A 3-STEP APPROACH FOR FDA UNIQUE DEVICE IDENTIFIER (UDI) COMPLIANCE

The Oracle UDI solution has been developed to comply with the FDA UDI regulatory requirements utilizing a 3-step process and provide the following business value:

- Rapid solution deployment
- Automated capture, cleansing, and validation of legacy UDI attributes for each SKU
- Create an FDA compliant auditable archive of all UDI attributes for each SKU/GTIN
- Support an interface for FDA GUDID uploads
- Enable downstream synchronization for UDI production traceability requirements (i.e. ERP, MES, MDM, labeling system integration)
- Provide an enterprise foundation for expansion and synchronization of other regulated business processes

When FDA announced the UDI mandate in 2007, Oracle consulted with the FDA to establish a fundamental understanding of the requirements, then began working directly with leading medical devices companies to define specific business challenges, and collaborated with GS1 to establish how current industry product code standards could be leveraged to satisfy the UDI mandate. This effort resulted in a streamlined solution that can be rapidly deployed to achieve initial UDI compliance. This foundation can also support expanded strategic enterprise business processes that enable enterprise compliance integrity and business efficiency.

The UDI Challenge

The FDA UDI mandate was initiated to enable better traceability of medical devices throughout the supply chain and to improve the information available to manage product quality issues, which could potentially impact the patient. Other global health authorities are also enacting similar requirements with which multinational companies will have to comply.

UDI compliance requires a strategic solution that can support the two elements of the regulation for each shippable SKU:

1. Registration of the UDI “static” device identifier (D.I.) attributes (11 required + 36 additional) with the FDA GUDID (timeline: 12 months after final ruling for Class III, 24 months for Class II)
2. Ensure traceability of the UDI “dynamic” production identifier (P.I) attributes by internal company processes (i.e. lot history, serialization, expiration data)
To access the feasibility of collecting, storing and retrieving this UDI attribute data, the FDA sponsored a six week UDID pilot. Participants included 6 manufacturers and 5 hospitals. A total of 621 discrete devices were loaded into the GUDID database for review with the following results:

- All suppliers provided data for the 11 required UDI attributes
- Only a few provided additional information for the other 36 UDI attributes
- Suppliers were significantly challenged with locating information as it was not in centralized system and in some cases not even documented
- Surprisingly, regulatory attribute data such as Market Authorization Codes, FDA Product Codes, and Country of Origin information was hard for suppliers to source
- All suppliers indicated it would be very burdensome to add a method for collecting, storing and reporting this information to the FDA

Based on this effort, many companies are budgeting up to $50M to achieve enterprise UDI compliance. The scope of this effort combined with the rapidly approaching deadline has made UDI compliance the #1 challenge in the medical device industry.

To address this challenge, companies need to assess the significant impact UDI requirements will have across all business functions of the organization. Organizations should not define a UDI initiative tactically as a regulatory requirement but as an enterprise strategy that not only efficiently achieves UDI compliance but also leverages the UDI foundation to enable enhanced business value as well.

The Oracle UDI 3-Step Solution

Based on significant engagement with several leading medical device companies a UDI solution that combines enhanced business processes with data capture to achieve UDI compliance in 3 steps has been developed by Oracle.
The Oracle UDI solution was developed to facilitate a rapid, cost effective approach to manage the capture and control of the (D.I.) attributes to achieve initial FDA – UDI registration compliance. This archive of UDI attributes can then be utilized to synchronize with the (P.I.) attributes through existing SOA integrations with transaction systems (i.e. ERP, MES, labeling systems) to ensure product traceability history for each SKU shipped. Deploying the Oracle UDI solution provides enterprise visibility to all UDI content for business process utilization, and provides an auditable history to ensure regulatory compliance.

