LIFE SCIENCES

DEVICE REGULATORY EXCELLENCE

A Licensed to Cure for Medical Devices Solution

PREPARE YOUR COMPANY TO MEET FDA UDI REGULATORY CHALLENGES TODAY AND OTHER COUNTRIES' UDI REQUIREMENTS TOMORROW

Part of the Licensed to Cure for Medical Devices Industry Experience, the Device Regulatory Excellence solution, powered by the Dassault Systèmes **3D**EXPERIENCE® platform, addresses medical device manufacturers' needs for regulatory device submission and is aligned with U.S. Food & Drug Administration (U.S. FDA) and international guidelines. Complying with the U.S. FDA's unique device identifier (UDI) deadline is important, but even more important is your customers' demand to implement UDI as soon as possible. If you don't, you could lose business to UDI-ready competitors. Device Regulatory Excellence helps you break down individual silos to create a more holistic, unified approach in taking products from ideation to market, significantly decreasing time-to-market.

CHALLENGES FACED BY THE REGULATORY MANAGER TO MEET NEW REQUIREMENTS

EFFECTIVELY USING GUDID

The global unique device identifier database (GUDID) serves as a repository of specific information about UDI-labeled medical devices, specifically using the device identifier (DI) as the primary key to identify a device down to the model/version number and through distribution and use. Regulatory Managers face specific challenges to provide the necessary data.

DATA AGGREGATION

Locating data for the DI submission to the GUDID is a very large scavenger hunt. UDI compliance requires collection and aggregation of data typically stored in multiple systems and formats. Data for the DI include elements like Device Identifier Type/Code, Make/Model, Brand/Trade Name, and Clinically Relevant Size. All the data may not be stored in a central location, and if there is no enterprise-wide "single source of truth" data repository infrastructure, data may be in different forms that need to be copied or manually re-written, leading to possible transcription errors. Most companies have multiple feeds of data coming into the organization, with the product data in multiple storage locations and formats. This may become a challenge if the number of SKUs is high.

EXPANDABILITY TO MEET OTHER COUNTRY UDI STANDARDS

U.S. FDA regulations for UDI became law in September 2013, with Class III medical device manufacturers required to comply by September 2014 and Class I and II manufacturers shortly thereafter. European regulations are expected to follow soon. A UDI system needs to be expandable and flexible to meet future requirements and add enhancements to maintain alignment with UDI requirements for the U.S. and EU, and future requirements in other countries (including Japan, China, and Brazil).

PROJECT MANAGEMENT

Regulatory managers need to interact with several departments and coordinate actions to assemble all the needed device attributes. To meet UDI requirements, medical device companies have identified between 70 and 120 individual attributes that have to be collected, depending on the specific product. Cross-functional effort and interactions are needed to assemble all of them, requiring significant time, resources, and effort.

TIME PRESSURE

At the time of the regulatory submission, all versions/SKUs that are planned to be launched must be included in the regulatory dossier. Since changes to packaging are part of an on-going process, changes need to be monitored and reported, creating time pressure to meet the deadlines posted by the U.S. FDA.

