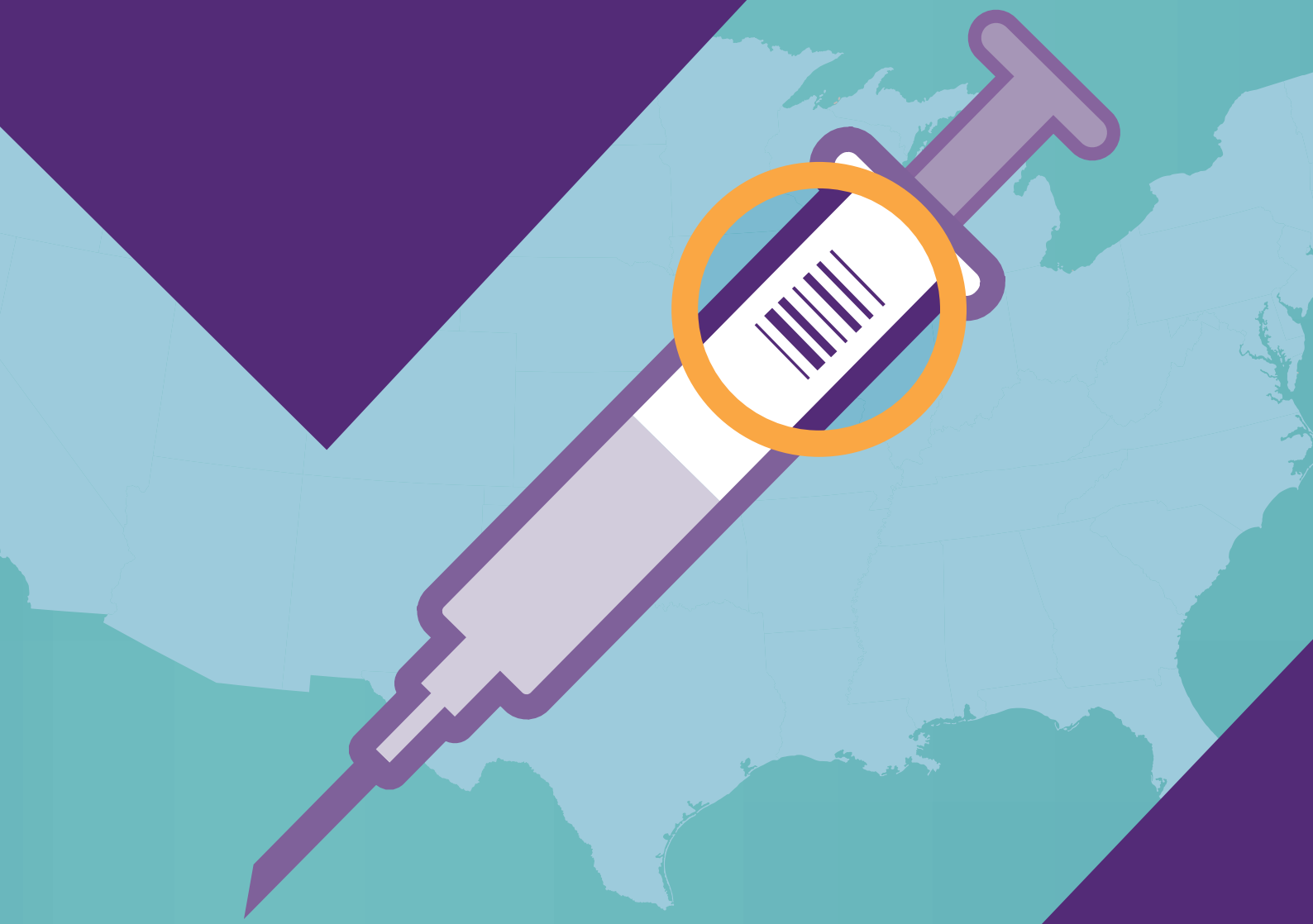
Unique Device Identification & Product Traceability for Medical Devices: The Case for Labeling Digitalization

A White Paper from Kallik



KALLIK

Preparing for increased regulatory scrutiny & the call for greater public transparency: a guide for manufacturers

In the context of an increasingly competitive medical device market, implementing the upcoming European Unique Device Identifier (UDI) will require considerable investment and strategic planning on the part of device manufacturers.

