GDSN Data Pools for Simplified UDI Compliance

Today's healthcare players are focused more than ever on patients and their safety. From manufacturers to providers, they are investing in a world where patients enjoy consistently safer and more effective healthcare, with safer treatments and shorter hospital stays. They are identifying redundant activities and cutting needless costs from operations while gaining greater visibility across supply chains. They are adopting standards and embracing regulations that help them be more responsive and precise—with a collective commitment to improve patient care.

For more than a decade, global manufacturers Abbott and B. Braun have used GS1 standards and contributed to regulations—teaming with partners and government to make positive, sustainable changes in healthcare. So, it was no surprise when each company took a similar approach to leverage GS1 standards when complying with the Unique Device Identification regulation.

Making a strategic decision

In September 2013, the U.S. Food and Drug Administration (FDA) released its Unique Device Identification (UDI) regulation to establish a common, worldwide system for uniquely identifying all medical devices entering the U.S. market.

As a result, many manufacturers have started transitioning from disparate or non-existent medical identification methods to the standardised UDI system, assigning and applying unique product identifiers to all medical devices.

As part of the regulation, manufacturers are responsible for submitting and maintaining their UDI data—which includes a set of data attributes for each device identified with a UDI—in the FDA's Global Unique Device Identification Database (GUDID). To do this, manufacturers may choose from multiple options supported by in-house resources, third-party solution providers or GS1-certified data pools.

For Abbott Laboratories (Abbott) and B. Braun, it was a strategic decision to use the Global Data Synchronisation Network™ (GDSN®) and their certified data pools to feed UDI data into the GUDID—to meet immediate FDA compliance needs as well as future regulatory requirements.

Tackling the data challenge

Volker Zeinar, Head of Global Coordination Auto-ID Affairs at B. Braun, has broad and deep experience with GS1 standards in healthcare.

"The UDI regulation has put significant emphasis on product data management within manufacturing organisations," says Zeinar. "With the proliferation of data, there is growing awareness of the value of standards, which is very exciting. Many players are now taking action to implement standards instead of simply talking about it."

Brad Depke, Director of Abbott's GS1 Program, agrees that many manufacturers are stepping up to adopt standards, making fundamental changes in how they conduct business.

"Manufacturers are being called on to collect and share more and more information," explains Depke. "For example, to meet UDI requirements, we're reporting about triple the data attributes that we shared in the GDSN three years ago."

And as manufacturers tackle the challenge of managing data, using GS1 standards will be highly beneficial for providers and patients. Depke adds, "With UDIs, providers will know exactly what medical devices they are using with patients—a classic example of how GS1 standards promote patient safety."

Building the foundation

For B. Braun and Abbott, the GDSN and certified data pools provide the necessary foundation and security for managing quality product data to efficiently run their businesses and share with customers, including the FDA.

B. Braun points to its business processes where electronic ordering through invoicing relies on the GDSN for product master data management. "Our order-to-cash transactions depend on the completeness and accuracy of our master product database," says Zeinar. "The GDSN is more than a technical tool; it's a critical driver for data quality and validation that, in turn, fuels our e-business processes."

Abbott is counting on the GDSN as the global mechanism to collect and share data from its multiple divisions in countries around the world. "We wanted to share the company's product data with various constituents in the most efficient way," explains Depke. "That's the appeal of the GDSN."

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— Brad Depke, Director, GS1 Program, Abbott

