WHITE PAPER

Everything You Need To Know About the FDA UDI Rule

LOWRY SOLUTIONS

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This year – after requesting input from the healthcare industry, clinical community and patient and consumer groups – the U.S. Food and Drug Administration issued a final rule for the unique device identification (UDI) system that will govern medical devices. In creating the UDI system, the FDA aimed to reduce the burden on the healthcare industry by building on systems that are already in place.

It is extremely important for businesses and professionals in the healthcare industry to be both educated and prepared for the final rule. The FDA is mandating compliance dates beginning September 24th, 2014 – and when it comes to implementing a new system, there is no time like the present to start the planning process.

This whitepaper will outline everything you need to know as you begin to adopt the UDI system in your unique business environment.

Basics

The FDA UDI final rule requires that the majority of medical devices distributed in the U.S. must carry a unique device identifier (UDI), including certain combination products that contain devices and devices licensed under the Public Health Service (PHS) Act, such as donor screening assays.

Creation

The UDI rule is beneficial for both businesses and the FDA, improving the information that flows between them. For businesses, implementing a UDI system can improve the quality of information in medical device adverse event reports. This will help the FDA identify product problems more quickly and easily and thoroughly perform recalls. And most importantly, the rule benefits the “end-user” so to speak – improving quality of information allows improved patient safety.

While developing the UDI system, the FDA worked closely with the industry, specifically the clinical community and patient and consumer groups, to conduct four pilot studies.

Unique Device Identifers

A UDI is a unique numeric or alphanumeric code that consists of 1) a device identifier (DI), or a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and 2) a production identifier (PI), or a conditional, variable portion of a UDI that identifies one or more of the following pieces of information when included on the label of a device:

- The lot or batch number within which a device was manufactured
- The serial number of a specific device
- The expiration date of a specific device
- The date a specific device was manufactured
- The distinct identification code for a human cell, tissue, or cellular and tissue-based product regulated as a device.

Exemptions

The FDA plans to phase in the UDI system based on the risks related to each medical device in question. They will first focus on high-risk devices, and many low-risk devices will be exempt from some or all final rule requirements. To eliminate unnecessary steps as your business begins to adopt the UDI system, seek information about the exemptions that will apply to your specific environment.

A few exemptions are detailed below:

Implantable devices – There will be no need for implantable devices to bear direct marking or require added verification or validation. Only devices that are intended to be reprocessed prior to reuse will require direct marking.

Convenience kits, combination products and constituent parts – Convenience kits or combination products require UDIs, but constituent parts do not. In addition, combination products that already bear a national drug code are exempt. This eliminates the need to create and manage new UDIs for constituent parts of kits or combination products.

Single-use devices – If distributed in a single-device package and intended to be stored in that package until use, and not intended for individual commercial distribution, single-devices are exempt. This eliminates the need for items individually packaged within larger boxes to require UDIs on the individual package.

Global Unique Device Identification Database

The UDI system also includes the FDA-created Global Unique Device Identification Database (GUDID). The database will make it easier for businesses to implement the system into their workflow, as it will include a standard set of basic identifying elements for each device with a UDI. The database will also serve to increase visibility/transparency and improve the patient and consumer experience, because most of this information will be made available to the public. In other words, patients and consumers using a specific medical device can easily look up information about it. However, the database will maintain patient privacy and safety standards – it will not contain any information about anyone who uses a device.

Challenges

The final rule will have an effect on just about every aspect of your business, specifically product development, order management, inventory and everyday operations. There will be significant time and labor associated with adopting the UDI system, so a systematic approach is essential to maintaining your business' productivity and profitability.

Time and Labor

Medical device manufacturers face challenges related to new labeling and label standards, new technology, data collection and product data management. As mentioned, significant time and labor resources are required to adjust to these changes – especially because many medical device manufacturers provide multiple product types, quality systems and IT applications.

Growth

In addition to applying the UDI system to their existing infrastructure, many companies are going the extra mile. They plan to expand the scope of their programs with more capable data management and quality systems. Although such changes would provide business benefits, it could interfere with a company's ability to meet compliance deadlines.

Benefits

As mentioned, the FDA worked closely with the health care and device industries to create a system that clearly documents device use in electronic health records and clinical information systems, allowing for improved safety. As a result, health care professionals and patients will be able to quickly, accurately and effectively carry out recalls and report medical device adverse events.

Here are a few ways that businesses can improve their reporting and documentation processes after adopting the UDI system:

The UDI system promotes standardization for medical device global commerce.

