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White Paper

Information Management FAQ for UDI

20 Questions & Answers about Complying with the FDA Requirement for Unique Device Identification (UDI)

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Executive Summary

Medical device recalls have doubled in the last decade, spurring the US Food and Drug Administration to implement new requirements for the identification and tracking of medical devices on the US market. For information management leaders who have struggled to get buy-in for a data governance program in the past, the UDI requirement may finally create the necessary urgency to persuade business leaders to provide funding and resources.

This Information Management FAQ was co-created by medical device and data management experts at First San Francisco Partners and Informatica to answer the 20 questions most commonly asked by medical device manufacturers about the UDI regulations. After reading it, you should understand:

1. What the UDI regulations are and who must comply.
2. The key data challenges involved in meeting UDI requirements.
3. How to build an effective EIM strategy and deploy a UDI compliance solution quickly and easily.

Unique Device Identification: An Introduction

Medical device recalls have doubled in the last decade. In response, the US Food and Drug Administration (FDA) has issued a new requirement, Unique Device Identification (UDI), to improve identification and tracking of medical devices. Under UDI, every medical device in use in the US will have a unique code embedded within it and displayed on the packaging. By tracking these codes in a central database and recording reports of adverse events, the FDA will be able to identify product problems faster, target recalls more accurately, and reduce related errors, injuries, and deaths. To comply with these new regulations, medical device manufacturers must be able to capture, enrich, and manage accurate device attributes from their enterprise databases so that they can then submit accurate, consistent, complete, and timely data to the FDA Global Unique Device Identification Database (GUDID). The best way to achieve this goal is through an Enterprise Information Management (EIM) strategy, supported by a UDI compliance solution that includes robust data management.

1. What is the FDA's Unique Device Identification (UDI) requirement?

The FDA is increasing its oversight of the medical devices industry to improve patient safety and reduce medical device-related errors, injuries, and deaths. To facilitate the new regulations, the FDA is introducing a consistent and automated way to identify and track medical devices distributed in the United States.

By September 24, 2014, all riskier Class III devices (comprising most of the implantable, life-supporting and life-sustaining medical devices) plus devices licensed under the Public Health Service (PHS) Act will be assigned a UDI code to be displayed on all devices and packaging. This code will be housed in a central FDA Global Unique Device identification Database (GUDID), which will serve as the FDA's master database, its "single source of truth" for all approved medical devices in the United States labeled with a UDI.

Most of this information will be made available to the public so that patients who have a medical device implanted can easily look up information about the device. The UDI does not indicate, and the database will not contain, any information about who has a device or personal privacy information.

A national UDI system can achieve improved medical device-related patient safety on many levels, such as:

- enabling faster and more accurate device recalls
- facilitating more reliable and efficient post-market tracking of devices
- reducing or preventing distribution of counterfeit devices
- eliminating medical errors due to device misidentification

2. What types of companies are affected by the UDI requirement?

The following companies are required to comply:

- Medical device manufacturers
- Medical device labelers
- Specification developers
- Single-use device reprocessors
- Convenience kit assemblers
- Repackagers
- Relabelers

3. Which roles will be affected?

The impact of the UDI requirement, and the costs of implementing it, will extend well beyond the supply chain. As companies develop their approach to managing associated processes and costs, they will need to include multiple functions, including:

- product development
- operations
- quality
- order management
- inventory
- information management

4. What drove the need for the UDI regulation?

Medical device recalls have doubled in the last decade, according to an FDA Center for Medical Devices report released in March 2014. And, quite frankly, the quality of data used in the medical devices industry is subpar. The industry as a whole has not adopted data quality management best practices. Medical devices distributed in the United States, unlike pharmaceuticals, don't have a standard system of identification and tracking. As a result, medical device information is dangerously fragmented, inaccurate, and inconsistent. This leads to slow, inefficient recalls and incomplete, unreliable adverse event reporting and tracking. Ultimately, it could cause poor decisions, injuries, and even deaths.

