Management of Global Master Data using GDSN

The importance of Data Quality

Challenges

B. Braun is faced with a **number of regulatory** and **customer requirements** for product information. These requirements relate to sharing **complete** and **accurate** product information in a **flexible way**, all the while supporting patient safety.
Today, B. Braun is faced with **numerous challenges** in order to meet the following requirements:

- **lack of consistent data standards**
- **high level of resources needed** to upload and maintain the company's catalogue
- customers don't currently **synchronise data** with their suppliers or within their own jurisdictions
- **unambiguous identification** of partners and subjects

In looking to address these issues and requirements, B. Braun wants to ensure that the process is **efficient**, **robust** and **comprehensive** to meet all customer requirements and result in high-quality data. This would ultimately **improve patient and clinician safety** and **lower healthcare costs**.

Scope of the Project

The scope was to **implement Global Data Synchronisation (GDSN)** across the organisation **on a global level** with a **local approach** by considering regulatory compliance requirements e.g. UDI and also commercial requirements. Therefore a GDSN implementation guideline for Global enterprise-wide GDSN adoption was created.
A global **Programme Management Office** (PMO) will set the direction and timeline to govern the overall GDSN implementation across all B. Braun countries, with support from the **Data Management Organisation** (DMO) in each of those countries.
The global PMO consists of both B. Braun staff and external support staff. The roles and responsibilities of the global PMO were defined as follows:

UDI & UDID

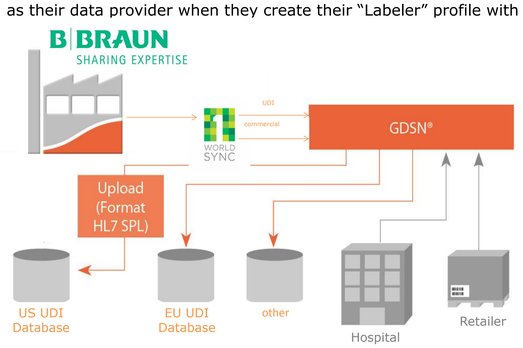
The Unique Device Identification (UDI) is a multinational initiative driven by several medical device regulators with the intention of improving patient safety and healthcare business processes. Each UDI regulation is expected to include a **database** which will contain **medical device product data**. This is referred to as a **Unique Device Identifier Database (UDID)**.
One of the most challenging areas related to implementation of the UDI regulation is the **Master Data Management and Governance**. Master Data Management and Governance (MDM&G) refers to a series of processes and protocols that should exist within an organisation to create, enrich, maintain and publish product information within and outside the enterprise. Equally important is "**data quality management**," which is a complementary cycle of activities aimed to ensure that the subject information meets high standards of quality and reliability. In short, the data created by the product manufacturer must meet the requirements of the intended use case. Medical device data which has to comply with UDI regulation is no exception.

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

- **Data quality checks** and **procedures**
- **Data management process** and **policies**
- Enterprise-wide data **governance policies**
- **Roles and responsibilities** which outline who has the authority to create, modify, approve and release the data

GDSN – for UDI and commercial purposes

B. Braun decided to use a **GDSN certified Data Pool** in order to register data using the HL7 Structured Product Labeling (SPL) standard. B. Braun has to list their data pool as their data provider when they create their "Labeler" profile with the FDA.



Lessons learned

B. Braun has successfully piloted and begun a production rollout of GDSN in the US. As an output of these activities, the lessons learned were leveraged to establish a methodology to facilitate a global rollout of GDSN. This methodology ensures that all divisions of B. Braun across multiple countries are **using a consistent process** for sharing product data via the GDSN.
The defined methodology includes **five areas of work**. Some activities in each of the areas of work can occur concurrently. These areas include:

- **Planning the overall GDSN initiative** for the **country involved**
- **Preparing the data**
- **Developing** a **sustainable process**
- Rolling out the **GDSN** initiative
- **Operationalising** the process or **development of the run model**

Holger Clobes, Global Head of eCommerce and AutoID at B. Braun Melsungen, is still committed to the collaborative approach the project was set up. "We decided to use the services of 1WorldSync to fulfill the requirements on a global level. It underlines our company strategy by thinking global and acting local. GDSN gives us a perspective to work on a global standardised way even if the communication to the partner (or data base) is using a different standard".

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