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Unique Device Identification (UDI) Compliance with Oracle's Rapid Three-Step Solution

The FDA will require that all Class III devices be compliant by mid-2014. All Class II devices must be compliant within two years after that.

Why Oracle?

For many years Oracle has partnered with Life Sciences companies to provide solutions to critical business problems. The three step Oracle UDI solution will provide a rapid and cost effective solution for UDI compliance.

- Rapid deployment
- Automated and accurate capture of legacy data
- FDA 21 CFR Part 11 compliant data management
- Validated synchronization, publishing and export of data
- Low total cost of ownership

The U.S. Food and Drug Administration (FDA) is in the final stages of implementing a Unique Device Identifier (UDI) initiative. When this initiative is fully implemented, all medical devices will need to have a label containing Device Identifier (D.I.) and Production Identifier (P.I.) data. This mandate is aimed at improving patient care and product quality by creating the ability to trace information about each medical device throughout the supply chain.

Addressing UDI Compliance Is a Top Priority for Medical Device Industry

Complying with the UDI initiative requires a solution that can support the two key elements of the regulation for each shippable Stock Keeping Unit (SKU). Every company must:

- Register the UDI "static" device identifier (D.I.) attributes with the FDA. There are eleven attributes required and 36 additional recommended. For Class III devices this must be completed within twelve months of the FDA's final ruling, and for Class II devices this must be completed within 24 months.
- Provide assurance to the FDA that shows appropriate internal company processes are in place to enable traceability of the UDI "dynamic" production identifier (P.I.) attributes. This may include lot history, serialization, and expiration data.

The scope of this effort combined with the short timeline within which to comply, has made UDI compliance a top priority in the medical device industry.

Oracle's Rapid Three-Step Solution to UDI Compliance

Based on extensive collaboration with industry experts and leading medical device companies, Oracle now offers a comprehensive solution that combines enhanced business process enablement with data capture to achieve UDI compliance. This solution delivers a rapid, cost-effective approach to managing the capture and control of the (D.I.) attributes to solve FDA registration requirements, as well as synchronizing (P.I.) attributes to assure internal traceability across systems. The Oracle UDI solution helps you achieve UDI compliance in three simple steps, as illustrated in Chart 1:

1. Source and cleanse legacy UDI data.
2. Process and manage UDI, Global Trade Information Number (GTIN), and SKU hierarchies
3. Extract and submit accurate data to the Global Unique Device Identification Database (GUDID) and Global Data Synchronization Networks (GDSNs).

With the Oracle UDI solution organizations are able to gain enterprise visibility to all necessary UDI content to provide the FDA with an auditable history to rapidly demonstrate regulatory compliance. This foundation can also be leveraged to enhance other business processes and improved efficiencies

Oracle and Inspirage

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

Specific requirements, approach and solution architecture may differ, but the Oracle UDI solution begins with the "UDI Foundation," which includes:

- 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

The Oracle UDI Solution Overview

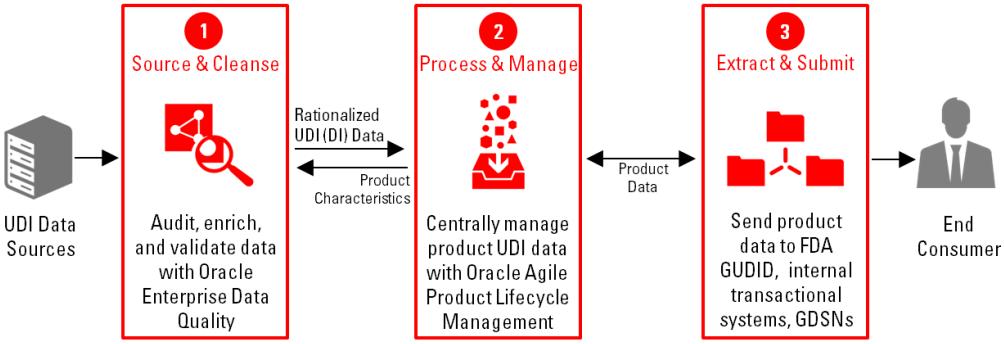

Chart 1. Oracle's three-step approach to managing UDI Compliance for Medical Devices

A Compelling Value Proposition

The Oracle UDI solution can be deployed rapidly at a low total cost of ownership, thus avoiding any business disruption associated with non-compliance. The capture, cleansing, and validation of all legacy UDI attributes for each SKU is automated to ensure information is current and accurate, and UDI data is centralized into an FDA compliant archive of all UDI attributes for each SKU and GTIN to streamline audits and improve productivity. The solution also provides an interface for FDA GUDID uploads to increase efficiency and accuracy. Finally, UDI is synchronized by integrating with downstream applications such as Enterprise Resource Planning, Manufacturing Execution Systems, Master Data Management, and Labeling Systems. The value of deploying this solution is not limited to meeting FDA compliance mandates. With the underlying technology in the Oracle UDI solution, a strong foundation to expand parallel business processes across the enterprise for compounding business benefit is provided. These additional business processes might include label change management, enterprise quality management (EQM), product registration synchronization, and Design History File (DHF)/Device Master Record (DMR) management. Linking accurate product data with standard Medical Device industry processes represents a compliant dataset, making the UDI initiative a strategic opportunity for your business, not just a tactical execution of a regulatory process.

CONTACT US

We invite you to learn more about the Oracle Three-Step UDI Solution. Schedule a demo, share your comments, network with peers, or ask questions by contacting Todd Hein, Sr. Director Oracle Life Sciences, Todd.Hein@oracle.com, 507.254.6319.