



Global Medical
Technology Alliance
Innovating for a Healthier World

Unique Device Identification (UDI):

Insights and Benefits from a Single UDI System in the International Arena



White Paper
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EXECUTIVE SUMMARY

The implementation of a globally harmonized unique device identification (UDI) system will positively impact many aspects of the medical device and healthcare ecosystem by increasing patient safety and optimizing patient care. There are, however, considerations that must be examined and addressed prior to the development of localized UDI requirements in a given market. These considerations include labeling requirements, implementation timelines, the treatment of products already in commerce, and the assembly and maintenance of a UDI database.

The United States Food and Drug Administration (FDA) was the first government agency to issue and implement UDI requirements. Manufacturers and the public provided input throughout the UDI rulemaking process and FDA sought input from a broad set of stakeholders, including the public, manufacturers, and other government health agencies. FDA based its rule on a number of international standards and external consultations, consistent with the International Medical Device Regulators Forum (IMDRF).¹ As a result of significant thought and consideration, the FDA's final UDI rule achieves a balance of the regulator's needs and industry's capabilities without compromising patient and user safety. This

has led to a successful set of rules and policies.

A globally harmonized approach to UDI is critical to realizing the benefits of such a system, is a prerequisite for medical device traceability in a globalized economy, and lays the groundwork for the worldwide exchange of medical device data.

In contrast, the creation of multiple UDI regimes will stifle innovation in the medical device industry, create product shortages, and cause confusion in the supply chain. For example, different criteria regarding events that trigger a new UDI for an existing product could lead to unintended outcomes and incompatible data, including significant changes to product labels, database entries, or additional product registrations, which would ultimately slow down time to market for product changes and impact patient access. In addition, variations among regions or countries would add significant effort and costs for device manufacturers, down-stream customers, health systems, and patients without any added benefit to patient safety.

Creating a globally harmonized UDI system is achievable when countries adopt similar UDI requirements. In this regard, a country seeking to implement new UDI rules should rely on the IMDRF UDI Guidance,² along

¹ See IMDRF, UDI Guidance, Final Document (Dec. 9, 2013), *available at* <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf>.

² See IMDRF, UDI Guidance, Final Document, p. 3 (“The UDI System is intended to provide a single, globally harmonized system for positive identification of medical devices. Healthcare professionals will no longer have to access multiple,

with reference to FDA’s final UDI rule as a model for constructing rules of their own.

Below, we identify: (1) The important aspects of the FDA’s final UDI rule that should be adopted globally; and (2) information learned while implementing the rule. This information is intended to assist the formulation of new UDI rules in a harmonized manner, which in turn will make compliance more achievable—with more efficient use of resources—for regulators and the medical device and healthcare ecosystem, ultimately enhancing patient safety.

As discussed more fully in this document, our recommendations are as follows:

1. UDI rules should be adopted in a globally harmonized manner.
2. UDI rules should offer a phased in approach with implementation based on product risk classification. The implementation period should begin no less than two years from issuance of the regulation and when the UDI database is available.
3. UDI rules and policies should rely on international standards and globally accredited UDI issuing agencies, in addition to the IMDRF UDI Guidance, and consider the evolution of UDI technology.
4. Manufacturers should be permitted to submit information to databases using

standards-based submission options to account for their variation in size and capabilities, such as the use of web interfaces or HL7 formats. Globally standardized core data elements should become the common denominator for any national implementation.

5. Regulators should provide assistance when implementing a new UDI system, such as setting up a help desk, providing training opportunities, and issuing guidance documents.
6. UDI rules should provide the regulator with an efficient and expedient mechanism to grant exceptions, exemptions, alternatives and extensions that may exist for specific product areas or for specific manufacturers.
7. UDI rules should exempt all devices manufactured or labeled prior to the UDI rule effective date, including those that are held on a consignment basis.
8. Regulators should understand the implementation variations that occur between manufacturers with respect to use of device identifiers and maintain flexibility to account for a manufacturer’s specific needs by staying within the established framework of the globally accredited UDI issuing agencies.

inconsistent, and incomplete sources in an attempt to identify a medical device and, its key attributes.”),

9. Regulators should drive global convergence for the use of new product identifiers.

10. Implementation timelines related to UDI database changes must account for industry's needs to update internal systems and processes.

