



# Improving Patient Safety Using Unique Device Identification

WHITE PAPER

The Food and Drug Association (FDA) in September 2013, announced the final ruling on Unique Device Identification. The UDI rule requires that manufacturers of most Class I, II and III medical devices assign unique identifiers to products and apply UDIs to all levels of packaging down to the lowest unit of use in both human and machine readable formats. Under the ruling, manufacturers are also required to submit product data to a global UDI database (GUDID) that will be made available to the public and health care providers.

The goal of the UDI Rule is to improve patient safety by requiring manufacturers of medical devices to uniquely identify and improve the traceability of their products. Key benefits include:

- Adverse event identification (facilitate effective global reporting information)
- Device authentication (close the counterfeit in the supply chain)
- Enhanced recall management (through device traceability)

The establishment of a UDI system enables the healthcare industry to improve patient safety by facilitating more accurate adverse event reporting and recall management. The work of device enumeration and GUDID population is no simple task. Most medical device manufacturers use proprietary identifiers for products and compliance with the FDA's UDI rule requires a substantial investment in change—from data used in internal systems and external transactions to physical packaging and labeling of devices.

As medical device manufacturers allocate significant resources to comply with the anticipated ruling, with Class III manufacturers

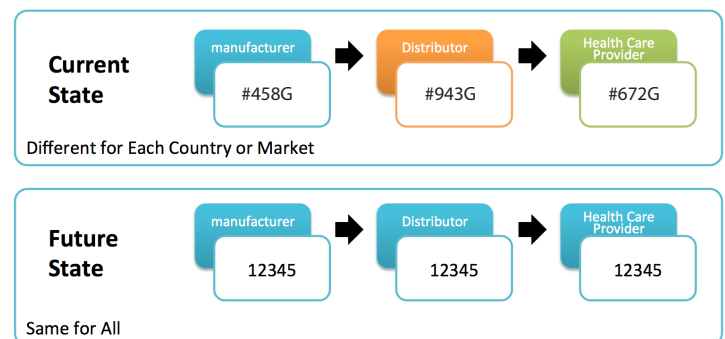
facing a deadline as early as next summer, businesses are searching for ways to add to the value of investment. One area where manufacturers can leverage UDI to drive greater operational performance is in quality management. By using unique device identifiers within an enterprise quality management solution (EQMS), a manufacturer can standardize device identification in quality data, processes and reporting across all markets, regions and countries, enhancing visibility, increasing efficiency and reducing risk.

Ineffective and inefficient device recall management is costly and burdensome. It can also place patient health—and in some cases life—at risk. The longer it takes for parties in the healthcare supply chain to identify recalled products and remove them from distributor and healthcare facility inventories, the greater the probability that patients will be treated with defective products. A successful recall both protects patient safety and reduces costs for the manufacturer in terms of liability since fewer patients are apt to face injury from faulty devices with quick and accurate recalls from the marketplace.

A U.S. orthopedic manufacturer has estimated that its recent hip implant recalls will cost the company between \$190 million and \$390 million, which includes patient testing, revision surgeries and settlements.

## Unique Device Identification Overview

Currently identification of medical devices in the healthcare supply chain is largely inconsistent, with medical device manufacturers, distributors and healthcare providers all using their own proprietary methods to identify devices within their organizations and in transactions with one another. Even within manufacturer organizations, different divisions, offices and facilities in different countries or regions identify the same devices in disparate ways.



**The Economic and Patient Safety Implications of Medical Devices Recalls**

Recent high profile recalls, such as that of the Poly Implant Prothèse (PIP) breast implants, have highlighted the need for comprehensive and accurate tracking of implants and other devices throughout the healthcare supply chain—from manufacture to use. Today, a major barrier to successful medical device tracking is the lack of consistency in the device identification process. Manufacturers, distributors and healthcare providers use different identifiers for the same product, making device recalls time consuming, labor intensive and costly in terms of direct costs to the manufacturer (e.g., administration of the recall, replacement products) and indirect costs (diminished brand reputation, loss of customers).

