



by **Holger Clobes,**  
B. Braun

# Management of Global Master Data using the Global Data Synchronisation Network by B. Braun

## B. Braun's strong commitment to quality data

### Abstract

B. Braun one of the world's leading medical device suppliers with 150 affiliate companies in over 50 countries, is faced with a number of regulatory and customer requirements for product information. These requirements relate to sharing complete and accurate master product information in a flexible way, while supporting patient safety. Today, B. Braun is faced with numerous challenges such as:

- lack of usage of a consistent master data exchange format (sometimes usage of word documents, excel, papers, ...)
- suboptimal efficiencies, as customers don't currently synchronise master data with their suppliers, across borders or within their own regions
- high level of resources needed to upload and maintain B. Braun's product catalogue
- lack of unambiguous identification of physical or legal locations involved in transactions

In looking to address these issues, B. Braun wanted to ensure that the process was efficient, robust and comprehensive to meet customer needs of high-quality data. This would ultimately improve patient and clinician safety and lower healthcare costs.

At the same time, B. Braun acknowledged the value of using GS1 Standards to identify products within their supply chain to overcome these challenges and meet their customer's requirements.

### Master Data Management: critical to comply with the Unique Device Identification system

On 24 September 2013, the United States Food and Drug Administration (FDA) published a rule establishing a unique device identification system for medical devices. Under the rule, the healthcare community and the public will be able to identify a device through a Unique Device Identifier (UDI) that will appear on the label and package of a device.

The UDI will provide a standardised way to identify medical devices across all information sources and systems, including electronic health records and devices registries.

In addition, device labelers will submit device information to the U.S. FDA database called the Global Unique Device Identification Database (GUDID). The GUDID will contain critical information about medical devices, and the UDI will provide the key for obtaining device information from the GUDID.

***"B. Braun decided to perform the UDI submissions via a Global Data Synchronisation Network (GDSN)-certified data pool. The data pool creates the HL7 Structured Product Labelling (SPL) messages and submits the device information via the U.S. FDA's Electronic Submission Gateway into a global UDI database. In summary, the GDSN data pool was authorised to submit the UDI data on behalf of B. Braun."***

Holger Clobes, Head of Global eCommerce & Auto ID

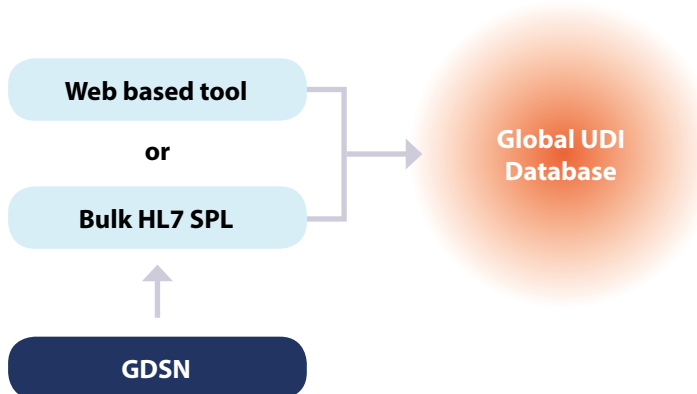




The U.S. Food and Drug Administration (FDA) UDI regulation was the first issued, but it is expected to be followed by other similar regulations in other countries across the world. Each UDI regulation is expected to include a database that will contain medical device product data, which is referred to as a UDI Database (UDID).

One of the most challenging areas related to implementation of a UDI regulation is the Master Data Management and Governance (MDM&G). 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 is accurate, consistent and complete, thus meeting 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 would have to comply with a UDI regulation, is no exception.

Completeness, consistency, and accuracy of product data are 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; and
- roles and responsibilities which outline who has the authority to create, modify and approve the data.

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(GDSN)-certified data pool. The data pool creates the HL7 Structured Product Labelling (SPL) messages and submits the device information via the U.S. FDA's Electronic Submission Gateway into a global UDI database. In summary, the GDSN data pool was authorised to submit the UDI data on behalf of B. Braun.