5. How do medical device manufacturers benefit from the UDI requirement?

The UDI system can benefit medical device manufacturers, distributors and purchasers by using better product information to:

- reduce costs and errors across all processes that rely on product information
- accelerate recalls and quickly identify where defective products are located
- streamline product development and supply chain processes
- improve customer engagement, sales and marketing

6. What are the penalties for failing to comply with the UDI regulation?

Manufacturers will not be able to sell their product in the US if it is not labeled and uploaded to the FDA's GUDID. Potential enforcement actions for violations of UDI requirements include seizure, injunction, and civil and criminal penalties.

7. What is the UDI code?

A medical device's UDI will be a unique two-part numeric or alphanumeric code.

UDI = DI + PI

- **DI:** a device identifier is a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and
- **PI:** a production identifier is a conditional, variable portion of a UDI that identifies one or more of the following 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 (HCT/P) regulated as a device

Each code will appear in plain text as well as at least one form of automatic identification and data capture (AIDC) technology, such as a barcode or a radio frequency identification tag (RFID). Labelers will create, assign, and maintain their own UDI codes with the help of accredited issuing agencies (e.g., GS1, HIBCC and ICCBBA).

8. What are the four core UDI requirements?

I. **Device and Package Labeling:** The label of a device as well as all levels of packaging must bear a UDI.

II. **Database Submission:** The FDA has identified a number of specific attributes—including, but not limited to, device model number or version, industry- and FDA-assigned codes and certain device or packaging conditions (e.g., sterility status)—to be submitted along with the device identifier component (but not the production identifier part) of the UDI code. The data about the device and its packaging must be submitted to the GUDID database.

III. **Date Formatting:** Any dates that appear on device labels, such as expiration or manufacturing dates, will use the format YYYY-MM-DD (all numeric).

IV. **Direct Part Marking:** Devices that are intended to be used more than once and reprocessed (e.g., cleaned, disinfected, or sterilized) before each use must have a permanent, direct part marking of the UDI code. This ensures that applicable devices remain identifiable even if they become separated from their labels.

9. What is required by the first deadline of September 24, 2014?

The riskier Class III devices (comprising most of the implantable, life-supporting and life-sustaining medical devices) plus devices licensed under the Public Health Service (PHS) Act are required to meet the first three UDI requirements:

- device and package labeling
- GUDID submission
- date formatting

By the second-year deadline, these devices must comply with the fourth core requirement—permanent, direct part marking—if the devices are intended to be used more than once and reprocessed before each use. In addition, all remaining implantable, life-supporting and life-sustaining medical devices will have to comply with those same requirements.

10. What's the submission process?

The submission process requires a GUDID account. There are two options for submission:

- **GUDID Web Interface**: enables structured input of device information as one DI record at a time.
- **HL7 SPL Submission**: enables submission of device information as XML files.

11. What data challenges will information management leaders have to manage?

Information management leaders should assess the current state of their company's data management processes to determine how long it takes, and how much effort it takes on a scale of 1 to 5 (where 1 is very easy and 5 is very difficult) to accomplish these tasks:

- collect, integrate, clean, and rationalize the data needed to internally prepare and create the UDI production identifier attributes (e.g. lot number, batch numbers, serial numbers, expiration data)
- prepare for the submission of static identifiers to the FDA's GUDID
- create a sustainable process to manage, maintain, and measure the success of UDI submissions to the FDA

12. What's the best strategy for overcoming these data challenges?

An Enterprise Information Management (EIM) strategy ensures that enterprise data, including data needed for UDI compliance, is:

- available, accurate, complete, consistent, secure, and standardized so it can be properly consumed by other systems
- efficiently managed and governed based on having the right organizational players, policies, processes, and technologies in place

Stakeholders all along the supply chain, from partners and distributors to end users, should have confidence that they can trust the data.