This lack of product data standardization increases risk throughout the supply chain, jeopardizing patient safety. With each party – manufacturer, distributor and health care provider – identifying the same medical device in different ways, there is no easy way to track recalled products or facilitate adverse event reporting. Furthermore, the inability to document medical device chain of custody from manufacture through final use increases the risk of counterfeit products entering the supply chain, hence the marketplace.

The current state also adds labor and cost to supply chain, inventory control and asset management processes. Manufacturers, distributors and health care providers struggle to communicate with one another in the procure-to-pay process without standardized product data, leading to costly transactional errors and rework. Providers also face challenges in documenting device use in electronic health records, clinical information systems, claim data sources and registries. This prevents manufacturers from conducting thorough post-market surveillance.

## The FDA UDI System

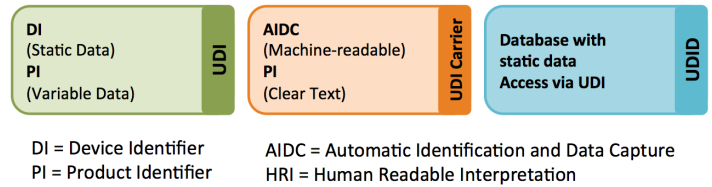
To address these issues, primarily those related to patient safety, the U.S. Food and Drug Administration (FDA) Amendments Act (FDAAA) of 2007 included language mandating the establishment of a unique device identification system for medical devices:

The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number.

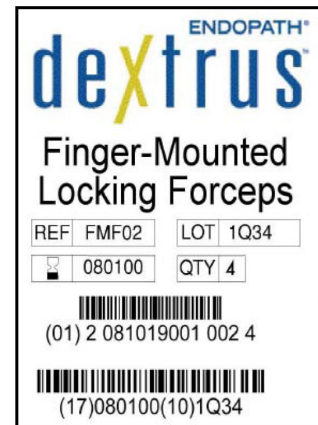
## UDI Requirements

Now that the UDI rule is final, manufacturers will be required to enumerate devices with a unique numeric or alphanumeric code that includes a device identifier, specific to the device model, and a production identifier, which includes the current production information for that specific device—such as the lot or batch number, the serial number and/or expiration date. The FDA has stated that it will allow manufacturers to use one of two ISO 15459 standards identify devices: the GS1 Global Trade Item Number (GTIN) or Health Industry Business Communications Council (HIBCC) Labeler Identification Code (LIC).

## UDI System



Manufacturers must apply UDIs to all levels of device packaging down to the lowest unit of use in human and machine-readable formats. The FDA’s proposed rule does not mandate which specific auto ID carrier must be used for the machine-readable aspect of UDI marking (e.g., linear bar code, 2-D matrix, RFID). The manufacturer must choose the carrier that best suits business needs and the needs of customers. For some device categories, such as implants or surgical tools, the FDA will require direct part marking of the UDI where a unique identifier would be required on the products themselves rather than the packaging.



Manufacturers must also transmit device UDIs, along with a set of standard information for each product, to a global UDI database (GUDID) so that end-users (e.g., health care providers) can easily look up information about the device.

## Timeline for UDI Compliance

The FDA is using a risk-based compliance timeline, with those manufacturers of Class III devices required to comply within one year of the final rule (2014); manufacturers of Class I or II devices that are “implantable, life-saving, and life sustaining” complying within two years (2015); manufacturers of Class II devices in three years (2016); and, manufacturers of non-exempt Class I devices (such as over the counter products) within five years (2018). For those devices requiring direct part marking, manufacturers can add one year to the class effective date. For example, manufacturers of implantable Class III devices would be required to comply within two years of the final rule (2015).

## Making the Most of Your UDI Investment

The processes by which device manufacturers assign UDIs to products, label products with both human and machine-readable codes, and populate the GUDID are complex and require a multitude of changes to internal systems, production, labeling, and packaging, as well as external communication with regulatory agencies, trading partners and other parties. As manufacturers allocate resources for the effort, many are asking how they can leverage investments that improve other areas of operations.

