Technology White Paper

Understanding the Role of Auto ID in the FDA's UDI Initiative

Data Acquisition and Verification Implications of the U.S. FDA's Unique Device Identification (UDI) Initiative

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What is the UDI program?

The UDI (Unique Device Identification) program is an initiative from the U.S. Federal Drug Administration (FDA). The goal is to improve the nation's health by standardizing the marking on medical devices so that all of those involved in their production, distribution, stocking, and usage can readily identify the device in question and get reliable access to critical data concerning its use and history.

The FDA has been active in promoting standards for labeling and identification of pharmaceuticals for many years. In 2005 the FDA turned its attention to systems for reliable identification of medical devices through distribution and use. After meetings and pilot studies were conducted, the 2012 Congress advanced the process by including a provision in the FDA Safety and Innovation Act (FDASIA) that required the FDA to publish a proposed rule for unique identification systems for medical devices by the end of 2012. The FDA, having had a draft rule created for some time, beat this deadline handily and published a rule for comment in July 2012 with comments due by November and a planned May 2013 effective date for the final rule.

Some might think that medical device identification will be very easy – just place a barcode on the box like every vendor of every item available at a typical supermarket. It turns out that it is not so simple. Some medical devices, such as heart valves and stents, tend to change their identity as they move through the supply chain. They may start with a manufacturer's part number, be re-branded for a particular market, get re-numbered by a distributor, and then get a new stock number when they get to a hospital stock room. There is also the issue of preserving the identity trail of devices that are implantable or subject to sterilization.

The aim of the UDI program is to provide a permanent globally recognized unique device identifier (UDI) for each device/package combination, which will also be indexed into a database containing the critical data for each device. The belief is that this will allow efficient recalls and adverse event tracking, deter counterfeits, and promote accuracy of patient records.

Auto ID Standards

The FDA's proposed UDI program contains much that is of interest to the Auto ID community and to manufacturers and labelers of medical devices.

The key points are:

- The FDA requires that automatic identification and data capture (AIDC or Auto ID) technology be used to mark a device's package with a unique device identifier (UDI) via a 1D or 2D symbol or some other Auto ID technology such as RFID. This information is referred to as the device identifier.
- The UDI program does not require a specific type of Auto ID technology but does specify that 1D or 2D symbols be accompanied by human readable text.
- The UDI program does not require serialization but does require that 1D or 2D symbols contain the serial number and expiration date if these are marked elsewhere on the package. This data is referred to as the production identifier.
- The program specifies that the UDI, and if present, production identifier, are formatted using one of a small number of established standards such as those provided by GS1 and HIBCC (Health Industry Bar Code Council).
- The UDI for a given manufacturer's product/model/package will be issued and registered by a small number of non-profit agencies such as GS1 and HIBCC. In the case of GS1 this will be based on the GS1 Global Trade Identification Number (GTIN) which can be thought of as a grown up version of the UPC codes that surround us at the supermarket.
- The UDI will be added to a database along with a defined set of product attributes (master data) such as version and model information, and any clinically important information such as sterilization requirements and latex content.

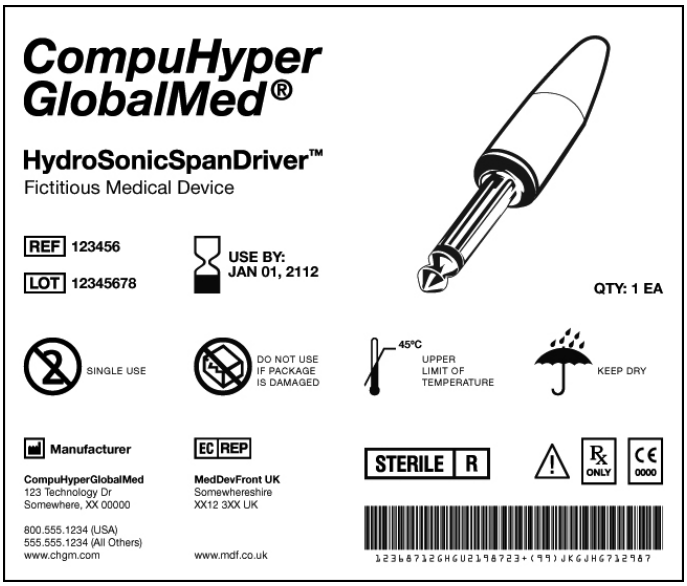
- Implantable devices and devices which are subject to sterilization must be permanently marked via direct part marking (DPM) where possible.

