CASE STUDY

B.Braun: Global Regulatory Compliance Achieves Additional Benefits

B | BRAUN
SHARING EXPERTISE

Challenge

The healthcare landscape is experiencing a significant transformation. Today's patients are savvy consumers, demanding access to trusted product information to make informed decisions about their health care. In parallel, local, federal, and global government organizations are supporting patient safety through regulatory mandates around traceability.

To meet these consumer and regulatory requirements, medical device manufacturers are challenged to find flexible methods of distribution that ensure distributors and patients have access to the right data at the right time. This requires a continuous process for compliant, current, and accurate product information dissemination.

On 24 September 2013, the United States Food and Drug Administration (FDA) published a rule establishing a unique device identification system for medical devices that spurred the industry into action. The FDA's Unique Device Identification (UDI) regulation requires all medical devices sold in the United States to be labeled with a unique device identifier and corresponding product information which must be submitted to the FDA's Global UDI Database (GUDID). The regulation is intended to ensure the availability of accurate and reliable information for providers, patients and members of the public, enabling visibility and transparency to recipients, and providers, of care. Like other healthcare brands, B. Braun, a leading global medical device manufacturer, assessed the impact that the FDA regulation would have on their business. In the process of mapping out their journey to compliance, they uncovered some key business challenges:

• How can B. Braun share trusted product information on a global scale while supporting patient safety?

• How can B. Braun improve its resource efficiency to lower healthcare costs?

To ensure that their organization delivered high quality product information to their trading partners and the FDA, B. Braun required an efficient and quality product information distribution methodology via a uniform deployment. The solution needed to incorporate a product data management strategy and system, with a focus on streamlining supply chain efficiencies and managing rising costs. Additionally, B. Braun felt that data quality management would be integral to ensuring

that product information is accurate, consistent and complete, meeting high standards of quality and reliability.

Where to Start?

In addition to preparing their systems for UDI compliance, B. Braun was committed to implementing processes that would ultimately improve patient and clinician safety, and lower healthcare costs. This required efficient, robust and comprehensive processes that would meet the regulatory mandate, satisfy customer requirements, and distribute high quality product information on a global scale. In order to achieve these goals, and efficiently distribute the required medical device product information to the FDA and other trading partners, B. Braun decided to utilize the **G**lobal **D**ata **S**ynchronization **N**etwork (GDSN®) on an enterprise-wide, global scale.

Solution

B. Braun began to assess the 1WorldSync certified data pool and services in May 2014. Requiring a global solution that met local considerations, such as regulatory and commercial requirements, B. Braun sought a trusted partner with a track record of success and a strong global presence. B. Braun selected 1WorldSync for data pool services, a connection to the FDA, and for professional services to plan, design, and execute on their

strategy. Their decision to partner with 1WorldSyc was based on key 1WorldSync capabilities including:

• Access to more than 23,000 trading partners, globally, via the GDSN

• Any to any distribution capability

• Direct integration to the FDA's Global Unique Device Identification Directory (GUDID)

• One pipe and one cost for global commerce and regulatory compliance

• Functionality to support additional global regulatory compliance

• Agile solutions for global product information exchange

The direction and timeline to govern GDSN implementation across all B. Braun countries was established by a global Program Management Office (PMO) with support from each country's Data Management Organization (DMO).

1WorldSync and B. Braun began their engagement with a priority focus on compliance with the FDA UDI regulation. The first step was to identify all of the data touchpoints within the organization. Throughout this process B. Braun came to recognize that system disparity, manual processes, and multiple data touchpoints were creating a significant challenge to achieving a high level of data quality and

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

Global Executive Sponsor			
External resource Support Manager (partly)	Global GDSN Coordinator	Global Process Coordinator	Country Business Sponsor

information sharing consistency. Once the data was centralized, 1WorldSync facilitated advanced data submission to the GUDID via a controlled test environment. The testing environment allowed for the collection of data errors and a re-evaluation of internal and systemic processes to ensure correct and accurate data submission in line with the first UDI Compliance deadline for Class III medical devices. As a result of the preparatory work B. Braun undertook with 1WorldSync, the organization successfully submitted all 450 Class III items in time for the September 24, 2014 compliance deadline.