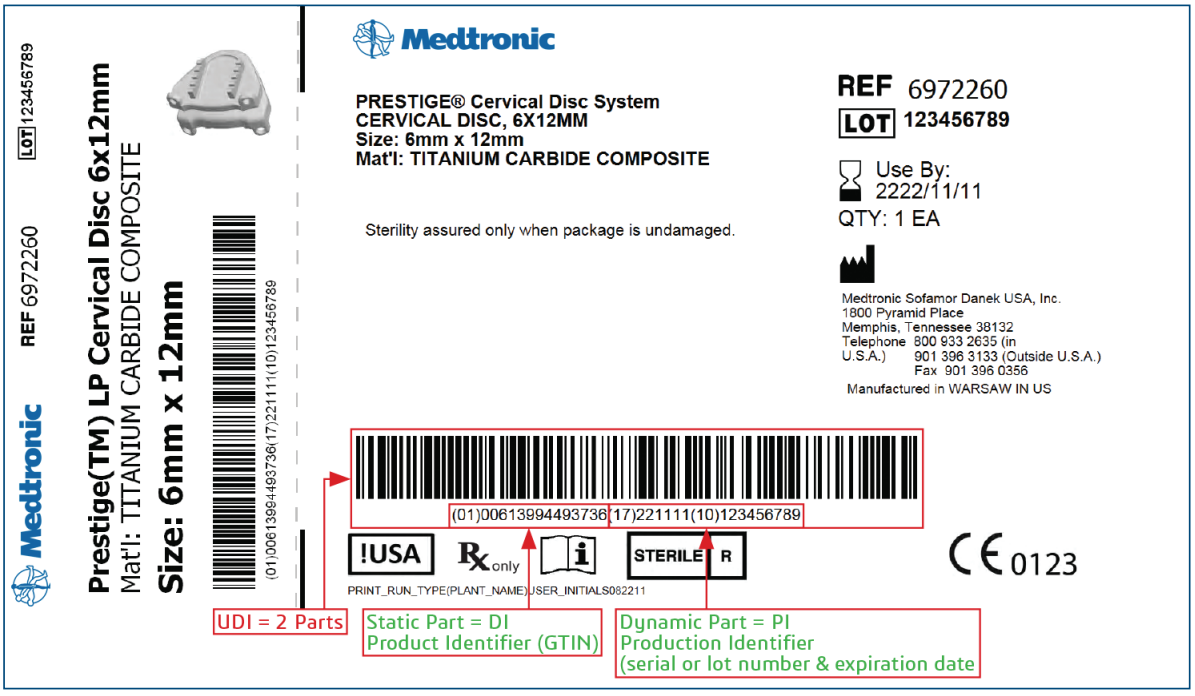
TRACEABILITY

The Regulatory Manager needs to ensure total traceability of the UDI process from collection of all required UDI attributes to submission to the U.S. FDA GUDID, acknowledgement to end of life, the internal approvers, and the U.S. FDA acknowledgement.

GLOBALIZATION

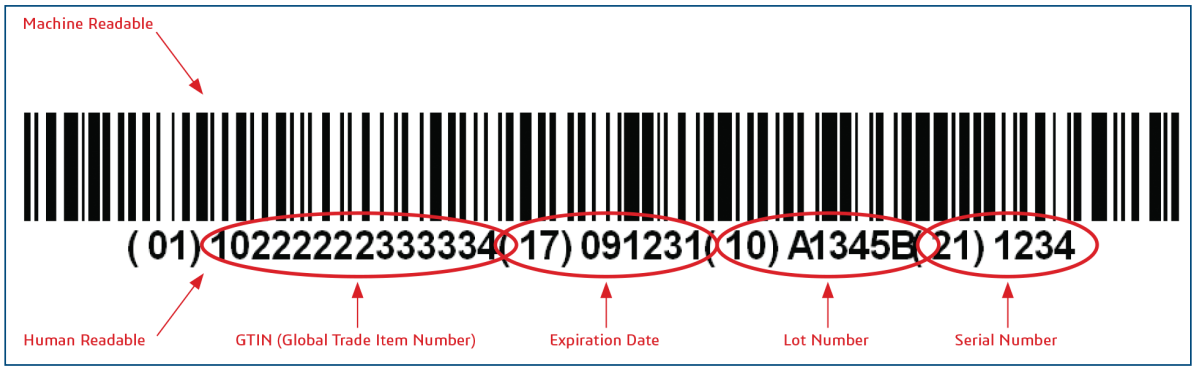
With distributed geo-global manufacturing operations and manufacturing final finished products for distribution in the U.S., EU, China, Japan, and other regions, the Regulatory Manager needs to leverage the collected records for the regulatory agencies in these regions.

Figure 1



Source: UDI Conference 2012 Jay Crowley, Senior Advisor for Patient Safety, FDA

Figure 2



Source: GS1 Leveraging GS1 Standards & UDI, April 5, 2013

MAKING A UDI SUBMISSION

To submit the information required for a UDI submission, specifically the DI information, the Regulatory Manager needs to complete these steps:

- **Prepare** the DI records by acquiring all the relevant data from various sources and documents. The data needs to be validated by departmental stakeholders to ensure that the information represents the final released product for the UDI submission.
- **Submit and Publish** the DI record to the U.S. FDA GUDID. The Regulatory Manager must wait for the acknowledgement of acceptance. If the submission is not accepted, the issues identified are addressed and the DI resubmitted.
- **Maintain and Monitor** the device status throughout the product lifecycle to keep the U.S. FDA product registration and GUDID up-to-date.
- **Bridge Information** between medical device reports and DI records to build root cause analysis of data and any issues. The Regulatory Manager needs to utilize the DI information as a holistic device master data file to associate device/patient issues with identified product to accelerate post-market surveillance activities (for example, adverse event reporting/aggregation, medical device recalls, tracking and tracing, and patient notification). Linking the DI to the production identifier (PI) allows manufacturers to quickly identify manufacturing lots and serial numbers (see Figures 1 and 2).

