Introductions

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- Co-lead of the Global UDI Program Management Office (PMO)
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- 13+ years at Abbott and formerly at GS1 US and Baxter Healthcare

Industry experience implementing UDIs

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Manufacturers need harmonized UDI requirements to successfully implement UDI

- **The foundation is:**

  - UDI System as defined by the International Medical Device Regulators Forum (IMDRF): IMDRF/UDI WG/N48 FINAL: 2019

  - Global Medical Device Nomenclature (GMDN) as the requested nomenclature

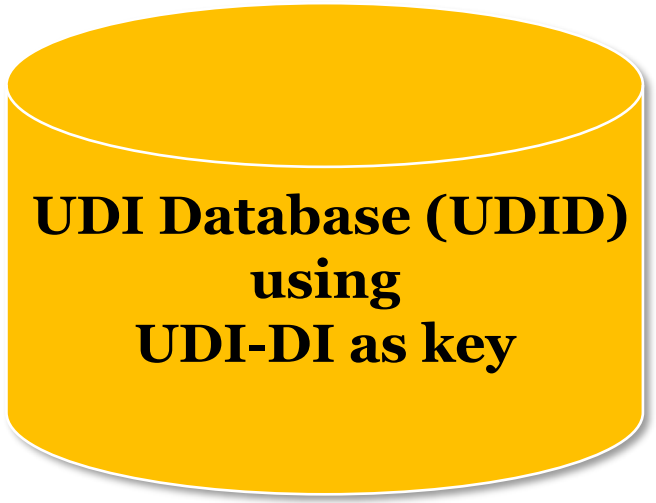
Unique Device Identifier (UDI)

The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market. The UDI is composed of the UDI-DI (UDI Device Identifier) and UDI-PI (UDI Production Identifier, e.g., lot #, expiry, serial #).

Note: The word "Unique" does not imply serialization of individual production units.

IMDRF defined Unique Device Identification System (UDI System)

A system that is intended to provide single, globally harmonized positive identification of medical devices through distribution and use, requiring the label of devices to bear a globally unique device identifier (to be conveyed by using Automatic Identification and Data Capture (AIDC) and, if applicable, its Human Readable Information (HRI) based upon standard, with the UDI-DI of that unique identifier being also linked to a jurisdiction-specific public UDI database.



IMDRF defined fundamental elements of a UDI system can be summarized as follows:

1) **Development of a standardized system of Unique Device Identifiers (UDIs);**
2) **Placement of UDIs in human readable and AIDC formats/forms on package labels and in some cases, on the device itself;**
3) **Submission of core UDI data elements to a UDID (to a jurisdiction-specific public UDI database);**
4) **Setting of appropriate transitional and implementation arrangements to ensure a smooth UDI system implementation.**

WHY? UDI System benefits per IMDRF

A globally harmonized and consistent approach to UDI is expected to *increase patient safety and help optimize patient care* by facilitating the:

a. traceability of medical devices, especially for field safety corrective actions

b. adequate identification of medical devices through distribution and use

c. identification of medical devices in adverse events

d. reduction of medical errors

e. documenting and longitudinal capture of data on medical devices

It is NOT about pricing and cost control.

Nomenclature defined

- **This is a standardized name given to a type of device, irrespective of the manufacturer. The nomenclature identifies medical devices that have the same function and similar design.**

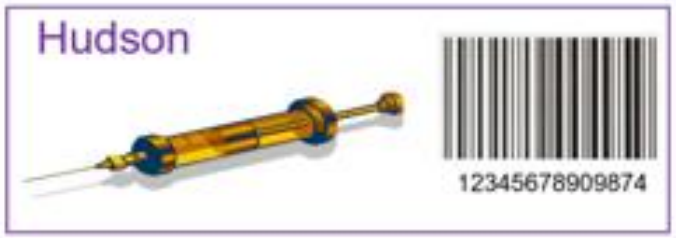
- **The most used nomenclature for medical devices is the Global Medical Device Nomenclature (GMDN) (www.gmdnagency.org). GMDN maintains translations in the Spanish and Portuguese languages. Access to the GMDN is free of any charge for all users, including manufacturers.**

Nomenclature details

- **Strongly support the adoption of the GMDN by regulators globally, as recommended by IMDRF**
- **Multiple nomenclatures raises significant regional/global challenges for the healthcare industry to implement, train, and maintain (besides error prone)**
- **Jurisdictions specific nomenclatures are costly to implement and more costly to maintain**
- **Jurisdiction specific nomenclatures are negative for patients, health systems and industry**
- **Nomenclatures are not static – changes are made to reflect new products and technologies**
- **The GMDN is a database attribute**

UDI and GMDN Comparison

Device type/model =
Unique Device Identifier
From a single supplier
(e.g. 12345678909874)



Device Group = GMDN Term
All suppliers use same code
*(e.g. GMDN Code **47017**)*

Term Name: General-purpose syringe

Product/Service Classification

- **This is a coding given to a product or service as part of the procurement process including spend analysis. It usually covers a wide range of products and services, such as medical devices, drugs, nutrition, clothing and consulting services.**
- **Due to the wide range of products, the descriptions tend to be simple and not suitable for other purposes, such as product safety assessment.**
- **An example of a product classification system is UNSPSC (https://www.unspsc.org)**
- **Classifications are not static – changes are made to reflect new products and services and/or improving useability**
- **The classification is a database attribute**

UNSPSC Example

Hierarchy	Category Number	Name
Segment	44	Office Equipment and Accessories
Family	10	Office machines and their supplies and accessories
Class	11	Office and desk accessories
	12	Office supplies
	15	Mailing supplies
	17	Writing instruments
Commodity	04	Ball Point Pens

UNSPSC 44101704 - BALL POINT PENS

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