FDA Unique Device Identification Requirement for Medical Devices

On September 24, 2013, the U.S. Food and Drug Administration announced the new requirement to identify medical devices that affect its safe and effective use through the use of UDI.

UDI Regulation Overview:

Device manufacturers have to create and maintain the Unique Device Identifier (UDI) which is specific to a device model, and a production identifier, which includes the current production information for that specific device, such as the lot or batch number, the serial number and/or expiration date.

UDI will be a unique numeric or alphanumeric code consisting of two parts, DI – identifies the labeler and the specific version or model of the device and PI – variable portion of UDI which is combination of lot/batch number, serial number etc.

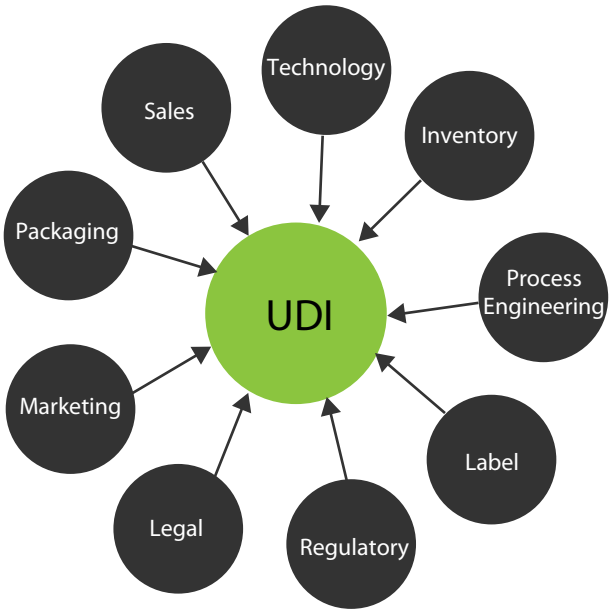
Issuing Agencies:

FDA recognizes three agencies (GS1, HIBCC and ICCBBA). Manufactures have to obtain the UDI from one of these agencies. Also Labelers have option to choose the type of AIDC (Automatic identification and data capture) technology. Agencies accept ISO 15459 series of standards.

Global Unique Device Identification Database (GUDID):

The GUDID serves as the repository of key device identification information which can be accessible by public. The DI serves as the primary key to obtain device information in database.

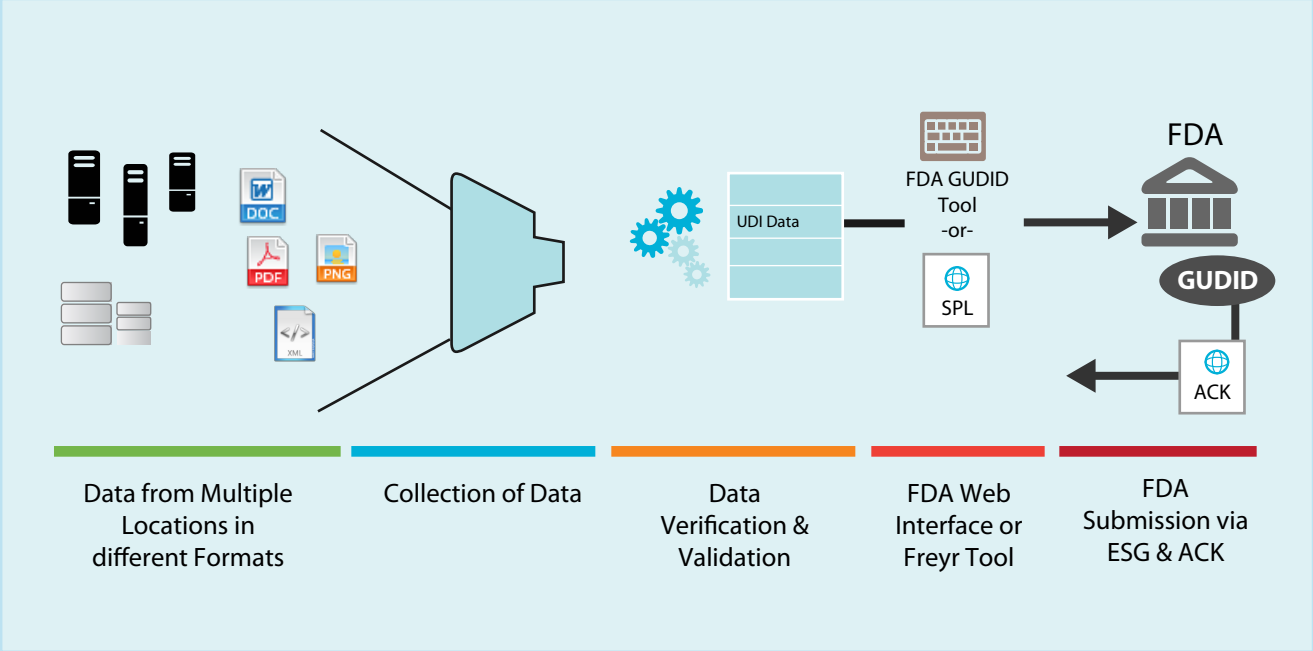
The data required are from multiple locations:



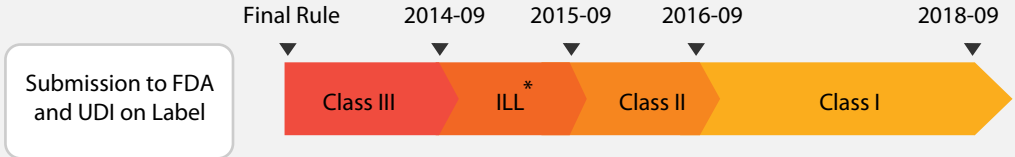
FDA released draft guidance on how to create Health Level 7 (HL7) Structured Product Labeling (SPL) in November 18, 2013; there are two ways to submit.

- GUDID Web Interface
- Structured Product Labeling (SPL) xml files, submission via the FDA Electronic Submissions Gateway (ESG)

Submission Process:



UDI Implementation Timeline:



*ILL – Implantable, Life-Supporting, and Life-sustaining Devices

References:

FDA: Unique Device Identification:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/

FDA: GUDID Database:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/default.htm