Unique Device Identification (UDI) Overview
Regulatory mandates in the U.S. are changing the way medical device manufacturers identify and provide data about their products ...

Regulatory mandates in the U.S. are changing the way medical device manufacturers identify and provide data about their products in an effort to improve device safety, facilitate access to device attributes, and promote more effective monitoring and reporting. Improving the technologies and processes used to both identify medical devices, as well as provide device attribute data that promotes the device’s use as intended are critical in order to keep pace with the advances in the devices themselves. As a result, regulations that address these needs have been enacted or will be enacted in the future.

Similar to the Pharmaceutical industry and Serialization regulations, the Medical Device industry faces challenges to promote patient safety. Unlike the Pharmaceutical industry, however, the challenges faced by medical device manufacturers are not related to counterfeiting or product adulteration, but rather are associated with the complexity and risk inherent in these important, life-saving and/or life-changing products. In addition, transformation is occurring within the area of post market surveillance of medical devices, specifically adverse event reporting, device registration, and recording and accounting of transactional data.

The U.S. FDA Unique Device Identification (UDI) Ruling seeks to implement mechanisms to provide information in a consistent format for all medical devices sold into the U.S market. Additionally, UDI seeks to harmonize the way in which devices are physically identified, both in human readable text as well as machine readable form such as bar code or data matrix code. While the U.S is the first market to pass a formal regulation for medical devices, the European Union and other countries are in the process of developing regulations. These efforts offer potentially powerful tools in the battle to protect both patients as well as those dedicated to serving them.

This document provides an overview of the U.S. FDA Unique Device Identification Ruling and the cross-functional challenges organizations will face as they seek to achieve UDI compliance.
Complexities in the use of medical devices, influenced by increased innovation and breadth of human interaction, is one of the driving forces behind the FDA Unique Device Identification regulations. Despite efforts by industry and the healthcare provider community, the issue regarding patient safety has not subsided. Estimates conducted by the World Health Organization (WHO) suggest that more than 1.3 million premature deaths occur annually globally as a result of unsafe injections conducted on patients (Shepard)\(^1\). Additionally, in the U.S., the reuse of single-use medical devices in hospitals is reported to occur 1 in every 4 instances (Shepard)\(^1\).

 Worldwide, these threats to patient safety have prompted action by governing regulatory agencies. The U.S. FDA UDI regulations require that the manufacturers/labelers of medical devices include labels with a Unique Device Identifier (UDI) using an approved data standard. The UDI will consist of a Device Identifier (DI) which indicates the product name and labeler, and a Production Identifier (PI) which includes the lot number, expiration date, and potentially other data such as serial number or manufacturing date where applicable. The combined DI code and the PI code equates to the full UDI. However, the law states this code can be presented on the labeling as one unified UDI code, or as two separate DI and PI codes. See illustration at the right.

The FDA requires that Automatic Identification and Data Capture (AIDC) technology be used to mark a device’s package using either a 1D or 2D symbol/barcode. Additionally, the FDA requires Human Readable Information (HRI) to accompany the AIDC code. These codes will be required to follow established standards such as GS1 and the Health Industry Bar Code Council (HIBCC), as well as the Global Medical Device Nomenclature (GMDN) coding system requiring all label date formatting to follow international standard (YYYY-MM-DD).

The FDA has implemented a data repository which will store information unique to all manufacturers’ medical devices. The Global UDI Database (GUDID) will provide a standardized way to identify devices across all information sources and systems including electronic health records and devices registries. Each manufacturer will be required to submit their product data for over 60 attributes required by the FDA which provide information regarding each of their specific medical devices sold in the U.S. market. The submission file to the GUDID can be provided in one of two ways. The first is via the secure GUDID Web Interface, and the second is per XML file following the HL7 SPL submission formatting.

Regardless of the submission options, the GUDID will require an account which identifies the marketing authorization holder (typically the manufacturer/labeler) and facilitates the submission of data. The FDA will allow the use of 3rd party providers to conduct the GUDID transmittal on behalf of the manufacturer.
JUNE 23, 2014
Extension Request Deadline

SEPTEMBER 24, 2015
Life-supporting, Life-sustaining devices (reprocessed devices)

SEPTEMBER 24, 2016
Class III devices (reprocessed devices)

SEPTEMBER 24, 2018
Class II devices (reprocessed devices)

SEPTEMBER 24, 2014
Class III devices & stand-alone software

SEPTEMBER 24, 2015
Implantable, Life-supporting, Life-sustaining devices & stand-alone software

SEPTEMBER 24, 2016
Class II devices & stand-alone software

SEPTEMBER 24, 2018
Class I, Non-classified devices & stand-alone software

SEPTEMBER 24, 2020
Class I & Non-classified devices (reprocessed devices)
The corporate business case for investment in a solution that enables the unique identification of medical devices should include more than basic regulatory compliance and the ability to continue marketing and selling the product in the target market without disruption. Integrating device data into internal and external supply chain events offers potential value for manufacturers beyond compliance to offset the capital investment and on-going depreciation expense that companies face.

### Patient Outcomes and Regulatory Oversight
- Reduced medical errors, misuse of medical devices, and adverse events
- Focused, and more effective, FDA safety communication

### Supply Chain Efficiencies
- Improved inventory tracking across supply chain nodes enabling improved forecasting, production planning, and distribution execution
- Improved stock rotation and inventory management

### Data Standardization
- Electronic Health Records (EHRs) and Personal Health Records (PHRs) featuring standardized date formatting
- Simplification of integrated information into data systems
- Electronic Data Interchange (EDI)

Despite the potential value proposition, UDI is a daunting organizational initiative. Challenges include implementing, operating, and maintaining the UDI solution components in a cost-effective manner. Upgrades to IT systems and infrastructure are considerable when managing changes to master data, standard product data entry, labeling and packaging, and 3rd Party Packager integration.