IMPLEMENTATION ASPECTS NOT COVERED IN THE IMDRF UDI GUIDANCE

UDI systems enable the linking of clinical records and information regarding device use, which enable more effective device safety surveillance and evaluation studies. Such a link can lead to a more complete safety and effectiveness profile for devices, enabling appropriate and timely remedies when potential safety concerns are identified. A globally harmonized UDI system will offer a number of additional benefits, including:

- a) More efficiency, accuracy and automation of capturing product information in the global supply chain;
- b) Increased visibility of device supply and movement through the healthcare supply chain to the patient, which leads to a reduction of fraudulent and counterfeited devices;
- c) Reduction in the risk of device shortages;
- d) Better visibility for adverse events;
- e) More information for the healthcare industry and public through supporting UDI databases, such as the FDA's Global Unique Device Identification Database (GUDID) public database;
- f) Increased global visibility to recalled devices;
- g) More effective mechanisms for healthcare providers to auto-capture device information consistently and accurately in systems and electronic medical records; and
- h) Reduction in medical errors.

In the context of this White Paper, UDI refers to “a series of numeric or alphanumeric characters that are created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market.”³ The UDI is comprised of the UDI Device Identifier (“DI”) and UDI Production Identifier (“PI”). The DI is specific to a model of medical device, whereas the PI identifies the unit of device production, such as a serial number, lot or batch number, software version, and manufacturing and/or expiration date.⁴

Below we offer our views on important aspects of the FDA's final UDI rule that should be adopted when implementing a new UDI system as they are not otherwise covered in the IMDRF UDI Guidance.

³ IMDRF, UDI Guidance, p. 8.

⁴ A UDI system is distinct from a “track and trace” postmarket system.

1. Utilization of a Phased-In and Risk-Based Approach

An important element of the FDA's final UDI rule that is not discussed in the IMDRF Guidance is an implementation scheme that offers a phased-in and risk-based approach. Class III devices (*e.g.*, the highest risk devices) were required to comply with the rule within one year of its issuance; class II devices that are implantable, life-sustaining or life-supporting were provided two years to comply; class II devices were provided three years to comply; and class I devices (*e.g.*, the lowest risk devices) were provided five years to comply. The phased-in approach allowed manufacturers to first concentrate their initial UDI compliance efforts on the highest risk medical devices, allowing such products to be managed throughout the supply chain and in reporting situations in a more expedient manner. FDA was also able to build its infrastructure incrementally and collaboratively with industry partners during this initial implementation phase. By granting more time to implement the rules for lower risk products, manufacturers and FDA were able to work together to clarify certain portions of the UDI rule and provide a more robust process and solution for implementation which resulted in a more consistent implementation interpretation and ultimately better data quality, particularly for the GUDID.

Recommendation: UDI rules should offer a phased-in and risk-based implementation approach. The initial implementation period should begin no less than two years for the highest risk devices.

2. Reliance on Standards and Globally Accredited Issuing Agencies

In addition to the IMDRF Guidance, the FDA's UDI rules and policies rely heavily on international standards and globally accredited UDI issuing agencies. This resulted in a least burdensome approach to implement specific labeling requirements already known and used in the global healthcare system. In particular, the FDA relied on the following globally accredited UDI issuing agencies and their associated issuing and use standards for automatic identification and data capture (AIDC):

- a) **GS1:** A globally recognized non-profit organization dedicated to the identification and labeling of consumer packages. Country-specific GS1 groups exist throughout the world with more than one million registered users and more than 112 locally-owned offices globally. GS1 issues bar code standards that medical device manufacturers use on a daily basis including linear and 2D formats.
- b) **Health Industry Business Communications Council® (HIBCC):** HIBCC is an industry-sponsored and supported non-profit council, founded in 1983, that develops a standard for data transfer using uniform bar code labeling. HIBCC was founded through

member organizations covering the Americas and European Union, and issues bar code formats that historically have been used by hospitals and healthcare organizations.