Leading medical device manufacturers have recognized they can leverage UDI investments to enhance product visibility, drive greater process efficiency and minimize risk by integrating unique device identifiers with enterprise quality management solutions (EQMS). By standardizing product identification within quality operations, device manufacturers can enhance a wide range of processes and activities, including product submission, registration tracking, change control and reporting.

UDI Implementation Timeline	
Class III	1 year
Class I/II Life Saving/ Life Sustaining	- 2 years - New requirement
Class II	3 years
Class I	- 5 years - Applies to Class I under GMP - Requires only device identifier/Class

## Enhance Visibility

By populating EQMS with UDIs, a manufacturer can easily gain a global view of products across quality operations. For example, if a manufacturer has a multinational product sold in multiple countries and markets, it can acquire the status of all activities for the product across the globe from a single UDI. Without UDIs in place, this same manufacturer would have to conduct separate queries for each of the product's various identifiers (e.g., part/product, site, country) and then reconcile the disparate information, a process that is inefficient, costly and prone to human error.

## Streamline Operations

The use of UDIs in an EQMS increases efficiency across a manufacturer's quality operations. To comply with the FDA's pending UDI regulation, a manufacturer will have to enumerate and label products with UDIs but also package and submit additional information on the products to the FDA for the GUDID.

By taking this information and making it part of the product record within EQMS, a manufacturer can easily access it for future use. For example, when it is required to re-submit product information to the FDA, it can easily access the data and make the necessary changes instead of creating a new data set for submission. A manufacturer can also use UDI data for additional purposes beyond the GUDID, such as product registration tracking, internal performance monitoring based on UDI rather than stitching multiple data together, effective recall track and traceability.

## Change Control and Management

UDIs can also be leveraged to streamline the change control process. The FDA, like most regulatory agencies, requires medical device manufacturers to re-register a device if a change has been made to the product, such as a change to the materials, packaging or labeling. In the highly competitive MedTech industry, where manufacturers are constantly enhancing and changing existing devices, a company can be faced with hundreds if not thousands of re-registrations each year.

By integrating UDI into the product registration tracking process, a manufacturer can quickly track product changes, identify the countries and markets in which the product is being sold and ensure that the necessary re-registrations are submitted in an accurate and timely manner.

## Manage Recalls and Mitigate Risk

By integrating UDIs into EQMS, a manufacturer can quickly identify problems that arise, investigate issues and determine the necessary actions to bring these matters to resolution. Without UDIs, a manufacturer attempting to correlate a quality issue found in one market relative to all other markets carrying the product faces the challenge of tracking the product by multiple identifiers. In this case, the process of gathering and reporting data is prolonged which increases the risk that a small problem could escalate into a major crisis. UDIs within its EQMS can streamline this process, identifying issues sooner and mitigating risk for manufacturers.

One of the main purposes of the FDA's UDI initiative is to facilitate better recall management to protect patient safety. With UDIs within the EQMS, a manufacturer can track recalled products, but also rapidly and effectively search for indicators that can lead to identifying trends in issues with other products in its portfolio to avoid additional recalls, avoid patient harm and preserve brand image.

## Conclusion

With the FDA's final UDI rule, medical device manufacturers must prepare for a multitude of changes that will require extensive time, labor and effort. While most manufacturers understand the patient safety benefits of unique product identifiers, many have not yet explored the business advantages that can be derived from UDI use across other functions and systems within the organizations. By populating its EQMS with UDIs, a manufacturer can easily leverage its UDI investment to gain visibility, streamline processes, increase productivity and reduce risk, driving greater operational and financial performance across quality operations.

To learn more about this topic and how Sparta Systems can help, visit [www.spartasystems.com](http://www.spartasystems.com)

Sparta Systems, an industry pioneer and leading provider of enterprise quality management software (EQMS) solutions, enables businesses to safely and efficiently deliver their products to market. Its TrackWise® EQMS, a trusted standard among highly regulated industries, is used by quality, manufacturing and regulatory affairs professionals to manage compliance, reduce risk and improve safety across the global enterprise. Headquartered in New Jersey and with locations across Europe and Asia, Sparta Systems maintains an extensive install base in the pharmaceutical and biotechnology, medical device, electronics manufacturing and consumer products markets.

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