# How Global Data Synchronisation enables Unique Device Identification (UDI)

## Introduction

Unique Device Identification (UDI) for medical devices is expected to improve patient safety and healthcare business processes. A single, global system of standards is fundamental to enable an efficient and effective implementation of UDI by all healthcare stakeholders worldwide. Major regulators working together via the International Medical Device regulators Forum (IMDRF) have made safety and integrity of the global supply chain a strategic priority.

The regulatory requirements for UDI propose to address today's supply chain and patient safety issues involving identification of medical devices, inefficient and ineffective product recalls, incomplete adverse event reporting, and inefficient hospital supply chain processes.

One of the most challenging areas related to the implementation of the UDI regulation is **Master Data Management**. This brochure highlights several areas which a manufacturer should consider when preparing their product data for registration in a UDI database, and the benefits Global Data Synchronisation brings to the community.

# Data Management

Completeness and accuracy of product data is the responsibility of the manufacturer. Each manufacturer should have an internal process to create, enrich and manage the data required by the regulator. This includes:

- Enterprise-wide Data Governance policies
- Data Management process and policies
- Data Quality checks and procedures
- Roles and Responsibilities which outline who has the authority to create, modify and approve the data

GS1 strongly recommends that each manufacturer ensure they have a robust Data Management process in place as part of their internal preparation process.

# Data Requirements

- The Device Identifier (DI) will be the primary key in the UDI database and will be linked to other product data elements
- Manufacturers will be responsible for submitting and maintaining their own data in the database
- The U.S. FDA Global UDI Database (GUDID) will not contain the Production Identifiers, i.e. Expiration Date, Batch/Lot Number, Serial Number or others

*"The core elements are the minimum elements needed to identify a medical device through distribution and use. Regional or National UDID may contain additional elements; however, these additional elements should be kept to a minimum"* - IMDRF UDI System for Medical Devices.

# Data Validation

Some regulators may include specific business and data validations to ensure data quality of the information provided by the manufacturer. Please refer to the specific regulation for more information.

# The Global Data Synchronisation Network

The GS1 System of standards supports all stakeholders to efficiently and effectively meet UDI requirements by enabling interoperability and compatibility within an organisation, between organisations and across borders. A single standard can ultimately accelerate implementation and increase compliance to the UDI regulations.

The Global Data Synchronisation Network (GDSN®) enables manufacturers, distributors and providers to share accurate product information electronically. In addition to receiving the initial product data, the customer can receive product update notifications automatically from the supplier.

The GDSN is an Internet-based, interconnected, network of interoperable data pools and the GS1 Global Registry that enables companies around the world to exchange accurate, standardised and synchronised supply chain data with their trading partners.
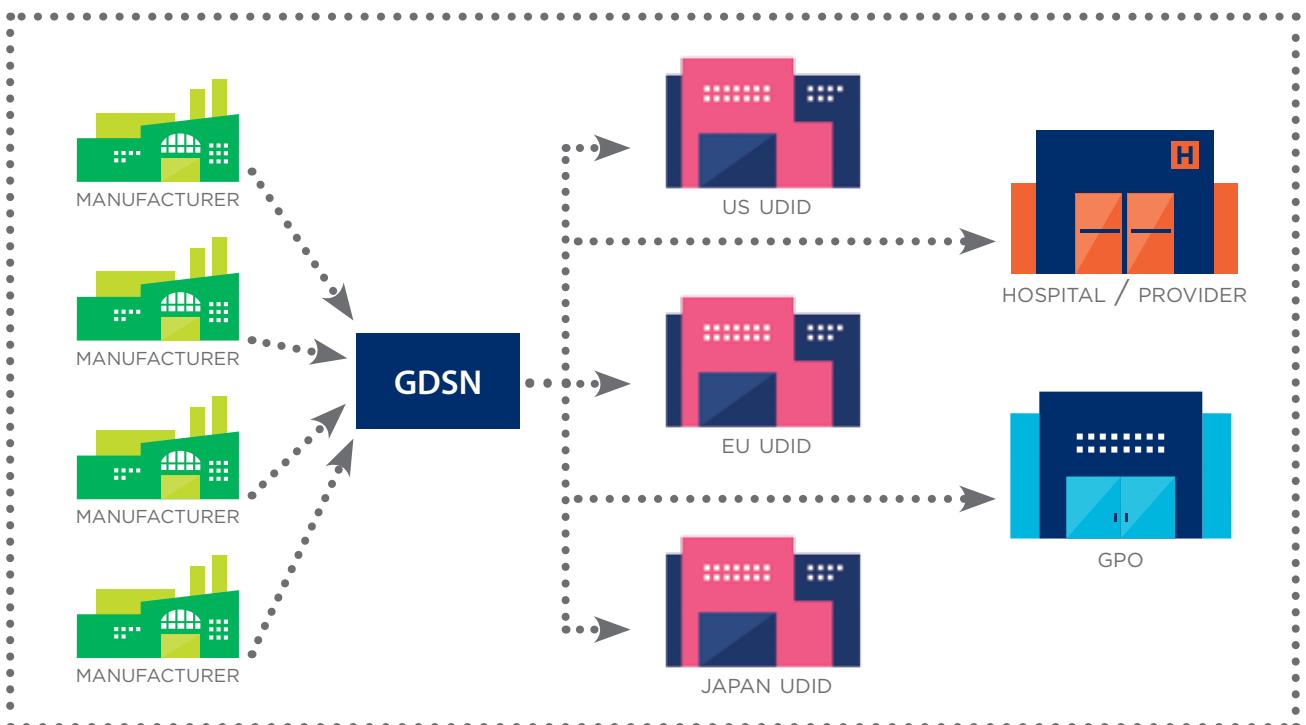
The GDSN provides a secure and easy way for manufacturers to register their product data with any UDI database, anywhere in the world, via a single connection. Refer to he GDSN website for a list of GDSN certified Data Pools http://www.gs1.org/gdsn