The obligation for UDI assignment applies from the date of application of the two new EU Medical Device Regulations: 26 May 2020 for medical devices and 26 May 2022 for In Vitro diagnostic medical devices. (This is despite the fact that the new MDR database, EUDAMED, has been delayed by two years.)

Viewed as a complete end-to-end process, it becomes clear that the medical device supply chain is actually made up of a series of largely discrete, siloed steps from product development through to delivery of products to the patient or healthcare provider.

Digitalization of all of these different stages can help remove these silos and contribute to a more integrated supply chain which is fully transparent to all of the players involved.

But what is involved; what is the role of labeling digitalization across the supply chain; and how can this improve efficiency and visibility – moving manufacturers beyond compliance-related costs to an investment that could drive broader company improvement?

In the following whitepaper, we explore the extent to which a more strategic approach to labeling digitalization can better serve the business, as well as industry regulators.

Cultivating consistency

Life sciences supply chains are highly complex, involving multiple tiers of suppliers and wholesalers. When considering the supply chain as a complete end-to-end process, it becomes clear that labeling content management is essential to smoothing the entire flow - from product development right through to customer fulfilment. In terms of medical device products, this content could form the instructions-for-use leaflet inserted inside the product packet (or published to the company's web site), or manifest as labels physically attached to the product, its packaging materials or to the bulk shipper cases.

The most important element in supply chain optimization is having a single source of content that is consistent across the entire ecosystem, which can be used right from the submissions activity through the design and production process. Serving all forms of labeling and packaging associated with the product, the single source could be a statement, symbol or image, or a common combination of the above, that has been approved as the correct, current 'master source'. By always being able to refer to the same single piece of content, everyone in the organization can be confident that they are always using the latest, definitive version of labeling content for the given purpose.

Ensuring interoperability

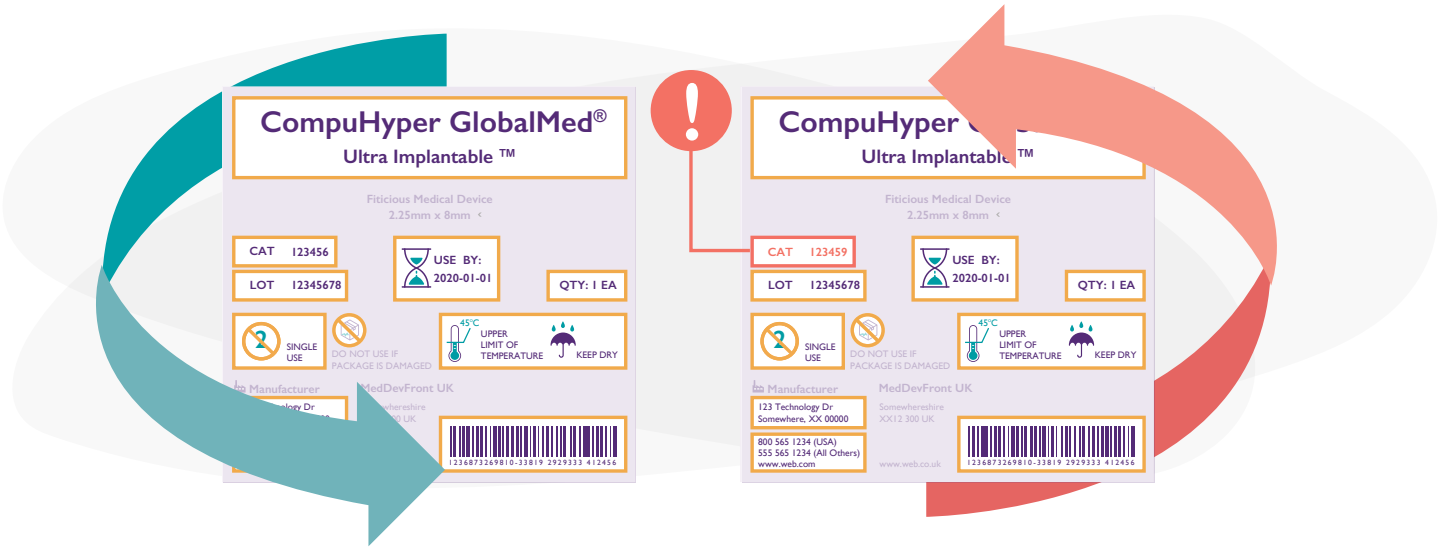
When looking to ensure labeling interoperability on a global scale, it is important to consider local regulatory requirements as well as any broader regional mandates. In addition to local safety statements and symbols, there will also be a need for local translations of any wording appearing on the labeling – whose integrity and clear meaning must be preserved for local readers.

