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The Inspirage-Oracle 3-Step UDI Solution
Enabling Medical Device customers to comply with the FDA UDI mandate by leveraging Oracle Agile PLM

The Challenge

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 are also enacting similar requirements with which multinational companies will soon have to comply.

The UDI/Traceability mandate began in 2015 and medical device companies must develop an enterprise strategy to satisfy these global requirements. An effective UDI solution is complex and the effort to achieve compliance is staggering with several large medical device companies budgeting in excess of $50M.

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

- Multiple product data streams must be synchronized to assure compliance

- An extensive IT platform must be integrated to achieve process efficiencies

Visit www.inspirage.com/udi to learn more about the **Inspirage-Oracle 3-step UDI Solution. We are the experts at helping you translate your supply chain vision into measurable business results. Contact us at info@inspirage.com to discuss how we can collaborate to improve these critical capabilities for your company.**

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The Solution

Oracle has partnered with Inspirage to deliver a **UDI Solution**, enabling Medical Device customers to comply with the FDA UDI mandate. Leveraging Oracle Agile PLM, our 3-step solution performs the following functions:
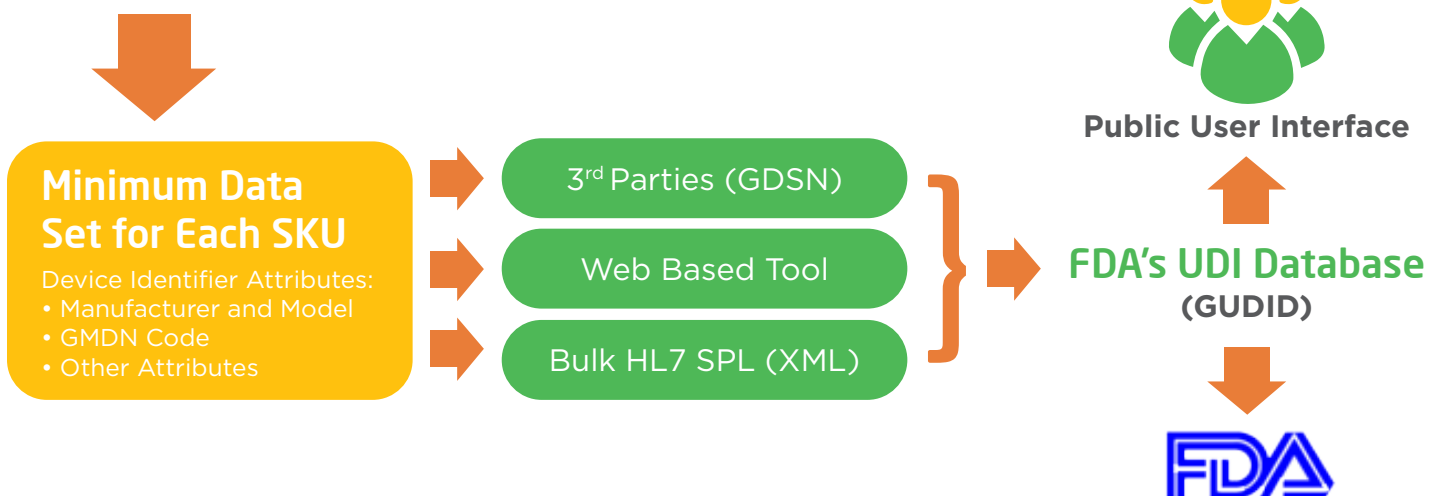

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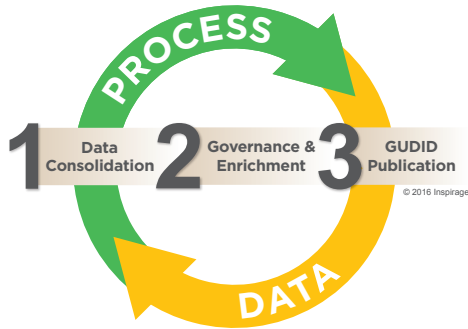
1. **Source & Cleanse:** Find & validate legacy UDI attribute data for all SKUs