13. What is needed to support an EIM strategy?

Three key pillars support a successful EIM strategy and UDI compliance solution:

I. **Data Governance:** Establishing or leveraging an existing data governance program to ensure the processes are in place to meet the UDI requirement

II. **Data Quality Management:** Ensuring product data needed for UDI compliance is accurate and complete

III. **Master Data Management:** Centralizing and ensuring the consistency of business-critical medical device data needed for compliance

14. What role does data governance play in UDI compliance?

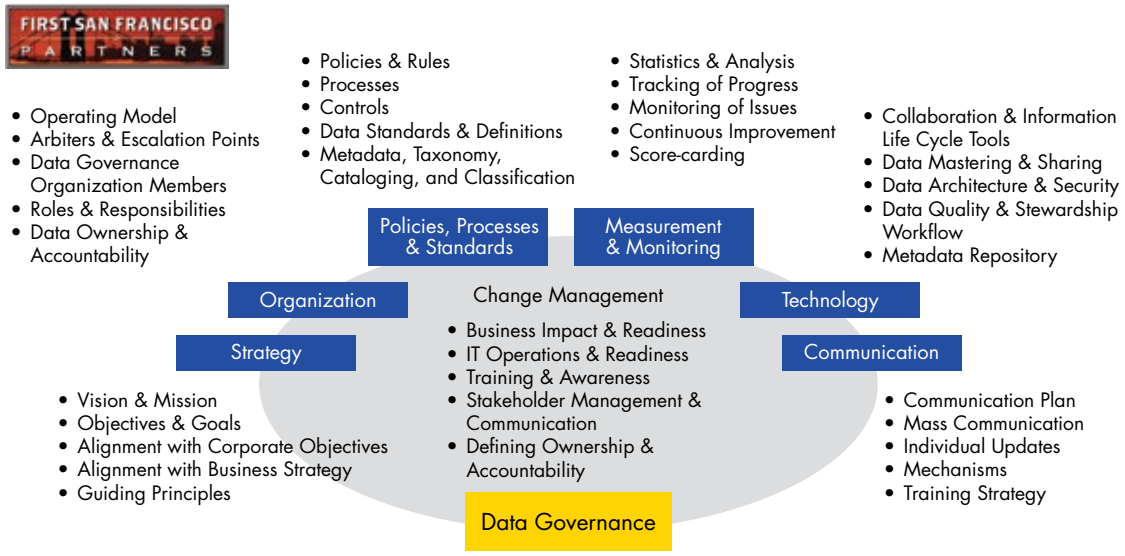
If your company already has a data governance program in place, you can leverage it for UDI compliance. If you don't have a data governance program, the UDI requirement can be used as a launch pad to an enterprise-wide data governance initiative.

Without a governance program in place, your company runs the risk that the changes initiated during the course of UDI compliance will negatively impact the quality, accuracy, usability, or availability of the data used by the rest of your organization.

Conversely, a solid governance program can facilitate the data, process, and application changes needed to comply with unique device identification. It can also accelerate an existing UDI initiative.

15. What are the components of a successful data governance program for UDI compliance?

- **Strategy:** When UDI compliance is a company priority, a data governance strategy explicitly and proactively focuses on governing the data elements needed to facilitate compliance.
- **Organization:** This collaborative, cross-functional approach creates an enterprise-wide culture of accountability with respect to data quality and usage that is essential as your company addresses UDI compliance.



