Tips to Ensure Your UDI Labeling Program Will Pass an Audit

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Since 2013, when the FDA announced new regulations for medical device labeling known as UDI (Unique Device Identifier), manufacturers have been working to ensure their products bear accurate labels that include all required information. So far, UDI labeling requirements have impacted some Class II and Class III devices. As more and more manufacturers implement UDI solutions that will meet the FDA's requirements, challenges are emerging and are being met by new best practices.

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One emerging pattern calls attention to a need for accuracy in the information uploaded to the Global

Unique Device Identification Database (GUDID). The other reveals a need for higher quality printing and control of label content to ensure consistent label readability. Preparing proactively to address both of these issues could be the critical difference between passing and failing an audit.

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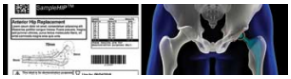
All Keyed Up

Since the implementation of UDI, medical device manufacturers have been working to design labeling systems within their facilities that meet the compliance requirements while maximizing the use of existing hardware, software, and personnel. Large companies that produce thousands of products tend to experience the least difficulty with compliance because their financial and human resources can bear the burden. At this level, manufacturing best practice is to upload UDI data to the GUDID using a software-based solution and a staff expert or independent software vendor to act as an intermediary between the manufacturer and the FDA. The staff expert or intermediary is especially critical if the manufacturer is global and contending with both U.S. and European market requirements.

DEEPER INSIGHTS



Aligning for Growth: The Evolution of Medical Device Labeling

At the opposite end of the spectrum, many small companies are struggling with data management because they have neither the IT budget to add a software-based data management system nor the personnel to implement and manage it. Many also feel their low number of products does not warrant such an expenditure. The resources needed to address the data aspect of UDI

compliance have caused some small companies to play a "wait and see" game—a reactive approach to compliance in which the manufacturer waits to be audited and then does what is required to comply. This strategy is strongly discouraged, as it can quickly backfire and invites the risk of a "stop ship," which is the complete recall of all non-compliant products and a halt on all shipping until compliance is met.

Small companies should also note that hospitals are beginning to develop their own expectations for UDI compliance. So, while they may have averted compliance changes because the FDA has not audited them, they may soon find their customers are demanding compliance. The only advantage a small manufacturer might have, if you can call it an advantage, is the number of products affected would likely be low, so corrections could be quickly applied. Still, that manufacturer runs the risk of losing a customer, depending on the time constraints of compliant product delivery.

The segment that seems to be experiencing the greatest amount of UDI pain is the mid-sized manufacturer. Mid-sized companies cross over into a larger breadth of products at higher volumes, but their operations are typically very lean in terms of IT infrastructure and personnel. This segment has been hit the hardest when it comes to adapting existing systems for UDI compliance, because they have a product volume that calls for a greater investment in software solutions to automate the data entry process, but they may not have the budget to match. As a result, many mid-sized manufacturers are continuing to rely on personnel to key in data for upload to the GUDID, which inherently includes the risk of human error. For every product submitted, there are more than 60 attributes that must be keyed in. Multiply the number of attributes by every size, every color, and every variation of a single product, and the risk of error grows exponentially to become almost a guarantee.

The most dependable solution for data upload is incorporating an automated software solution, but this can be challenging for many small- to mid-sized

manufacturers. The next best thing is identifying a staff member or members who understand the relationship between the company and the FDA's UDI requirements. These personnel are likely the best qualified to prepare data accurately for the GUDID. If someone with this experience and knowledge base does not exist, training is the next order of business, and many resources are available, including the FDA's annual UDI Conference this April in Baltimore.

The Sticky Side of Labels

In addition to addressing data entry issues related to product volume, other common struggles with UDI labeling continue to surface. At the outset of UDI, companies wrestled with replacing distributed printers with on-demand equipment or adapting existing equipment for new printing needs. Now that many of those issues have been worked out, the industry is seeing a new set of obstacles arise, particularly in the area of label readability.

Engineers designing UDI compliance systems are not label engineers; therefore, they may not be considering all of the necessary factors when selecting the right solution. One of the most common problems with labeling is the unreadable label. Unreadable labels have a few common causes: print quality, label material, and barcode size. Print quality, especially when a number of different printers are involved across an enterprise, can be degraded by something as simple as a dirty print head. So, a printer maintenance plan and routine quality control are essential elements in generating consistently readable labels.

Labeling methods and materials are also critical considerations, especially for reusable devices, as labels can degrade over time when exposed to cleaning solutions and chemicals used in a hospital environment. Once a label degrades and can no longer be read, device data cannot be retrieved, making product tracking, safety and recalls impossible. Considering the environmental factors and the expected lifespan of the label will lead to better material selection and a label designed to last.

Additionally, because so much information must fit on the label, many manufacturers erroneously shrink the barcode size to the point it becomes unreadable. While barcode guidelines have been offered from organizations like GS1 and the Health Industry Business Communications Council, implementation has primarily been left up to the manufacturers. This has led the medical device community to develop its own set of best practices. One best practice is to employ some form of machine vision verification to guarantee the label's readability and accuracy, though this may be a costly system addition and out of reach for smaller companies.

Another more recently adopted recommendation is printing labels at 600 dpi or 300 dpi versus 203 dpi to ensure their readability, especially when printing extremely small 2D barcodes and text. The FDA requires that barcodes meet an ANSI grade C or higher for reliable scannability. Taking these steps will instantly improve readability with a smaller financial investment.

Finally, security around preventing unauthorized personnel from knowingly or accidentally altering a label format instead of only being allowed to print established formats can cause more non-compliance headaches around inconsistent labeling.

Across the Board

Whether a manufacturer is adopting new data management software or installing label printing equipment, best practice dictates changes must occur consistently across the enterprise. There is little benefit to using software to upload product data in one facility if staff in another facility can manipulate product data. Likewise, upgrading a printing system in one department does little to improve your chances of compliance if another department has not been upgraded. Compliance is most quickly achieved when hardware and software is common throughout the manufacturing environment and personnel follow the same procedures to assure quality control.