### Lessons learned during the pilot

B. Braun successfully piloted this UDI submission process early 2014 and began a production rollout in the U.S. The pilot results were leveraged to establish a methodology to facilitate a global rollout of GDSN. This will ensure that all of the company's divisions across multiple countries are using a consistent process for sharing product data.

Consequently, the implementation process now includes five areas of work, some occurring concurrently. These areas include:

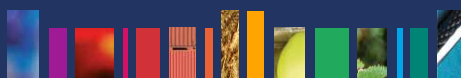
1. Planning the overall GDSN initiative for the country involved
2. Preparing the data
3. Developing a sustainable process
4. Rolling out the GDSN.
5. Operationalising the process or developing the run model.

### Implementing Global Data Synchronisation globally

Now that the UDI pilot is complete, B. Braun aims to leverage the GDSN to also synchronise data with their customers worldwide. This includes leveraging regulation and commercial needs to maximise the benefits enterprise wide and with its customers. To facilitate this process, an internal GDSN implementation guideline for enterprise-wide adoption was first created.

It was decided that a global Program Management Organisation (PMO) would be created to steer the programme. It will set the direction and timeline to govern the overall GDSN implementation across all of B. Braun's divisions and countries. Local B. Braun affiliates will support the implementation through their Data Management Organisation (DMO) representing the local organisation working on data management tasks.

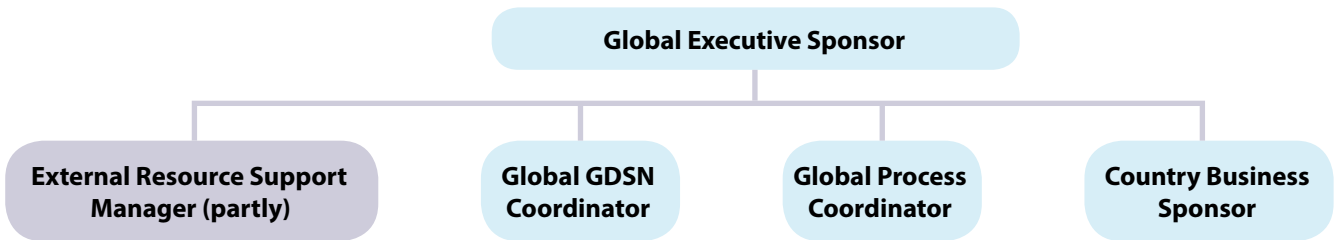
B. Braun is committed to undertaking this project in a collaborative approach. The global PMO consists of both B. Braun staff and, as





necessary, external support staff. The roles and responsibilities of the global PMO were defined as follows:

### B. Braun Global Program Management Organisation (PMO)



External partners (External Resource) are included in the project as support members of the PMO with the required expertise regarding GDSN implementation, GS1 standards, data pool provider, and middleware. The first countries to undertake the project will be those where customers are requesting specific and aligned data. At the same time, some countries will benefit from activities being undertaken by local healthcare-focused GDSN working user groups, steered by the GS1 member organisation in the affected country.

#### Success Criteria

As part of the project planning, success criteria were established such as:

- Implementation timeline
  - As part of the project plan, a realistic timeline should be developed to track to project milestones

- Other success criteria coexist depending on B. Braun affiliate needs and customer demands
  - Sales organisations/Product Category considerations
    - Number of items per sales organisation/ category
  - Trading partner considerations
    - Number of items being traded with that trading partner(s)
    - Number of categories being traded with that trading partner(s)
    - Revenue share of that trading partner(s) compared to others in that country

#### Summary

The increase of legal and customer requirements stresses the importance of up-to-date and high-quality master data. The use of GDSN will undoubtedly help B. Braun meet the challenges they face as a complex, global organisation.

#### About the author

**Holger Clobes** is Head of Global eCommerce & Auto ID at B. Braun, one of the world’s leading healthcare suppliers. He has been working at B. Braun for more than 30 years, with the last 17 working closely with GS1 Germany in the development and implementation of GS1 Standards.

#### About B. Braun

B. Braun is one of the world’s leading healthcare suppliers divided into four divisions: hospital, surgery, private practice (medical care and doctors’ offices) and extracorporeal blood treatment. Today the company has 150 affiliate companies in over 50 countries.

