EXPERIENCES FROM THE U.S. FDA UDID PILOT
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OVERVIEW

- What is GDSN and UDID
- Purpose of the pilot
- Work done in support of the pilot
- Pilot results
- Next steps
WHAT IS GLOBAL DATA SYNCHRONIZATION NETWORK

The GS1 Global Data Synchronization Network™ connects customers and suppliers, via their selected GDSN-certified Data Pools, to the GS1 Global Registry® - based on the GS1 GTIN standards (unique identifier of products).

The GS1 GDSN is an automated, standards-based global environment that enables secure and continuous data synchronization, allowing all trading partners to have consistent item data in their systems at the same time.

A Mechanism to Publish UDI to FDA GUDID
UDI (Unique Device Identification)
- DI = Device identifier = GS1 Global Trade Item Number® (GTIN®) allows the unambiguous identification of a specific medical device
- PI = Production Identifier = GS1 Application Identifier (AI) for lot/batch no., serial no., expiry date, in any combination in combination with GTIN

UDID (Unique Device Identification Database)
- The Global Data Synchronization Network (GDSN) enables feed to UDI databases via data pools across the world

AIDC (Automatic Identification and Data Capture)
- ISO compliant machine-readable data carrier on the product or it’s packaging, which contain the UDI: linear or 2D barcodes, RFID
UDID POPULATION USING GDSN
Manufacturers are able to provide data to all UDI databases and their customers (hospitals, distributors, wholesalers, GPOs) simultaneously, with one single connection.
(G)UDID (UDI Database) Overview

- HL7 SPL Submission
- FDA Electronic Submissions Gateway (ESG)
- UDI Web Interface
- Public Users
- Unique Device Identification Database (UDID)

Compliments of FDA – August 2012
CURRENT UDI REQUESTED* ATTRIBUTES

- Primary Device Identifier (DI) (no control information)
- Secondary Device Identifier (if applicable)
- Unit of Use DI (if different form DI)
- Manufacturer’s Name, Address, and Contact Information
- GMDN
- Device Description
- Additional Product Description
- Trade Name/Brand Name (of DI and if part of a device family)
- Model Number/Catalog Number (of DI and if part of a model family)
- Clinical Size (volume, length, gauge, etc)
- Storage Conditions
- Sterile?
- Sterilize prior to use, and method of sterilization
- Type of Control (PI) (serial number, Lot/Batch, Expiration Date, and/or manufacturing date) (not actual number or date)
- Can DI be reused?
- Contains Latex?
- Contains Human Tissue?
- FDA Numbers–
  • Product Code
  • Listing Number
  • Premarket Authorization, 510K
  • Supplement Number
- Direct Marking DI (if different from DI)
- Direct Marking Exemption Reason
- Marketing Status
- Is DI part of a Kit? Or a Combination Item?
- DI Discontinued Date (if applicable)
- Higher level information
  • Parent DI, Child DI, Child Quantity

*As per the UDI Proposed Rule of 2012

Data to be Published for UDI to FDA GUDID
FDA UDID PILOT

• The FDA pilot was to test loading data into the UDID Beta environment
  – 2 Data Pools participated
    • 1Worldsync
      – Abbott, Cardinal
    • GHX
      – Covidien, GE Medical, Cook Medical, J&J, Terumo, Siemens

• Data loaded by manufacturers into the UDID via GDSN

• Pilot ran September 17 to October 5
HOW WILL IT WORK?

• Manufacturers can use the GDSN as a single point of entry for publishing an item’s master data
  – UDID data to the FDA and other similar UDI databases globally
  – Supply Chain, Market, and Public UDID data to GPOs and Providers

• Benefits to the approach
  – Single entry platform
  – Population of data one to many
  – GPOs and Providers receive public UDID data elements

• GDSN has begun modifications for UDID
  – Additional attributes needed
  – Process flow for data pools to generate and send SPL messages to the FDA
RESULTS OF THE UDID PILOT

• GDSN is a way to feed data into the UDID

• UDID Attributes have been mapped to GDSN
  – missing attributes have been identified and added to the GDSN

• Allows the manufacturer to enter one message and provide
  – Supply Chain data to trading partners
  – Regulatory data to the UDID
  • Only those requested elements will be sent along
NEXT STEPS

• Evaluation of
  – UDID implementation guides
  – Final release of the regulation

• Revisions of GDSN (if necessary)

• Driving adoption
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