, and being able to track and manage online materials - which may need updating more frequently, and come under multiple regulatory jurisdictions (because they could be accessed from anywhere in the world, requiring different quality controls to printed materials) – will absolutely require careful coordination and ongoing vigilance.

As 2019 gives way to 2020, and budgets come up for renewal, CxOs will do well to re-examine their current approach to global labeling strategies in the light of developing and emerging trends, and the way they envisage their own business progressing.

Kallik is the market-leading enterprise labeling company, providing organizations in regulated industries with a definitive, global, end-to-end label management platform they can trust.