- c) **International Council for Commonality in Blood Banking Automation (ICCBBA):** ICCBBA is a non-profit association whose goal is the adoption of ISBT 128 for all medical products of human origin. It enhances patient safety by promoting and managing the ISBT 128 international information standard used in more than 77 countries across six continents and is widely endorsed by the professional community.
- d) **Global Medical Device Nomenclature (GMDN):** The GMDN is a system of internationally agreed terms used to identify medical devices. The GMDN database identifies more than 23,000 different medical devices and has been in use for over 16 years, with a high proportion of regulators and manufacturers now familiar with its use. The database is used by regulators, hospitals and manufacturers to identify medical devices that are of the same generic type. This supports market surveillance, adverse event reporting, product recall and other healthcare management activities.

The following international standards were also recognized as valuable in the development of the FDA's UDI rule and should be leveraged when developing new UDI rules and policies:

- a) ISO/IEC 15459, Parts 1-4, 6. Information Technology—Unique Identifiers;
- b) ISO/IEC 646:1991. Information technology—ISO 7-bit coded character set for information interchange; and
- c) ISO 8601:2004. Data elements and interchange formats—Information interchange—Representation of dates and times.

Recommendation: In addition to the IMDRF Guidance, UDI rules and policies should be based on international standards and globally accredited UDI issuing agencies, including those mentioned above, and existing organizations that support healthcare supply chains. In addition, regulators should consider the evolution of UDI technology by adopting technology neutral regulations.

3. Access to Information; Submission Methods

The FDA stores UDI data in the GUDID, which can be searched, analyzed and reviewed by the general public.⁵ The FDA provides manufacturers with multiple modes to interface and enter data into the GUDID. These include direct web interfaces, submission of data as an XML file in accordance with HL7 formats, and leveraging existing systems such as the Global Data

⁵ We note that certain confidential data is not displayed to the public in the GUDID. Only the regulator and submitter may review this more sensitive data.

Synchronization Network (GDSN). This flexible approach to data entry allows manufacturers to adopt business-appropriate solutions, enabling improved implementation speed and data accuracy. Moreover, recognition of global standardized approaches to data collection, such as GS1 Standards via the Global Standards Management Process (GSMP), promotes harmonization, which improves implementation speed, data accuracy and patient safety.

In addition, regulators should leverage a standard set of UDI fields and limit free text. Whenever possible, Boolean (yes/no) or numeric field types should be used. If text is necessary, a list of values (LoV) should be considered to allow manufacturers to submit standardized master data that countries can display in multiple languages by translating the field titles or list of values. This is especially valuable for countries that have more than one national language.

Recommendation: Manufacturers should be permitted to submit information to databases using standards-based submission options to account for their variation in size and capabilities, such as the use of web interfaces, HL7 formats or GDSN.

4. Providing Assistance to Industry: Help Desk, Training and Guidance

Manufacturers have found that ongoing assistance and interaction from the regulator, such as help desks, training, and guidance documents, are beneficial throughout the implementation phase of new UDI rules. In order to assist industry with implementation of the final UDI rule, the FDA established a help desk, has and continues to hold frequent training opportunities, and issues consensus-based guidance documents on complex and nuanced topics to ensure consistency of interpretation and maintain data quality. Other regulators should provide similar assistance when implementing a new UDI system.⁶

a. Help Desks

The FDA's UDI Help Desk has proven beneficial to large and small companies, as well as to the agency. The Help Desk is administered through a web-based form, and there are several linked paths on the FDA's website to help users arrive at the Help Desk efficiently. The Help Desk website asks the user to input various identifying information, including contact information. Responses to simple questions generally are emailed to the requester within a few days. In cases where the questions or responses are complex, the FDA may take more time and may request additional information, or even a teleconference. The FDA has done a good job at providing standardized answers for frequently asked questions helping to align the interpretation of the rule

