



Oracle, Inspirage and USDM Life Sciences

Teaming to deploy best-in-class solution for rapid UDI compliance

The FDA UDI (Unique Device Identifier) mandate was initiated to enable better traceability of medical devices throughout the supply chain and to improve the information available for managing product quality issues that could potentially impact the patient. Other global Health Authorities such as the Global Harmonization Task Force (GHTF) are also enacting similar requirements with which multinational companies will soon have to comply.

The UDI/Traceability mandate will be implemented in phases starting in September 2014 and medical device companies must develop an enterprise strategy to satisfy these global requirements. An effective UDI solution can be perceived as complex and the effort to achieve compliance staggering with several large medical device companies budgeting in excess of \$50M. Inspirage, Oracle and USDM have partnered together to bring a simple, straight forward solution to market to help companies become UDI compliant.

The scope and scale of these UDI initiatives have several complexities:

- The UDI initiative will impact 100% of a company's Class I, II & III devices
- There are influencing factors causing companies to phase in UDI solutions ahead of the FDA stipulated timelines
- A formal UDI policy and implementation program is needed for IT, labeling, packaging and supply chain
- Multiple product data streams must be synchronized to assure compliance
- An extensive IT platform must be integrated to achieve process efficiencies

**Learn more about Inspirage/
USDM/Oracle UDI Solutions.
Please contact Inspirage at
info@inspirage.com or visit
www.inspirage.com/udi.**

Inspirage/Oracle/USDM 5-Step UDI Solution

Inspirage, USDM and Oracle have partnered to deliver a best-in-class proven rapid start UDI solution, enabling Medical Device customers to meet the imposed sunrise date. The Inspirage solution combined with USDM's expertise in UDI and FDA compliance offers customers with a proven way to help meet UDI regulations.

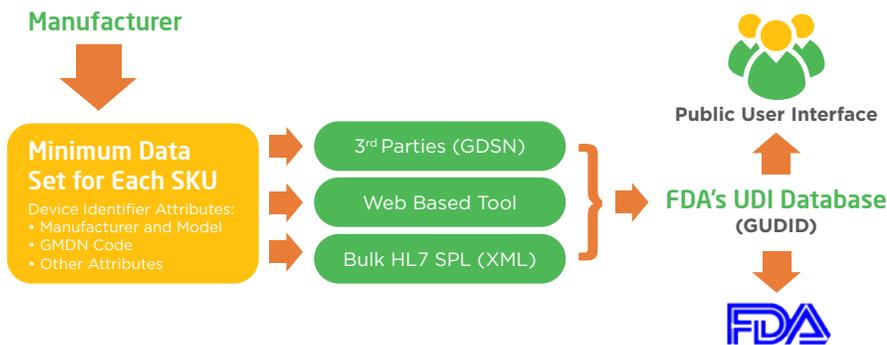


The UDI solution performs the following functions:

- **Establish Policy:** Establish the UDI regulatory policy to address all products and packaging hierarchies
- **Source & Cleanse:** Find & validate legacy UDI attribute data for all SKUs
- **Process & Manage:** Attribute revision management & GTIN synchronization
- **Extract & Submit:** FDA GUDID upload & integration to UDI (PI) systems
- **Validate:** Revise and validate downstream systems, equipment and processes for UDI compliance

The FDA UDI Database

The FDA requires that Device Identifier (DI) attributes (Static) are submitted, and Manufacturers will be responsible to maintain Production Identifier (PI) information (e.g. Lot Controls).



3 is better than 1

Inspirage, Oracle and USDM have teamed our resources to provide a best-in-class solution that leverages the strengths of each company.

Oracle Offering

This Solution leverages Oracle's proven business process, change and configuration management tools to deliver an FDA Part 11 Compliant UDI platform. This platform allows for configurable solution that can be implemented as a stand-alone UDI solution or one that can easily be integrated into an existing Oracle environment.