Interoperability will have a direct bearing on the end-to-end traceability of all label content. Harnessing a master file which contains the correct, approved source content means that throughout the organization and right along the supply chain it will be possible to trace back the types of labels, as used in all marketing anywhere, to the original single source - thereby giving complete global visibility and traceability.

Challenges of harmonizing labeling identification

The main challenges of implementing a single, harmonized system for positive identification of medical devices are largely organizational rather than technical. Where organizations adopt point solutions to solve localized issues, such as local factory printing, this can create unhelpful silos and compromise end-to-end traceability.

Establishing ownership of the content is important, too. Data governance is a critical element in labeling management, and is not just a localized issue but rather a corporate, strategic matter. Understanding who is responsible for making decisions about changes and updates to the labeling is critical to satisfying local market requirements.



Decision-making in the supply chain

Just as systems and data need to be joined up, so stakeholders need to operate more seamlessly and collaboratively as a fluid ecosystem. All partners - including regulatory, marketing and manufacturing teams - need to have access to the same system that oversees the master content, with the right level of permissions to enable them to update/modify and review labeling content as needed. This stakeholder group might include third-party partners and contract manufacturing organizations as part of the extended supply chain.

Strengthening supply-chain infrastructure

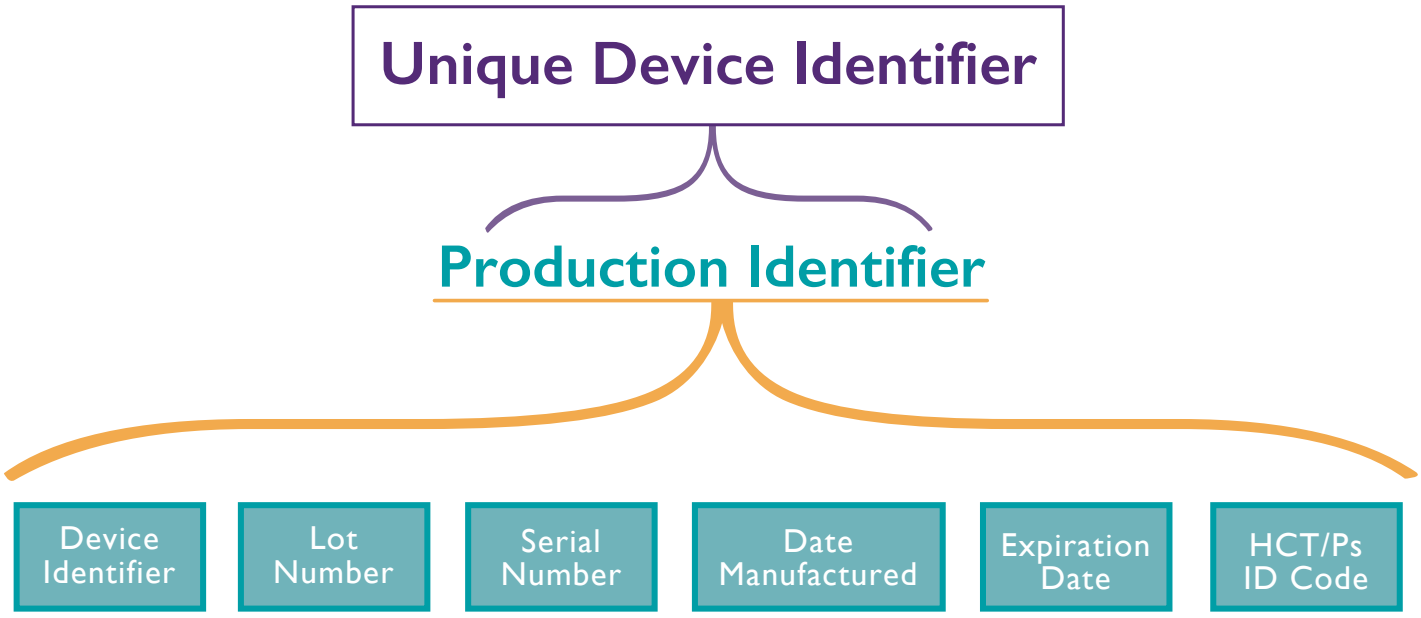
All the interconnectivity in the world won't automatically deliver visibility, so surfacing activity right along the supply chain needs to be another priority. When launching new products, there can be a temptation to defer to the most recently-used symbol or statement - which is not always the latest version. So it is critical that an authoritative master copy of the content for a particular label is easily identifiable throughout the process so that all players can be confident they are working with the most up-to-date version. If multiple instances of the same content exist across different factories and production facilities, this could compromise compliance with EU traceability requirements.

To avoid any ambiguity, there must be visibility right across the supply chain of the most recently-approved content, along with details of who approved it and when.

Challenges in digitalizing the supply chain

