3 Major Trends in Barcode Labeling for Medical Devices

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Trend: the general direction in which something is developing or changing. In the medical device industry—one of the fastest-growing and dynamic industries—trends are growing at the same pace, despite significant headwinds. Major trends take hold as rules and regulations are finalized, implementation dates are set, and initiatives turn into standards.

Three major trends are flowing through the medical device industry, promoting patient safety and implementing positive changes. How will these trends affect your labeling processes? They will change the way you label product, help minimize costs so the excess can be allotted for other sections of your business, and increase efficiencies through your organization and the industry supply chain.

1. Increased FDA Standards for Recalls and Patient Safety

In response to the growing emphasis on patient safety, more and more medical device organizations are faced with new technology trends and regulations—for example, medical device labeling. With the final rule announced on September 24, 2013, unique device identification (UDI) regulations should now be top of mind for many medical device organizations. Per the U.S. Food and Drug Administration (FDA), the labels of medical devices are now required to include a UDI through distribution and use, except where the rule provides for an exception or alternative placement. A UDI is a unique numeric or alphanumeric code that consists of two parts: a device identifier (DI) and a production identifier (PI). Each UDI must be presented in a human-readable format as well as in a form that uses automatic identification and data capture (AIDC) technology.[1]

The first compliance date set is one year after the final rule was published: as of September 24, 2014, the labels and packages of Class III medical devices and devices licensed under the Public Health Service Act (PHS Act) must bear a UDI.

(Device classification determines the type of premarketing submission required for FDA clearance to market.)

What is the benefit of medical device labeling?

This trend has the potential to improve the quality of information on adverse event reports for medical devices, which will allow the FDA to more easily identify recalls and improve patient safety.

2. Automation Must Support Lean Manufacturing

The controversial medical device tax, as well as the costs associated with implementing new regulations like UDI, has put pressure on medical device organizations to save money in other areas. Since they cannot pass the increased

tax and regulation costs onto their customers, organizations need to find new ways to cut costs internally—for example, by streamlining their supply chain—rather than outsourcing production.

With barcode label software, organizations can integrate label and radio-frequency identification (RFID) technology into existing business processes, increasing both efficiency and control. Whether the ultimate goal is streamlining asset and resource management, controlling distribution channels and stock levels, tracking documents and RFID tags, or managing data records, barcode label software provides a cost-effective solution that supports lean manufacturing.

Automation allows businesses to control a process by automatic means, minimizing human intervention. Minimizing human intervention in the label printing process decreases the chance for errors that can result in returned shipments or regulation penalties—both avoidable costs.

What is the benefit of automation?
Organizations will become lean, minimizing costs where they can, protecting their top lines and profit margin.

3. Renewed Focus on Medical Device Logistics and Traceability
Organizations in many markets are interested in establishing systems to track and trace products throughout the supply chain. These systems can have major benefits in the Medical Device Industry, as they support regulatory requirements, product recall and withdrawals, logistics and quality management, and to support patient safety. Two relative GS1 Standards are already in place: the AIDC Application Standard for Small Instruments and the GS1 Global Traceability Standard.

The Standard for Small Instruments specifically covers the marking of surgical instruments to enable traceability throughout the instrument reprocessing cycle and, in particular, to and from the sterilization department. The scope of the GS1 Global Traceability Standard includes labeling all traceable items based on the use of voluntary GS1 business standards.

The following GS1 standards enable implementation of the GS1 Global Traceability Standard for Healthcare[2]:

- Global Trade Item Number (GTIN)
- Global Location Number (GLN)
- Serial Shipping Container Code (SSCC)
- Electronic Product Code (EPC)
- Global Data Dictionary (GDD)
- GS1 XML and EANCOM e-business messages (Align and Deliver)
- Pedigree Ratified Standard (DPMS)
- General Specifications (data carriers)

What is the benefit of traceability?
Traceability supports efficient recalls and increases patient safety. Adopting and

implementing GS1 standard barcode labeling enables the effective and efficient rollout of AIDC and maintains the traceability of medical devices throughout the healthcare supply chain.

Conclusion

All three of these trends support the goal of increased patient safety through identification, automation and traceability. In the coming years, more trends will emerge that reinforce this goal. As we've seen in the past, a trend can be the beginning of an industry standard and should be taken seriously. If a new trend develops promoting patient safety, look into implementing it and stay ahead of the trends.

For more information, visit www.teklynx.com [1].

[1] https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system [2]

[2] http://www.gs1.org/sites/default/files/docs/gsmp/traceability/Global_Traceability_Standard_Healthcare.pdf [3]

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[1] http://www.teklynx.com
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