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 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:

- Global Executive Sponsor
  - Global GDSN Coordinator
  - Global Process Coordinator
  - Country Business Sponsor

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.

UDI & UDID

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 Clöbes, Global Head of eCommerce and AutoID at B. Braun Meßungen, 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.”