# One Connection to Many UDI Databases

While regulators are working together to align their regulations as much as possible, each one will have distinct data requirements.

Manufacturers using GDSN will be able to **provide data to all UDI databases** and their customers (hospitals, distributors, wholesalers, GPOs) simultaneously, **with one single connection.**
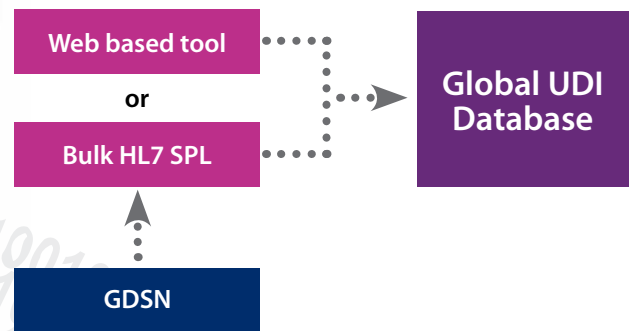The GDSN to UDID process has been tested and proven in a pilot with the FDA GUDID, and has already been selected by a number of suppliers.

# U.S. FDA GUDID Options

There are different options for registering data in the US FDA Global UDI Datase (GUDID)

**Data Registration**
- Manual data entry via the Web based tool
- Bulk data registration direct from a manufacturer's internal application using the HL7 standard
- GDSN Data Pools can register data on behalf of the manufacturers using the HL7 Structured Product Labeling (SPL) standard

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Web based tool
      or
Bulk HL7 SPL   ┄┄┄▶  Global UDI Database
      ▲
      ┊
    GDSN
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# Translation UDI to GS1

| UDI | GS1 Standards |
|---|---|
| **UDI** <br> Unique Device Identification | **GS1 Standards** <br> Product Identification |
| **UDID** <br> Data Elements linked to the Device Identifier | **GDSN** <br> Attributes mapped to each UDID data element |
| **DI =** <br> Device Identifier (DI) | **GTIN** <br> Global Trade Item Number |
| *Production data is not stored in UDI or GDSN databases* | |
| **PI =** <br> Production Identifier (PI) (if applicable) <br> Production Identifier data will vary by medical device type and manufacturer current practice. | **AI** <br> Application Identifiers (AI) <br> • Expiration Date AI(17) e.g. 141120 <br> • Lot/Batch AI(10) e.g. 1234AB <br> • Serial Number AI(21) e.g. 12345XYZ |
| **DI + PI = UDI** | **GTIN  -or- GTIN + AI(s) = UDI** |

# GS1 Standards

GS1 is a neutral, not for profit organisation that develops supply chain standards. GS1 has over 110 Member Organisations and more than 2,000 employees worldwide providing support to users on how to implement UDI in their local language and understanding the local requirements for implementation.

# References

- For more information on UDI at a global level refer to http://www.gs1.org/healthcare/udi
- For more information on the IMDRF refer to http://www.imdrf.org/
- For more information on the U.S. FDA UDI refer to http://www.gs1us.org/industries/healthcare/gs1-healthcare-us/fda-udi
- For more information on the GDSN refer to http://www.gs1.org/gdsn
- For more information on GS1 Healthcare refer to http://www.gs1.org/healthcare
- For country support contact your local GS1 Member Organisation http://www.gs1.org/contact