2. **Process & Manage:** Attribute revision management & GTIN synchronization

3. **Extract & Submit:** FDA GUDID upload & integration to UDI (P.I.) system

The Challenge

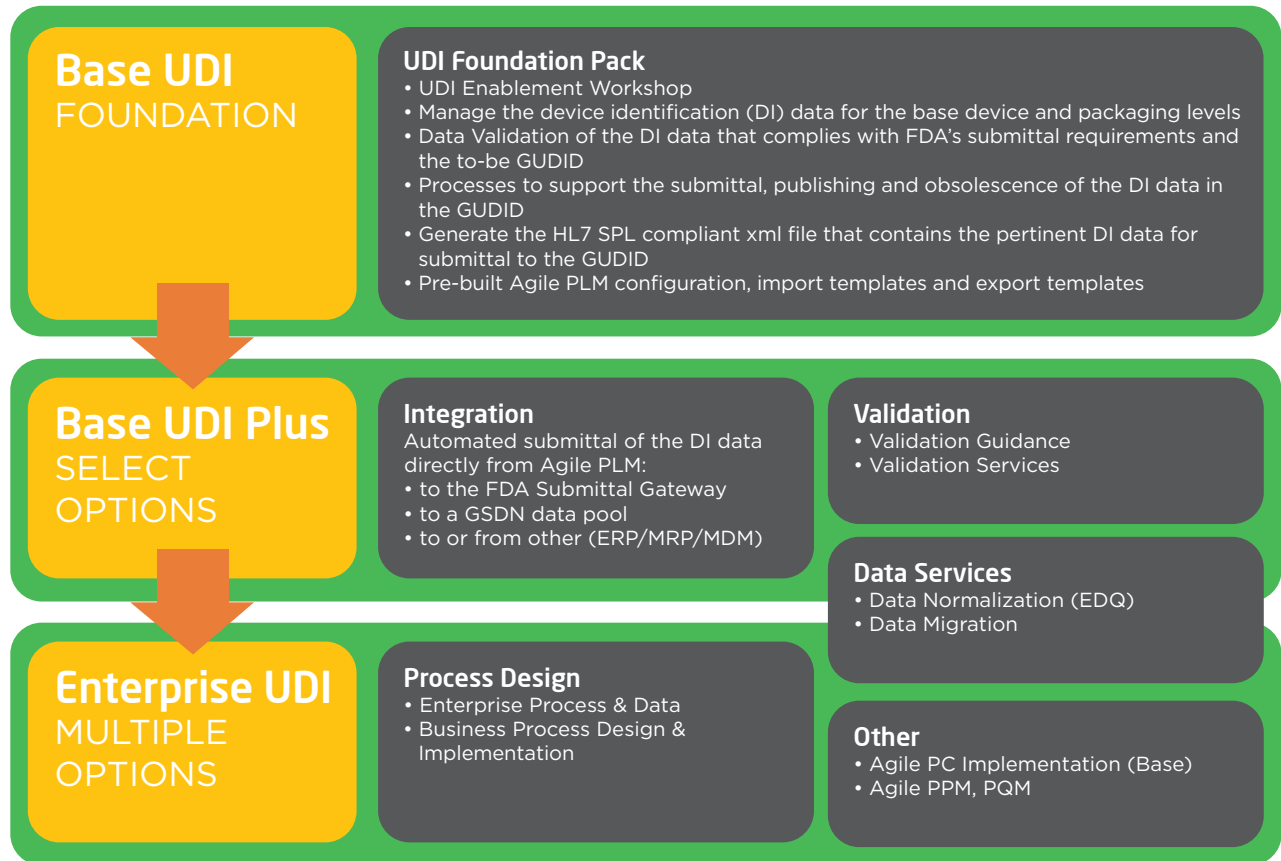**There are several business challenges for Medical Device customers including:**

- 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?

Manufacturer

Minimum Data Set for Each SKU

Device Identifier Attributes:
- Manufacturer and Model
- GMDN Code
- Other Attributes

- 3rd Parties (GDSN)
- Web Based Tool
- Bulk HL7 SPL (XML)

Public User Interface

FDA's UDI Database (GUDID)

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).

Base UDI FOUNDATION

UDI Foundation Pack
- UDI Enablement Workshop
- Manage the device identification (DI) data for the base device and packaging levels
- Data Validation of the DI data that complies with FDA's submittal requirements and the to-be GUDID
- Processes to support the submittal, publishing and obsolescence of the DI data in the GUDID
- Generate the HL7 SPL compliant xml file that contains the pertinent DI data for submittal to the GUDID
- Pre-built Agile PLM configuration, import templates and export templates

Base UDI Plus SELECT OPTIONS

Integration
Automated submittal of the DI data directly from Agile PLM:
- to the FDA Submittal Gateway
- to a GSDN data pool
- to or from other (ERP/MRP/MDM)

Validation
- Validation Guidance
- Validation Services

Data Services
- Data Normalization (EDQ)
- Data Migration

Enterprise UDI MULTIPLE OPTIONS

Process Design
- Enterprise Process & Data
- Business Process Design & Implementation

Other
- Agile PC Implementation (Base)
- Agile PPM, PQM

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Inspirage UDI Offerings

Leveraging Oracle Agile PLM

The Inspirage **UDI Solution** leverages the Agile Product Collaboration (PC) application which helps enterprises achieve seamless integration of internal and external design, supply, and manufacturing data and enables management and collaboration of product record information and processes across the extended supply chain.

Inspirage helps our clients leverage the Oracle Agile PLM solutions to innovate profitably and optimize all aspects of designing, developing, launching, servicing, and disposing of products in an integrated, best-in-class model. Oracle's Agile PLM is the industry's most comprehensive enterprise PLM solution, and a key building block required to manage product supply chains.