THE DEVICE REGULATORY EXCELLENCE SOLUTION HELPS YOU MORE EFFECTIVELY MANAGE MEDICAL DEVICE COMPLIANCE

Dassault Systèmes Device Regulatory Excellence solution provides highly efficient data collection, submission, tracking, and reporting capabilities for regulated medical devices. This reduces the manual burden of data management typically associated with data transcription errors and increasing efficiency and productivity associated with UDI compliance.

Key UDI capabilities for device regulatory excellence include:

- Manage DI records collection as a project, using an enterprise process workflow to assign tasks to different parties to provide information from across your organization
- Store all device attributes (based on a pre-formatted data model aligned with U.S. FDA guidelines) in one enterprise repository (device information, packaging and secondary information, and device characteristics)
- Review and approve DI record using electronic signatures to stay compliant
- Submit and publish DI record to U.S. FDA GUDID via the U.S. FDA Electronic Submissions Gateway (ESG)
- Receive acknowledgement from GUDID when a submission is successful or receive rejection notices for invalid DI record submission
- Increase information sharing throughout the enterprise using this centralized repository of DI records
- Perform "where used" analysis to highlight relationships with other databases, such as complaints (internal/external)

3DEXPERIENCE PLATFORM—MANAGING DATA TO IMPROVE QUALITY AND PATIENT SAFETY

A centralized place to govern device information helps ensure that your organization can properly manage and rapidly respond to changes in the data. Having a "single source of truth" becomes even more valuable today in light of all the acquisition activity common in the medical devices industry. Companies that have grown through acquisition often end up with a plethora of different systems to use for creating and managing device data. Each acquired entity may also maintain its own labeling systems, processes, and standards, making it even more difficult to track and manage uniformity, accuracy, semantic persistence, stewardship, and accountability of label identifiers, as well as other device data elements. You can depend on the Dassault Systèmes Device Regulatory Excellence solution to:

- Improve data quality, information sharing, interoperability, and supply chain transparency
- Demonstrate traceability and transparency to regulators
- Reduce time and effort to identify affected production lots
- Reduce time and effort to trace registered owners (healthcare facilities, healthcare providers, and patients)
- Send adverse event report notifications to the U.S. FDA efficiently and effectively in a short time, averting possible U.S. FDA warning citations due to delays
- More effectively manage medical device recalls through a standardized identifier
- More efficiently track medical devices
- Enable more accurate reporting, review, and analysis of adverse events so that problem devices can be identified and corrected more quickly
- Improve consistency with the company's internal patient registry
- Set up a sustainable process that could expand to other geographies when needed by other regulatory agencies

Dassault Systèmes Licensed to Cure for Medical Devices Industry Experience allows medical device companies to dramatically accelerate device design and evaluation with the rigor of an explicit, repeatable, and fully traceable development process for product innovation, regulatory, and quality management, and provides a true 360-degree view of patient and physician requirements.

DASSAULT SYSTÈMES IN LIFE SCIENCES

Dassault Systèmes **3DEXPERIENCE** platform for the Life Sciences industry provides purpose built solutions for Medical Device, Pharma & Biotech, and Patient Care companies to connect innovative virtual 3D designs with patients, physicians, and other research, regulatory, and clinical communities. Our solutions help leverage the wealth of information resident in their enterprise so they can aim to have the right product, at the right place, at the right time.

Dassault Systèmes has a long history in the Medical Device industry, helping leaders create and launch breakthrough innovations. For Class I, II, and III devices, from small organizations to global enterprises integrated with suppliers, our solutions help companies accelerate innovation to market safely, more quickly, at a lower cost while maintaining quality and reducing regulatory risk.

For more details about the Device Regulatory Excellence solution and the Licensed to Cure for Medical Device industry experience, visit http://www.3ds.com/industries/life-sciences/

Our 3DEXPERIENCE platform powers our brand applications, serving 12 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the **3DEXPERIENCE®** Company, provides business and people with virtual universes to imagine sustainable innovations. Its world-leading solutions transform the way products are designed, produced, and supported. Dassault Systèmes' collaborative solutions foster social innovation, expanding possibilities for the virtual world to improve the real world. The group brings value to over 170,000 customers of all sizes in all industries in more than 140 countries. For more information, visit **www.3ds.com**.

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