- **Policies, Procedures and Standards:** These play an important role in the creation, implementation, and enforcement of policies, process and standards, including:
  - reaching agreement on device data definitions and associated attributes
  - managing changes to device data and how data changes are proliferated across systems and departments
  - encouraging accountability for the accuracy of device data needed for device classification and required for submission to the GUDID
- **Measurement and Monitoring:** This helps establish processes and requirements for measuring data quality, usage, and accountability. It can serve as the data monitoring function for the UDI compliance team to ensure data accuracy, completeness, auditability, traceability and continuous process improvement.
- **Technology:** The same technology functions and deliverables important to any data governance program can be extended to assist with UDI compliance. For example:
  - Data flow diagrams produced by the governance team can help the UDI team understand where the necessary data is located, transformed and updated.
  - Established audit trails can be leveraged for security and proof of compliance.
  - Master data programs for product data consolidation, existing or newly created, can optimize submission of device data to the GUDID.
- **Communication:** Leverage your data governance program's communication channels and structures to educate employees on the priorities, accomplishments, and importance of UDI. UDI data requirements can be incorporated into the training created for data management and governance to ensure all employees understand their involvement in UDI compliance.
- **Change Management:** A UDI program can take advantage of the plan, approaches, and implementation process involved in change management to ensure that adherence to UDI becomes a new operational norm.

16. What role does data quality management play?

Poor data quality can make it difficult to meet UDI compliance requirements. If you don't effectively manage the quality of your data in each system that contains medical device data on an ongoing basis, this may prevent you from meeting compliance requirements within required timeframes. As a result, your organization may be fined or subjected to other negative regulatory actions.

Incomplete, inconsistent, duplicate, or incorrect data may be the result of:

- Manual data entry
- Data standards, policies, and processes that are inconsistent across systems, departments, and lines of business
- Data that is unsynchronized or fragmented across systems, departments, and lines of business
- Inconsistencies between data from external sources and data from internal sources

First San Francisco Partners' Data Quality Framework involves Seven Dimensions

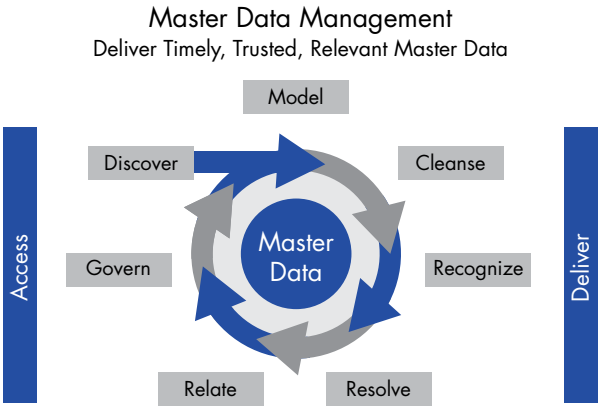
DIMENSION	KEY QUESTIONS	IMPACT
Completeness	Is all appropriate information readily available? Are data values missing or in an unusable state?	Incomplete data necessitates increased manual manipulation and reconciliation in creating a UDI or submitting data successfully to the GUDID
Conformity	Do data values conform to expected formats?	Lack of conformity, such as with the mandated date format, results in ambiguity and confusion
Consistency	Is there conflicting information about the same underlying data object in multiple data environments? Are values consistent across all data sources?	Data inconsistencies cause problems in data reconciliation across different systems and applications, resulting in manual effort to reconcile data and prepare it for aggregation and GUDID submission
Accuracy	Do data objects accurately represent the "real-world" business values they are expected to model?	Incorrect or stale data, such as old product or manufacturer information, that is submitted to the GUDID can result in faulty (and potentially dangerous) reporting and analysis
Duplication	Are there multiple, unneccessary representations of the same data objects within a given data set?	Data redundancy prevents the efficient creation of a unique identifier
Integrity	Which data elements are missing important relationship links that would result in discrepancies between two data sources?	Lack of integrity witht attribute and other data prevents full compliance as well as limits auditability and traceability of records
Timeliness	Is data available for use as specified and in the time frame in which it was expected?	Lack of timely data entry and submission to the FDA will hinder compliance as well as prevent rapid response to problems

After determining where your data quality falls short, you can take steps to mitigate the pertinent dimensions:

1. Profile the data to identify gaps and discrepancies.
2. Cleanse the data according to your business requirements and the UDI guidelines.
3. Validate the data to ensure it complies with the standards.
4. Measure and monitor the data to verify it adheres to the quality thresholds over time.