⁶ The closer a national UDI regulation is aligned with the global standard, the less regulators will be required to assist with these activities because the general principles of the regulation will be already understood.

across the industry.⁷ We have also found it useful when agency experts provide answers to more nuanced questions.

b. Training

The FDA offered a number of training opportunities throughout the implementation phase of the final UDI rule, and convenes GUDID user groups in advance of compliance dates, both of which have proven useful. Training opportunities may be provided in a conference setting, with both the FDA and industry serving as speakers during UDI-specific conferences, as well as through FDA moderated webinars. Conference settings provide more extensive programs with detailed information and multiple opportunities for participants to collaborate with one another. Webinars can be offered at no cost to large numbers of participants, and can provide a forum for live question and answer sessions between the FDA and industry. These interactive methods have provided widespread collaborative information sharing in which industry shares experiences and the agency learns about various product labeling and distribution scenarios, which allow for more consistent interpretation and implementation of UDI rules and definitions.

c. Guidance Documents

The FDA has issued a number of guidance documents interpreting the regulation. These documents are invaluable to both the FDA and industry, as they provide detailed information about the UDI rule and compliance obligations often for complex and nuanced issues. Because they are not rules, guidance documents can be updated more easily in the future as the FDA and industry become more fluent about the intricacies of implementing a UDI system.

Taken together, a help desk, training opportunities, and guidance documents are valuable helping tools for industry as a UDI system is implemented. Regulators benefit as well, because information exchanges promote greater common understanding of the regulation, which will in turn facilitate continued compliance by industry and create consistency and better UDI data quality.

Recommendation: Regulators should provide assistance when implementing a new UDI system, including at least the following:

- a) Establish a Help Desk that manufacturers can access easily throughout the implementation period of a UDI rule, and make such responses available to the public.

⁷ FDA does not currently post answers to Help Desk questions to its website. However, we believe such a practice would benefit industry and reduce the need for the regulator to respond to duplicative questions.

- b) Offer frequent training opportunities for manufacturers prior to and during the system's implementation period, including webinars with question and answer sessions and in-person training events.
- c) Issue guidance documents in a timely manner that explain how the agency interprets complex and nuanced portions of the UDI rule, and update the guidances as needed.

5. Exceptions, Exemptions, Alternatives and Extensions

The FDA's final UDI rule provides a mechanism for manufacturers to request exceptions, exemptions, alternatives and extensions of time for certain aspects of the rule.⁸ This element of the rule has proven important as it enables manufacturers to address directly with the agency implementation challenges in a positive and constructive manner. We recommend UDI systems include a mechanism to issue exceptions, exemptions, alternatives and extensions, as well as the following:

- a) Ensure the request mechanism applies to all aspects of the UDI rule to avoid administrative challenges in granting appropriate exemptions; and
- b) Establish an administrative means for quickly communicating and publically disseminating request responses that would apply generally to the entire industry, so as to avoid use of agency resources responding to the same issues with multiple manufacturers.

Recommendation: UDI rules should provide the regulator with an efficient and expedient mechanism to grant exceptions, exemptions, alternatives and extensions that may exist for specific product areas or for specific manufacturers.

INFORMATION LEARNED WHILE IMPLEMENTING THE UDI RULE

The FDA's UDI rule provides numerous features beyond the information contained in the IMDRF UDI Guidance that are beneficial to industry. That being said, as can be expected in a rulemaking process that establishes and implements a new regulatory regime, the medical device industry and FDA learned valuable information during the implementation period. This section identifies those lessons so that other countries can benefit from this experience as they develop UDI rules of their own.

⁸ FDA's website lists a number of public exceptions, exemptions and alternatives at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIExceptionsAlternativesandTimeExtensions/default.htm>.