Implementation

The proposed rule was published by the FDA in July 2012, with publication of the final rule planned for May 2013.

The first group of devices for which UDI labeling will be required are Class III devices that are critical for life support. These must have UDI labels one year after issuance of the final rule. The next group is implantable/sterilizable devices, which must be directly marked two years after the date of issuance. Class II devices, which include clinical analyzers and reagents, must be labeled three years after the final rule is published.

While the UDI program does not specify which type of Auto ID technology must be used, it does require that the UDI be issued by one of a small number of approved agencies. The program also requires conformation to current ISO international standards with respect to encoding and formatting of data. The overall goal is to promote a globally harmonized system in which the identity of a device can be readily established beyond national boundaries. Current National Drug Code (NDC) identifiers used on medical devices will be replaced by the UDI program.



Example of what a universal device identifier (UDI) label would look like on a medical device label. The label contains information about the product name, its expiration date, reference and lot numbers, manufacturer information, barcode, details about the item, and an illustration of the item. (via U.S. FDA website)

Included Devices

The proposed UDI program explicitly includes clinical diagnostic devices and reagents as medical devices. Class 1 devices such as bandages are not required to be marked at the individual unit of use, though they may require UDI labels at higher levels of packaging.

Devices that are sold at retail locations without a prescription are excluded. However, convenience kits which contain a device that is required to have a UDI label must include a UDI label at the kit package level.

All package combinations – single use packs, and other package counts of a device – will each require a UDI label.

The FDA will create a Global UDI Database (GUDID) to which manufacturers must submit the UDI and master data prior to the date that a UDI-bearing device is distributed. Most of the GUDID will be publicly accessible, allowing easy access to anyone using the device or within the supply chain.

Example of a barcode, or 1D symbol, and human readable text.

This direct part mark example shows a laser etch 2D symbol (Data Matrix) on a metal medical device.

Impact

The task of creating systems for issuing unique device identifiers will fall on the approved issuing agencies. Manufacturers will need to have or create systems for managing the label data. The largest single task is expected to be the collation, management, and submission of UDIs and master data to the GUDID.

Manufacturers will need to choose Auto ID data carriers, data formats, label design, and in some cases research and implement direct part marking programs.

From the manufacturer, through the supply chain, to the device user, those with a need to identify medical devices will have to understand the latest automation identification and data acquisition technologies such as 2D symbols or RFID data carriers. Current 1D barcodes and handheld laser scanners will not do the job if manufacturers adopt labels with 2D symbols, and camera-based 2D imagers of varying levels of complexity will be required.

In spite of all of these challenges it should be noted that there is wide acceptance of the goals and benefits of the UDI program in the health care community, particularly in distribution and at the hospital level. The UDI program is not likely to meet the same kind of industry and institutional resistance as the FDA Serialization (SNI) initiative.

Microscan

Microscan has been actively following the progress of the FDA's initiatives for medical device identification for several years. As a global leader in Auto ID technology, Microscan has a clear understanding of the issues facing manufacturers and labelers who must create labels or direct part marks that conform to specific standards for format, content, and quality. Microscan products include DPM readers and verification systems that grade 1D and 2D symbols to ISO and AIM standards and validate GS1 label data formats.

Microscan also has 25 years of experience in pharmaceutical label verification systems – experience that is directly applicable to the UDI program.

The UDI program will require the information on labels and parts to be verified and validated. Microscan AutoVISION™ software has advanced label verification tools that match data in 1D and 2D symbols to their human readable equivalents, and that verify the correctness of GS1-formatted symbologies. AutoVISION software also has the capability to check GS1 marks, to inspect and grade 1D and 2D symbols to formal ISO specifications, and to verify the legibility of human readable text using the Optical Character Verification (OCV) tool.

When the medical device industry adopts the UDI initiative, Microscan will be ready with the latest products and technology.

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