Repurposing data stewards to address UDI data quality requirements is a good way to leverage existing resources to maintain consistency across your information management practice.

17. Why should I consider centralizing my business-critical medical device data?



Master data management (MDM) software can provide a "one-stop shop" for your business-critical product data, UDI codes, and data needed for FDA-mandated submission? If you have an existing MDM hub to master product data, you may be able to leverage it to meet UDI compliance requirements. If you have a multidomain MDM solution managing customer information, you may be able to extend it to master product data as well. If not, you may want to invest in one.

An MDM hub for product data enables you to create a cohesive view of product data across the company. The MDM hub does this by pulling together business-critical data from various systems in different business units, lines of business, and functions into a central repository, where it can be mastered, managed, and shared with other systems on an ongoing basis. When you need to respond rapidly to changes to product data, you know exactly where to find it.

Much as the FDA's GUDID serves as a MDM hub for approved medical devices, a device manufacturer's MDM hub for product data enables your organization to unify and manage all of its medical device information.

An MDM hub for product data can also support your company's M&A strategy. Companies that have grown through acquisition often end up with many different systems for creating and managing medical device data. An MDM hub for product data can bring data together from all of those systems in a single central repository for easier management.

18. What about integrating with third party issuing agencies accredited by the FDA?

An MDM hub for product data also provides a landing place for the data enrichment and third-party data needed to build a complete UDI record. Medical device manufacturers will create, assign and maintain their own UDI codes according to ISO standards with the help of issuing agencies accredited by the FDA, including:

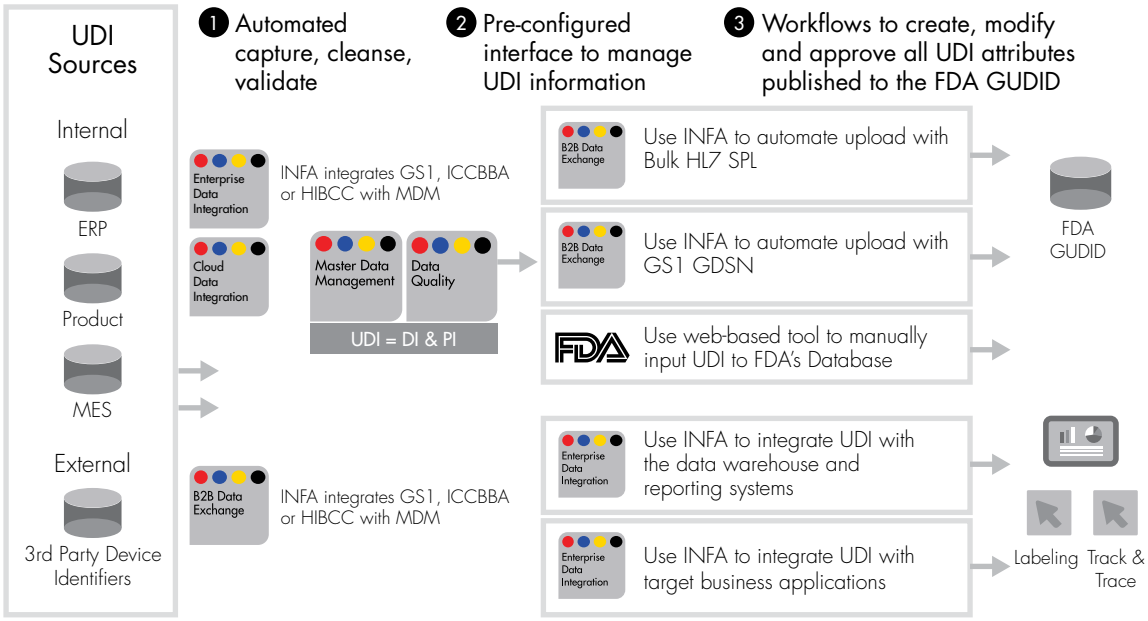
- GS1
- HIBCC (Health Industry Business Communications Council)
- ICCBBA (International Council for Commonality in Blood Banking Automation)