1. Initial Implementation Timelines Should Be Two Years or More

While the FDA's UDI rule included a phased-in and risk-based implementation scheme, our experience indicates that a one year implementation period for the first cohort of products subject to the rule is not adequate. There were a number of implementation questions that required clarity from the FDA, and industry did not have sufficient time to coalesce around a standardized labeling approach. This is particularly true given that device manufacturers must typically prepare their device labeling as much as one year in advance of a product's release. Moreover, an initial one year implementation period did not provide manufacturers and FDA with sufficient time to build a robust IT solution to work with the GUDID.

Recommendation: An initial implementation timeline of at least two years will better permit a smooth transition for the first set of devices subject to the rule. Doing so will provide industry—and the regulatory agency responsible for UDI implementation—sufficient time to address initial implementation concerns prior to the first effective date.

2. Clarify Date of Manufacture When Defining Production Identifier

When the date of manufacture is not used in the traceability or identification of a device because other means of production identification appear on the device label, it is not necessary to include it as a required production identifier of the UDI. Including the date of manufacture in the AIDC (barcode) presents technical challenges, such as redesign of product labels, manufacturing equipment upgrades, and modification of software applications used in printing labels, label inspection, and product selection in distribution warehouses.

Recommendation: The device's date of manufacture should not be a required production identifier when other means of production identification appear on the device label.

3. Small Medical Device Exemption

When the UDI rule was published there was insufficient information available to allow for the establishment of objective criteria to guide manufacturers in deciding when a label was too small to accommodate a UDI. After experience with the rule and the capabilities of software applications used in printing labels and label inspection, a general exception for medical devices that can only accommodate labels with a height of 50 mm or less and, if applicable, a diameter of 30 mm or less is appropriate because the small label size will not accommodate a UDI along with other required regulatory label information.

Recommendation: UDI rules should provide for a general exemption for small medical devices.

3. UDI Rules Should Exempt All Devices Manufactured or Labeled Prior to the UDI Rule Effective Date

In general, devices sold and placed in commerce prior to the UDI rule effective date should be categorically exempt from the UDI requirements. Many devices have long shelf lives (*e.g.*, blood glucose meters and lancets) and may therefore remain in commercial distribution for a significant period of time. Moreover, numerous healthcare systems rely on consignment inventory,⁹ many of which hold such inventory for multiple years. Such devices include but are not limited to: Non-sterile implant devices distributed in sets, intraocular lenses (IOLs), and various active implantable devices (*e.g.*, cardio, neurostimulator) and non-active implants (*e.g.*, instruments, heart valves, catheters, stents, and venous closure devices).

It is therefore imperative that any UDI rule fully exempt devices from its requirements that are placed into commercial distribution prior to the rule's effective date. Doing so will ensure that a smooth and successful transition to UDI will occur. Locating, removing, storing, and/or reworking these devices after the UDI compliance date to either re-label or destroy them is unproductive to the healthcare system, and could lead to significant and serious product shortages.

Recommendation: UDI rules should exempt all devices manufactured or labeled prior to the UDI rule effective date, including those that are held on a consignment basis.

4. Drive Global Convergence for use of New Product Identifiers

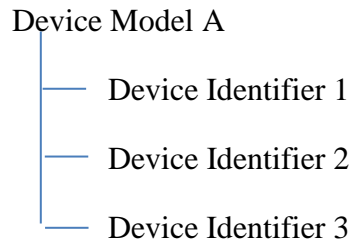
The FDA and globally accredited UDI issuing agencies provide structured rules that manufacturers must follow to determine when a new device identifier must be used in order to ensure they are unique and consistent on a global basis. For example, the FDA requires a different device identifier for each version or model of a device.¹⁰ Globally accredited UDI issuing agencies also require manufacturers to use different device identifiers under certain

⁹ Medical device sets containing a variety of device types and sizes, arranged in a manner to benefit patient care, are consigned to healthcare facilities to facilitate rapid deployment according to clinical need. The medical device industry and healthcare providers developed this consignment model for these sets of devices to ensure rapid access to needed clinical components and mitigate costs to health care facilities. Devices not distributed in sets may also be consigned to reduce the cost burden to healthcare facilities. This approach facilitates the placement of a vast assortment of device types and sizes within immediate reach of healthcare providers, including devices that are commonly used and some that are rarely used.