The Oracle UDI 3-Step Solution deployment process:

1. **Source, Cleanse and Validate legacy UDI attributes for each shippable SKU:**

   The FDA UDI pilot program noted that the biggest UDI challenge will be to source legacy UDI attribute data from multiple sources. An automated process can expedite this effort and improve data accuracy compared to manually searching for this information and compiling it into spreadsheets. Utilizing Oracle Enterprise Data Quality (EDQ), multiple data sources (i.e. ERP, MES, RA databases, etc) can be automatically searched for attributes and aggregated for all legacy SKUs. Inconsistencies in attribute taxonomy (i.e. description & UOM) can be identified to be cleansed, validated and shaped into a standard format for enterprise synchronization with all GTINs. This process can save significant labor, improve data integrity and establish enterprise standards for all UDI attribute taxonomy. This information can then be imported into UDI step #2 through established integrations.

2. **UDI attribute revision management and synchronization with each SKU/GTIN:**

   Legacy UDI attribute data that has been collected and cleansed must be managed under FDA 21 CFR part 11 revision control and synchronized with each SKU/GTIN to provide an auditable archive. In addition, the UDI (D.I) attributes associated with the “unit of use” for each product must be managed across multi-level
packaging hierarchy configurations to support enterprise use of this critical data. Prebuilt UDI attribute templates with configuration rules and change management functionality support management of this data in a structured format, and provide an auditable archive to support regulatory compliance.

3. **UDI attribute reporting to the FDA GUDID through the FDA gateway server**

Registration of product UDI (D.I.) attributes to the UDI database it must be organized in a Structured Product Label (SPL) format and transmitted to the FDA using an HL7-XML protocol. Third party datapools can provide this service but annual subscription cost for this service can be expensive (est. as high as $600K/yr). Oracle and our Platinum Partner, Inspirage, have developed an automatic generation of the HL7 SPL XML UDI data in a submission ready format which requires no annual subscription cost.

The Oracle 3-Step UDI solution not only supports FDA reporting of the UDI static (D.I.) attributes but also supports synchronization with the transactional systems (ie. ERP, MDM, MES, Labeling systems) to capture the dynamic (P.I.) attributes.

In addition, the Oracle UDI solution provides a foundation for additional business processes such as label change management, enterprise quality management (EQM), product registration synchronization, and DHF/DMR management.
Oracle and Inspirage

The Oracle 3-step UDI solution was developed in partnership with Inspirage, an Oracle Platinum Partner. The resulting solution provides a “Rapid Start” template approach to ensure that the aggressive FDA deadlines can be met.

Specific requirements, approach and solution architecture may differ, but the solution begins with the “UDI Foundation,” including:

- UDI enablement workshop
- Management of the device identification (D.I.) data for the base device and packaging levels
- Data validation of the (D.I.) data that complies with the FDA’s submittal requirements and the GUDID
- Process design to support the submittal, publishing and obsolescence of the DI data in the GUDID
- Generation of the HL7 SPL-compliant .xml file that contains the pertinent DI data for submittal to the GUDID
- Pre-built UDI configuration, import templates and export templates

A Clear Value Proposition

The Oracle UDI 3-Step solution can be deployed faster and ensure regulatory compliance with a lower Total Cost of Ownership (TCO) compared to alternative approaches. This solution is intended to provide an integrated, cross-functional solution that provides linkage between business functions and visibility across the entire process with the additional advantages of providing an enterprise foundation for future business process expansion and synchronization.

The Oracle UDI - 3 Step Value Proposition

1. **Speed & Accuracy**
   “Expediting by reducing manual process and errors though automating the process of finding, standardizing and mastering the legacy product attributes with **Enterprise Data Quality (EDQ)**”

2. **Compliance**
   “Attribute change management synchronized with GTIN mastering in a part 11 compliant archive with **pre-built attribute hierarchical templates in Agile PLM** for uploading content from EDQ”

3. **Lower TCO**
   “Direct UDI submissions to the FDA UDI database without need to subscribe to 3rd party datapools with the **Agile Bulk HL7 SPL (XML) Integration**”

An Invitation to Continue the UDI Discussion….

Please contact us to learn more about Oracle’s perspective on UDI or participate in best practices discussions with industry-peers. The Oracle UDI point of contact is:

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Contact Us
For more information about the Oracle UDI solution, visit oracle.com or call +1.800.ORACLE1 to speak to an Oracle representative.