Other third-party data required for submission to the GUDID include:

- GMDN (Global Medical Device Nomenclature) code(s)
- D&B D-U-N-S number for the manufacturer
- FDA product code and listing number or premarket approval submission number (as applicable)

An MDM hub for product data allows you to aggregate data from the multiple feeds coming into your organization, facilitate the integration of this data with company-produced data, and create a unified data management environment. By aggregating both internal and external data, an MDM hub for product data provides a single repository from which you can draw the data required for submission to the FDA. Having all product data in one place simplifies every stage of your data management efforts, from validating data before submission to handling exceptions and errors that bounce back from the GUDID as part of the submission process.

19. What does the architecture of a potential UDI compliance solution look like?



The architecture is comprised of three components:

I. Data Management

- Automated capture, cleansing, and validation of legacy UDI attributes for each of the multiple sources for a medical device
- FDA-compliant, auditable archiving of all UDI attributes for each device
- Ability to cross-reference the product repository of UDI (DI) attributes with Product Identifiers (PI) to ensure product traceability history for each SKU shipped
- Sophisticated workflows to create, modify and approve all DI's published to the FDA GUDID
- Key UDI and other device attributes for new device labeling requirements and systems
- Pre-configured data model to store UDI attributes
- Pre-configured user interface to manage UDI information
- Pre-configured charts to demonstrate key metrics, such as:
  - Device identifier (DI) conformity metrics
  - Task management metrics
  - Source system metrics
  - Exception and rejected code metrics

II. Data Requirements

- The Device Identifier (DI) will be the primary key in the UDI database and will be linked to other product data elements
- The FDA GUDID repository will not contain the PI, but will contain PI flags to indicate which PI attributes (lot or batch number, serial number, expiration date, and manufacturing date) will appear on the label of the device.

III. Data Registration

- Manual entry via the FDA web-based tool
- Automatic generation of the HL7 Structured Product Label (SPL) XML UDI message in a submission-ready format via GDSN, providing a secure and easy way to register product data with any UDI database, anywhere in the world, with a single connection.

20. Can I reuse any of the investments I've made complying with the UDI requirements?

Absolutely. If you have struggled to get buy-in for a data governance or data management program in the past, the UDI requirement may create the sense of urgency needed for your business leaders to get on board to fund and resource data governance or data management initiatives. You can also leverage your data quality and MDM hub efforts for other compliance requirements as well as revenue-generating projects:

- Provide product data to customers (hospitals, distributors, wholesalers, GPOs) simultaneously with one single connection
- Enable downstream synchronization of product data with ERP, MES, labeling systems, etc.
- Use this integrated, best-in-class model to design, develop, launch, service and dispose of products
- Add other types of product data to your MDM hub to be better prepared for future regulatory requirements or other, separate product data projects
- Add other types of data domains such as customers, employees, or suppliers to your MDM hub to get valuable insights from the relationships between them, such as which healthcare providers have purchased which medical devices from which employees
- Add other types of data domains such as physicians, organizations, locations, and sales employees to your MDM hub to get valuable insights from the relationships between them for projects such as physician spend management or sales territory management

Your MDM hub can provide clean, consistent and connected business-critical data to any operational and analytical systems to improve business processes and decisions in both the front and back office.

About FSFP

First San Francisco Partners (FSFP) is a unique consulting firm that specializes in the definition and implementation of enterprise information management (EIM) and big data strategies. As EIM specialists, FSFP helps organizations better govern, manage, integrate and share their critical information assets to ensure companies can maximize profits, reduce risks, increase operational efficiency and reduce operating expenses. Service offerings are customized to meet each client's specific needs and business objectives. FSFP consultants work collaboratively with the business and IT stakeholders to help the organization make informed decisions about EIM planning, implementation and organizational alignment. Visit www.firstsanfranciscopartners.com for more information.

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