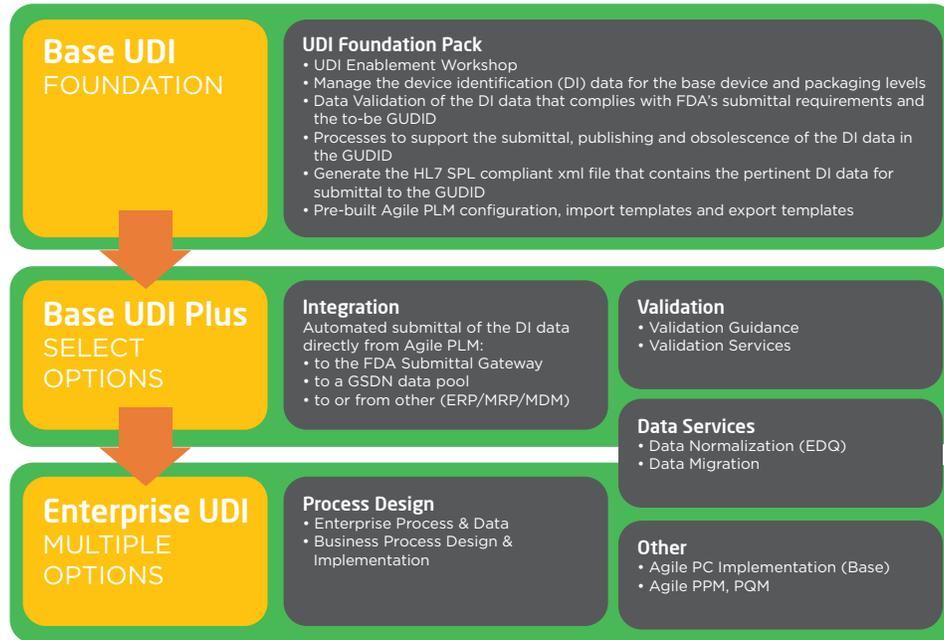
The Challenge

There are several business challenges for Medical Device customers including:

- How do regulatory executives ensure that the company's UDI response addresses all product-specific issues?
- How do Medical Device customers manage the necessary attribution and identifiers for UDI?
- How do Medical Device customers manage change?
- for the DI attributes and relationship back to the DMR, specifically the labeling and FG data?
- How do Medical Device customers generate and store the unique item identifier (i.e. GTIN)?
- How do Medical Device customers submit the data to the FDA Submittal Gateway?
- How do Medical Device customers pass the DI data to their supply chain/manufacturing systems to enable the proper label to be generated with the PI data?
- How do Medical Device customers ensure that all systems, equipment and process changes are validated and ready for production?

Inspirage Offering

Inspirage leverages the Oracle platform to deliver a pre-configured solution which has allowed companies go live quickly and begin start on the path toward UDI compliance. More than just a “database of UDI attributes,” the Inspirage solution has pre-built validations and business logic that enforce the rules, processes and lifecycles defined by the FDA. Furthermore, the solution can meet not only UDI needs but can be used to address pending standards such as IMDRF and AWHP.



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USDM Life Sciences Offering

USDM Life Sciences provides strategic UDI regulatory guidance, implementation and validation services to enable medical device companies to meet the UDI requirements and achieve benefits of improved product identification throughout the supply chain. USDM's services include:

- **Strategic Regulatory Guidance and Corporate UDI Policy & Strategy Development**
 - Support FDA responses
 - Establish UDI policy
 - Analyze product portfolio relative to UDI requirements
 - Help determine FDA-accredited organization for assignment of UDIs and auto ID barcode.
- **Implementation services to build and execute UDI**
 - Determine FDA UDI requirements impact by device and organize products
 - Analyze gaps with legacy systems, connectivity to GUDID, labeling/packaging/inspection and supply chain systems and requirements for UDI
 - Establish the strategy and plan (activities, schedule, budgets, responsibilities, partners)

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Inspirage is the integrated supply chain specialist firm solving business critical challenges from design to delivery. The company delivers end-to-end consulting and implementation solutions that link Innovation Management, Supply Chain Management and Logistics Management. Inspirage partners with their customers to break down information silos and optimize performance to accelerate innovation, fuel growth and achieve operational excellence.