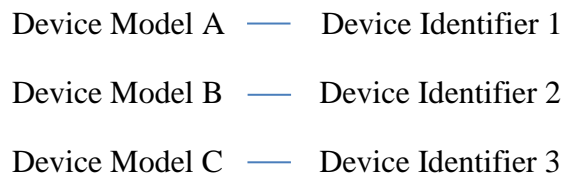
¹⁰ See 21 C.F.R. § 830.40(b) (explaining that “version” or “model” is defined as a device that has specifications, performance, size and composition within limits set by the manufacturer).

circumstances, generally requiring a new device identifier when the customer is expected to distinguish one product from another.

Given the rapid and iterative innovation cycle of medical devices, not all product changes require a new device identifier under the FDA's rules or a globally accredited UDI issuing agency's guidance. As a result, manufacturers institute their own individually developed processes within the context of the given framework established by FDA and globally accredited UDI issuing agencies. These processes are based on internal needs when assigning device identifiers to each product and level of packaging. In this regard, manufacturers are not consistent in the way they internally assign device identifiers to each product and package level, particularly for changes to a device that do not trigger a new device identifier under the issuing agency's guidelines. For example, a manufacturer may group identifiers as demonstrated below:



In contrast, a manufacturer may also organize device identifiers in a 1:1 relationship to the device model number, as demonstrated below:



Criteria for what triggers a new UDI-DI should be globally harmonized to avoid divergences between regulations and issuing agencies, and also allow sufficient flexibility for manufacturers. It should also be acknowledged that mergers and acquisitions occur frequently in the medical device industry. Therefore, UDI database systems should accommodate for transfers of ownership and the variations by which identifiers may be assigned within a given organization.

Similarly, there are many types of third party relationships that exist within the medical device industry, including suppliers, manufacturers, distributors and service providers. These relationships are managed through contracts where each party agrees to their responsibilities to ultimately manufacture and distribute a medical device. It is important to note that the manufacturer or supplier of a device may have contracts with multiple entities throughout the industry. Furthermore, the party that holds the FDA clearance (*e.g.*, regulatory file) is not always the brand name owner of the labeled device. As such, third party supply chain relationships may overlap with multiple finished device manufacturers. Therefore, it is important to acknowledge

that UDI rules must accommodate for and provide flexibility with respect to who bears the responsibility for compliance with the rules.

Recommendation: It is important to understand the implementation variations that occur between manufacturers with respect to use of device identifiers and maintain flexibility to account for a manufacturer’s specific needs by staying within the established framework of the globally accredited UDI issuing agencies.

5. Changes to Databases

At times it may be necessary to make changes to the UDI database (*e.g.*, GUDID). Such changes may include new or amended data fields, entry mechanisms, and codes. Medical device manufacturers have established procedures and processes, including internal IT systems, specifically tailored to these databases to automate and streamline data entry. When database changes are made, the medical device manufacturer must subsequently update their internal IT systems as well. These changes can take many months to implement because the new changes must be translated into local requirements, systems must be re-configured and updated, new software must be validated, quality system changes must be updated and documented, and user training and remediation plans must be performed.

Recommendation: Changes to a UDI database should be minimized as much as possible. Implementation timelines related to a UDI database change must account for industry to update internal systems and processes. This holds true even for what may appear to be a simple change. Providing adequate time to implement database changes will ensure the data flow remains accurate and timely.

In addition, system downtime should be published in advance when possible, and allowances made for submissions when a system’s downtime may have interfered with the applicable compliance date.

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