Labels will require an international date format (YYYY-MM-DD) and devices will adopt the Global Medical Device Nomenclature coding system.

The system can serve as a crucial step in the crisis management process.

Businesses will be able to use a standardized identifier that allows manufacturers, distributors and healthcare facilities alike to effectively manage medical device recalls. And more precise documentation will help them to better review and analyze adverse event reports, allowing them to identify and correct problem devices much more quickly. Not to mention, in providing a stable foundation for the global distribution chain, medical emergencies and counterfeiting can be addressed in a more organized, immediate fashion.

The system can also help to make medical procedures more precise, thus protecting patients.

Businesses can reduce medical errors by allowing healthcare professionals to quickly identify devices and obtain important information about the device's characteristics. When adverse events occur, the medical device's UDI can be used in safety alerts and recall notices, allowing healthcare professionals to quickly identify any patients who were or are using the device.

The system also supports mHealth initiatives.

mHealth is a significant breakthrough in the healthcare industry that has gained ground in recent years. Businesses can improve their analysis of devices by providing an organized, standardized way to document device use in electronic health records (EHR), clinical information systems, claim data sources and registries. Imagine the benefits that would result from a medical device identification system that is used around the world.

Compliance

To keep in compliance with the UDI final rule, as well as plan a successful and effective implementation plan for the UDI system, it is important for businesses to be aware of the compliance dates and deadlines. Prior to the compliance date, each company's existing inventory will have a three-year grace period to distribute manufactured and labeled products – rather than redirecting finished goods not in compliance.

The FDA worked closely with the health care and device industries to create a system that clearly documents device use in electronic health records and clinical information systems, allowing for improved safety.

Labelers seeking more information as they prepare to submit information to the database can read the FDA's Draft Guidance for Industry, which describes key GUDID concepts – such as accounts, user roles, device identifier record life cycle, package configurations, and GUDID data attributes and descriptions.

Accredited Agencies

Issuing agencies help manufacturers comply with the requirements of the FDA UDI final rule. These agencies have been accredited by the FDA and their standards meet the government's criteria for UDIs.

As of yet, the FDA has accredited the following agencies:

1. GS1 – www.gs1.org

Contact: Siobhan O'Bara, Senior Vice President - Industry Engagement
Phone: (609) 620-8046
Email: sobara@gs1us.org
Date of initial accreditation: December 17, 2013

2. HIBCC – www.hibcc.com

Contact: Robert A. Hankin, PhD., President and CEO
Phone: (602) 381-1091
Email: rhankin@hibcc.org
Date of initial accreditation: December 26, 2013

3. ICCBBA – www.iccbba.com

Contact: Pat Distler, Technical Director
Phone: (909) 793-6516
Email: pat.distler@iccbba.org
Date of initial accreditation: February 12, 2014

Initial accreditation is granted for three years, as of the start date. The FDA will continue to post its decisions on requests submitted by prospective issuing agencies as they become available.

As mentioned, it is imperative for healthcare professionals and organizations to adequately prepare for these changes – and the sooner, the better. The compliance date is quickly approaching. And why wait? Once implemented, the changes will allow healthcare facilities to run much more smoothly.

About Lowry Solutions

Since 1974, Lowry Solutions has been implementing technology innovations nationwide, and with over 10,000 customers, it has established itself as a premier Enterprise Mobility and Auto-ID system integrator focused on barcode, RFID, biometrics, enterprise mobility, and asset management solutions.

Lowry understands that each enterprise has its own specific issues and requirements, and that in order to provide best-in-class solutions to address these issues, a deep understanding of our clients' unique business processes is a necessity. To us, success is rooted in our ability to enhance and grow our customer's business.

Our Approach

We don't push technology or brand — we encourage partnerships. Our success depends on how we enhance and improve our customers' business.

Our Employees

Our employees are highly experienced, certified, and accredited individuals with vertical and application specificity that are continually trained on relevant technologies, solutions, and standards.

Our Relationships

We have long-standing relationships with leading Enterprise Mobility and Auto-ID hardware manufacturers, providing us access to the best equipment for the application — at a more affordable price.

Our Solutions

The solutions we provide are customized for each client to ensure the greatest impact and most aggressive ROI — and we support these solutions with world-class, 24/7 service.

Our Experience

We are one of the most venerable Enterprise Mobility systems integrators, with a track record of nearly 40 years of success delivering solutions to our valued customers.

LOWRY SOLUTIONS

Lowry Solutions, Inc.
(888) 881-2477
info@lowrysolutions.com | *www.lowrysolutions.com*