SMOOTH COMPLIANCE: CONSIDERATIONS FOR UDI LABELING INITIATIVES

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Tuesday, 01 September 2015

Understanding the FDA labeling directive.

Peak-Ryzex, Inc., Columbia, MD

In September 2013, the FDA announced new regulations for medical device manufacturers known as UDI (Unique Device Identifier) that would require all medical devices to bear a label containing specific information by the year 2020. The regulations were designed to phase in over a seven-year period, affecting different classes of medical devices at different compliance deadlines.

Since the announcement, device manufacturers have been working to not only understand the UDI requirements, but also design new systems within their facilities that meet the compliance requirements while maximizing the use of existing hardware, software, and personnel. Many manufacturers have already been through this process, as the first compliance deadline in September 2014 has come and gone. Others have yet to address the regulation, as new deadlines for different classes of devices quickly approach. Still others are simply procrastinating because they are uncertain about the capital investment that may be required to comply.

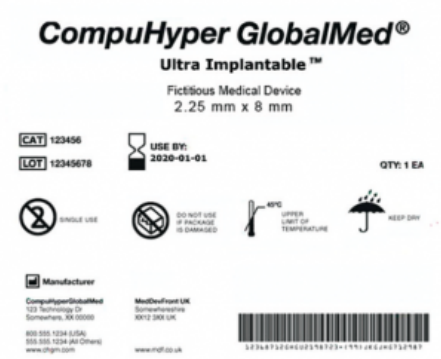

Fig. 1 – A sample UDI label provided by the FDA.

Fortunately, much has been learned since the regulation was introduced, and a few key considerations can help manufacturers efficiently and effectively meet this new requirement.

As with any new regulation, the first step is understanding its purpose. According to the FDA, the UDI's purpose is to "improve patient safety, modernize device postmarket surveillance, and facilitate medical device innovation," which it accomplishes by uniquely identifying and labeling medical devices for tracking throughout their distribution and use within medical environments.

Tracking devices allows manufacturers to distribute products more securely, reduce risk of counterfeiting, and effectively manage recalls. Likewise, clinicians and other end users benefit by having a system to quickly identify and report device problems, obtain important information, and reduce medical errors. The shared benefit is a global, secure supply chain that promotes accurate reporting, quick identification, and efficient correction of problem devices.

What's Needed?

While there are tangible benefits for all parties involved, what will it require from medical device manufacturers in terms of hardware, software, and personnel to comply? A key consideration is to understand the label requirements. For example, Class III and PHS Act devices, which already complied in 2014, had to bear a UDI on the package label. The UDI that appears on the label comprises two parts: a device identifier (ID), which signifies the labeler and the specific version or model of the device, and a production identifier (PI), which is a variable portion that identifies product details such as: lot or batch number, serial number, expiration date, manufacture date, and, in some cases, a distinct identification code for human cell, tissue, or cellular- and tissue-based products. (See Figure 1)

The next class of devices scheduled for compliance in September 2015 are Class II devices, which include implantable and life-sustaining devices and software. Class II has requirements distinct from Class III and Public Health Service Act devices because it includes multi-use devices, such as an infusion pump. Multiuse devices must bear a UDI as a permanent marking on the device itself—a requirement that introduces a new set of considerations related to environmental conditions. Wash-down procedures, chemicals, or bodily fluids could compromise the integrity of the label, so it is important to select the proper marking equipment and durable label media for any given environmental conditions.

For many manufacturers, compliance may simply mean adapting or augmenting existing systems, like label tracking using serial numbers, but with two key differences. One involves the labeling portion of the regulation, as manufacturers find they want to move from distributed printing to on-demand printing. Planning ahead for what must

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appear on the label, as well as future label fields, is also crucial to avoid costly changes later. For example, will it need to be bi-lingual, or require any pre-printed colors, custom symbols, or brand identification? Even text size is important to consider as companies review requirements.

A Global Database

The other is uploading UDI information to the Global Unique Device Identification Database (GUDID)—the FDA database that stores the reference catalog for all registered devices. For small manufacturers with fewer products, this step can often be accomplished using existing staff who can key in data by hand. But, for larger manufacturers making hundreds or even thousands of products, uploading UDI data to the GUDID likely requires a software-based solution and at least one staff expert, who serves as an intermediary, to establish the data transfer between the manufacturer and the FDA. An expert and software-based solution is especially critical if the manufacturer is global and must contend with both US and European market requirements. Ensuring the proper data makes it on to the device label and matches what is in the database is critical. These areas are where most capital expenditure is occurring.

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So far, most missteps in compliance have occurred because manufacturers do not fully understand the requirements and may have misperceptions about implementation time and cost. To prepare for the next deadline, manufacturers should consider the following questions:

- What hardware/software is currently used to manage device inventory and distribution?
- What volume of devices does the company handle? (Note: Each revision of a device counts as a different device.)
- Does the device production volume allow someone to manually key in the information to the GUDID, or will a software solution for higher volume be needed?
- Is there a staff member who understands the relationship between the manufacturer and the FDA, and is that person qualified to prepare data for the GUDID?
- Is there a budget and project time frame for the implementation?

Gathering this information before meeting with a supplier or systems integrator will help expedite the identification and implementation of a UDI-compliant system.

Many manufacturers will try to avoid capital expenses by getting the longest life possible out of their existing equipment, but those aging thermal printers down on the floor may not meet the demands of UDI. Similarly, scrambling for interim stop-gap solutions can result in incorrect data, non-compliance and even a halt in sales—a price no manufacturer can afford.

As always, it pays to be proactive—the next deadline is always just around the corner.

This article was written by Tom Heitman, Manager, Solutions Consulting, Peak-Ryzex, Inc., Columbia, MD. For more information, visit http://info.hotims.com/55593-164.

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