In addition to the major ‘upstream’ challenges, consider these other key challenges and uncertainties:
- Interpreting the rules and determining strategy
- Unclear emerging market regulations
- Risk aversion within an organization
- Aggressive compliance timelines
- Lack of resources and experience in this area
- Implementation must be balanced with other competing initiatives
- Existing packaged inventories
- Downstream markets’ readiness to receive UDI labeled products

Ultimately, both the threats and opportunities presented with FDA regulatory mandates requiring Unique Device Identification can be categorized across the following three dimensions:
- **People**
- **Technology**
- **Process**
The following descriptions summarize the key impacts and considerations of Unique Device Identification across these dimensions:

| **People:** | Across an organization, stakeholders involved in the implementation of UDI could include and are not limited to the following:
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<td>• Regulatory Affairs</td>
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<td>• Quality Assurance</td>
<td></td>
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<td>• Supply Chain</td>
<td></td>
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<td>• Information Technology</td>
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<td>• Graphics/Label Design</td>
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<td>• Packaging Engineering and Operations</td>
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<td>• Customer Service</td>
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<td>• Brand Protection/Marketing</td>
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<td>• Commercial and Trade</td>
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<td>• Sales and Operations Planning</td>
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<td>• Master Data Management</td>
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Indeed, implementing a UDI strategy across an enterprise represents substantial organizational change. There are many questions which require attention that did not require to be addressed in the organization previously, for example:

- Who owns the UDI attribute data?
- Who needs access to it and why?
- Who is responsible for updating the organization with regard to changes to existing regulations?
- What are the downstream implications?
- What changes are required to standard operating procedures, and resulting training requirements?

Effective planning, collaboration, and communication across all functional areas within the organization are critical to success.

| **Technology and Process:** | Achieving effective data governance within the organization requires various business functions accepting that they own the data associated with the products, and are responsible for its accuracy and maintenance. This ensures the quality of the information, and provides change control procedures to ensure its currency.
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<td>• Development and transmission of GUDID data submissions</td>
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<td>• Maintaining and controlling UDI attribute data collected and stored</td>
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<td>• Collecting/retrieving data attribute information from internal systems</td>
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UDI initiatives require business and Quality Assurance functions to modify existing processes, policies, and procedures. This often results from new or upgraded technology sets required for packaging lines, such as the following:

- Printing/marking equipment for unique bar codes (1D linear, 2D Data Matrix)
- Vision (camera) inspection stations to verify barcodes/labels are printed accurately and with the appropriate quality
- Automation controls for inspection, conveyor transport/sorting, and rejection stations
- Direct marking equipment/technology for implantable and reprocessed devices

Process impacts are not only due to equipment technology changes. Other business functions such as Quality Assurance, Supply Chain, and Customer Service must enhance existing processes to accommodate the additional UDI data that must be managed and controlled. Equally, the downstream processes impacted by the UDI-driven label changes should consider the impact on affiliates, trading partners, distributors, and customers.
KPMG recognizes the complexities that Life Sciences companies face as the world moves toward the unique identification of medical devices. Our internationally-experienced team offers clients the advantages of in-depth industry understanding, extensive experience in defining the strategy for and implementing regulatory driven change, the application of key lessons learned, and knowledge of proven technologies and processes necessary to enable the implementation of timely and effective UDI solutions within and across borders.

- Overall strategy and solution planning
- Business process modeling
- Enterprise solution architecture and integration
- Implementation management and governance
- Supply chain planning and operations
- Program and project management
- Budgetary planning
- MDM governance strategy and implementation
- Business and system requirements definition
- System testing and qualification services
- Integration management and data flow strategy
- Regulatory monitoring and compliance
- Vendor evaluations

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### Terms to Know

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<th><strong>Unique Device Identifier (UDI):</strong></th>
<th>A unique numeric or alphanumeric code that consists of two parts: Device Identifier (DI) and a Production Identifier (PI).</th>
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<tr>
<td><strong>Device Identifier (DI):</strong></td>
<td>Static data used to uniquely identify the model and device globally throughout the healthcare value chain.</td>
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<td><strong>Production Identifier (PI):</strong></td>
<td>Dynamic data used for production control values such as: serial number, lot number, expiration date, and manufacturing date.</td>
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<td><strong>GUDID:</strong></td>
<td>Global UDI Database which serves as the repository of key device identification information containing device attribute information.</td>
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<td><strong>Attribute:</strong></td>
<td>Data related to a component of device master data (e.g. GTIN, weight, dimension), structured in a pre-defined format.</td>
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<td><strong>Automatic Identification Data Capture (AIDC):</strong></td>
<td>A technology used to automatically capture data. AIDC technologies include bar code symbols, smart cards, biometrics and RFID.</td>
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<td><strong>U.S. Food and Drug Administration (FDA):</strong></td>
<td>A branch of the U.S. Department of Health and Human Services primarily responsible for regulating the approval and use of drugs, medical devices, cosmetics, and food.</td>
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Reference:
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KPMG is a leader in healthcare convergence, assisting organizations across the Healthcare and Life Sciences ecosystem to work together in new ways to transform the business of healthcare. With more than 1,500 U.S. partners and professionals supported by a global network in 156 countries, we offer a market-leading portfolio of tools and services focused on helping our firm’s clients adapt to regulatory change; design and implement new business models; and leverage technology, data, and analytics to guide them on their path to convergence.