Leveraging the framework of the successful Class III advance readiness engagement, 1WorldSync and B. Braun are
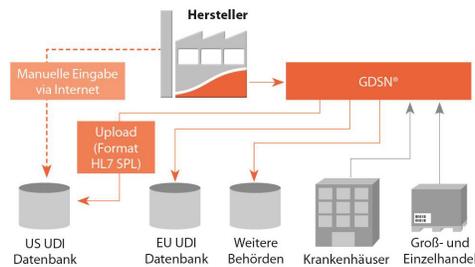
currently readying 14,000 medical devices for the Class II - Imp (Implants, and Life Sustaining/Life Supporting) compliance deadline of October 24, 2015. As a part of this process, an enterprise–wide effort is under way to streamline internal systems and consolidate data touch points in support of sustainable product information aggregation and distribution processes via the GDSN.
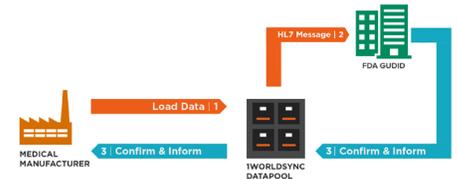
Outcome & Benefits

As of September 2014, B. Braun is successfully synchronizing medical device product information with the FDA on 450 products in compliance with the Class III deadline. In preparation for the upcoming Class II deadline, B. Braun is working with 1WorldSync to prepare an additional 8,000 medical devices for the Class II compliance deadline of September 24, 2016 and approximately 10,000 medical devices for the Class I compliance deadline of September 24, 2018.

B. Braun achieved a number of benefits on their journey to product information readiness for UDI compliance. The implementation of a globally harmonized data exchange model created a common language for B. Braun business units, distributors, GPOs, and hospitals. This one-to-any distribution mechanism, continuously updated through synchronization among trading partners, provides a single source of up-to-date, accurate product information for all data recipients.

Internal B. Braun data systems were streamlined, increasing quality and efficiency, while decreasing costs and complexity. Ultimately, the product information exchange framework built to enable compliance also laid the foundation for B. Braun omni-channel initiatives, such as e-Ordering, e-Invoicing, and more.

An additional, and critical, benefit achieved is an overall improvement in data quality. "In implementing the GDSN it became apparent that sustainable data maintenance processes were put into place in order to provide accurate product information in line with GDSN validation rules," said Holger Clobes, B. Braun Head of Global eCommerce and Auto ID.

Moving Forward

Building on the success of their initial implementation, B. Braun plans to extend their usage of the GDSN for regulatory compliance to commercial engagement. As a next step, B. Braun is expanding the use of GDSN to new recipients throughout Europe, such as hospitals, GPOs, and the National Health System in the United Kingdom, as well as to new geographies in the Asia Pacific. Committed to providing a seamless and trusted network for their product information exchange, B. Braun

is truly leveraging their success to enable efficient global trading partnerships.

Furthermore, as an extension to their product information management initiatives, B. Braun is engaging with trusted partner 1WorldSync to prepare their systems for GDSN Major Release 3. Slated for May 2016, this is the single largest change to the GDS network in more than ten years. Moreover, 1WorldSync is supporting B. Braun for digital asset management, to share medical device images, hazmat information, and more.

As a leader in the healthcare industry and a dedicated advocate for global industry harmonization via GS1 Standards and the GDSN, B. Braun is making a tremendous impact on the global community. Identifying global harmonization as a strategic organizational and industry imperative, B. Braun has joined other industry leaders as a member of the GS1 Global Healthcare Leadership team, as well as several GS1 Global data quality sub-groups. Their commitment to standardization underlies their organizational dedication to be *the* trusted brand in Healthcare products, as well as an industry pioneer for trusted product information exchange.

About B. Braun™

B. Braun supplies the global healthcare market with products for anesthesia, intensive medicine, cardiology, extracorporeal blood treatment and surgery, as well as services for hospitals, doctors and the homecare sector. Through dialogue with those who use B. Braun products daily, continually gaining new knowledge which it incorporates into product development. So the company with innovative products and services worldwide contribute to optimize the working processes in hospitals and medical practices and to enhance the safety, both for patients and for doctors or nurses. 50,000 people work in 61 countries for B. Braun. 2013, the company achieved a turnover of 5.17 billion euros.
http://www.bbraun.de

About 1WorldSync

With more than 16,000 customers across 54 countries, 1WorldSync is the leading product information network and data pool solutions provider, certified within GS1 Global Data Synchronization Network™ (GDSN®). 1WorldSync solutions and services enable businesses to exchange product information across their buy and sell side trading partner communities, via a single cloud based platform – with solutions including Supply Chain Enablement, Product Risk & Compliance, and Omni-channel Commerce. 1WorldSync is jointly owned by the member organizations of GS1 Germany and GS1 USA. GS1 is the preeminent organization for the development of global standards, for identifying, capturing and sharing product information.
www.1worldsync.com

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CONNECTING TRUSTED PRODUCT DATA EVERYWHERE

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