Digitalizing labeling management across the supply chain is not immediately straightforward. That's usually because much of the existing label content will have originated or been amended in PDFs, printed documents or emails – ie non-editable formats from which it is difficult to readily deconstruct the content to create a single master resource from which everything else can follow.

In the medical device industry, it is quite common for labeling content to exist in PDF form – yet for firms not to be able to locate the original source of the content on which that file was based. The content needs to be made available at an atomic level so it can be broken down into specific elements - phrases, statements or symbols. Then these can be reconstructed and reused as appropriate to form correct new labeling.



The future of the UDI-based supply chain

It is likely that the next couple of years will see organizations continuing to re-engineer their processes around the creation and control of labeling content.

As they go about this, it is important that they firstly address data governance (where it resides, who can access and edit it, along with the usability, integrity and security of data). Once they have done this, they will have the ability to quickly update and repurpose content for different types of print and packaging - as well as electronic media, which is rising in importance for a number of reasons, not least MDR's provision for e-labeling (where medical device manufacturers have an existing web site, the new regulations require that an electronic version of patient instructions-for-use is provided online).

More broadly, e-labeling will become an important enabler for enhanced ecosystem-based collaboration. This is because preparing label content so that it can be accessed electronically will aid visibility and sharing between supply-chain partners. Furthermore, it is likely that, within the next five years, IFUs will be accessible by patients and healthcare providers via mobile devices.

Generally we can expect much greater online and mobile accessibility of information, and less reliance on the printed format of labeling, which will offer numerous additional benefits to device manufacturers – not least in reducing the cost of physical printing, and the delay in updating content as safety advice is revised or as regulations are refined over time.

To find out more about **managing** and delivering UDI-based traceability via digitalized labeling management, email **info@kallik.com**

As a global provider of labeling and artwork management solutions for highly regulated industries, Kallik enables organizations worldwide to accurately produce print-ready labeling for their medical device packaging.

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.