The GDSN allows Abbott to be highly responsive when fielding requests from customers for product data updates. "With GDSN as our common platform, we can fulfil requests for data in much less time," says Depke. "To provide UDI information to the FDA in a streamlined way, we simply considered the FDA as another 'customer,' sharing our data attributes with them by using the GDSN and our data pool."
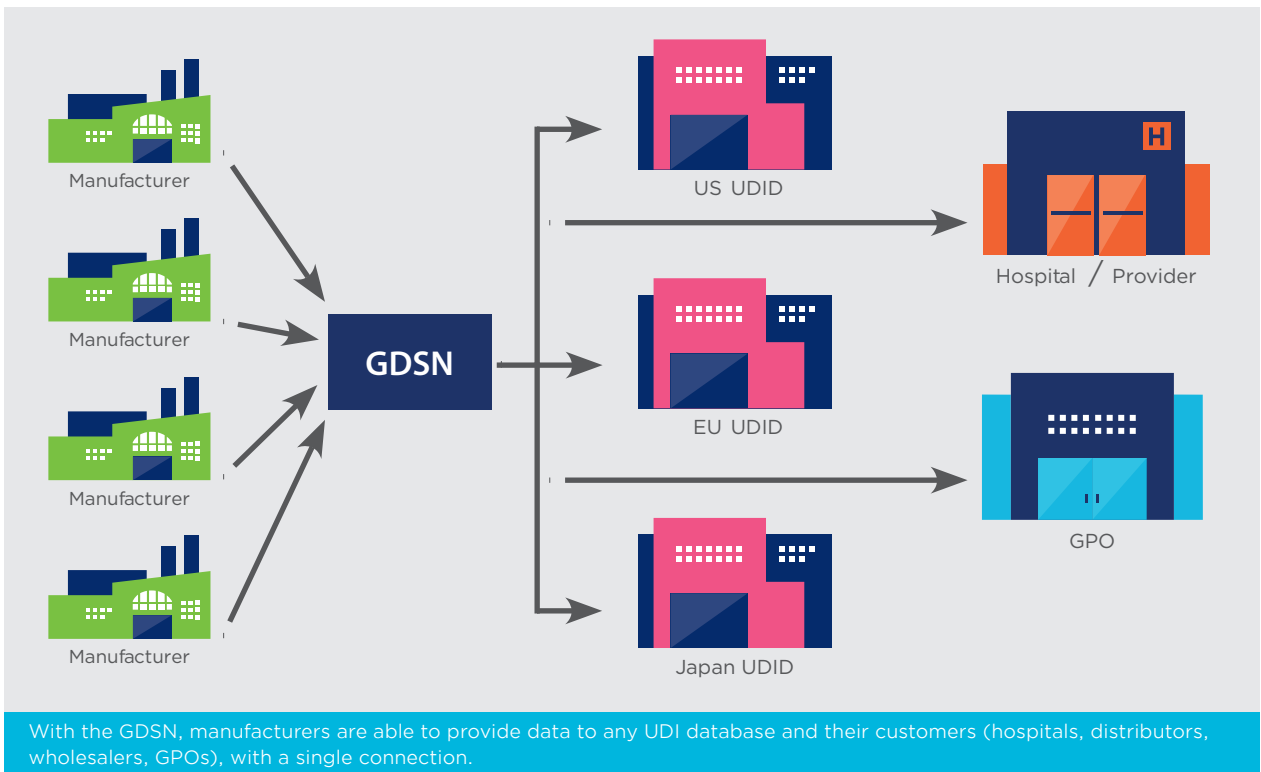
Using GDSN data pools for compliance

For Abbott, significant planning went into the decision to use the GDSN-data pool model. In fact, Abbott developed its GDSN implementation with the UDI data attributes in mind, merging its business requirements with FDA requirements. "We positioned the GDSN to support the UDI regulation as part of our overall data management strategy," says Depke.

B. Braun was also an integral part of the FDA's UDI regulation planning process. Zeinar advises the company's choice to use the GDSN and data pool was a strategic decision since it "greatly simplified our implementation efforts."

1WorldSync and GHX, both GDSN-certified data pools, provide services for manufacturers that want to take advantage of the GDSN-data pool model when loading UDI data into the GUDID. Data pool services include technical services such as mapping a manufacturer's data attributes to those required by the FDA and converting data formats to the FDA-required HL7 SPL format. Both data pools provide advisory services that give manufacturers guidance and support with ongoing data governance strategies.

Matt Houston, Executive Director of Product Management, GHX advises, "By embedding GDSN-data pool data attributes and practices into their product data management processes as well as carefully planning and pre-validating their FDA GUDID submission data, manufacturers can actually save time, effort and, in the end, overall costs when compared to directly submitting data into the GUDID. The preparation and pre-validation that we provide have proven to be invaluable in helping manufacturers be successful when submitting to the GUDID."

With the GDSN, manufacturers are able to provide data to any UDI database and their customers (hospitals, distributors, wholesalers, GPOs), with a single connection.

"We work with all sizes of manufacturers to help them not only comply with the UDI, but also create an environment for standardised quality product information," says Nick Manzo, Senior Director of Global Industry Development, 1WorldSync. "The beauty of the GDSN is that it allows small and mid-sized organisations to efficiently share and use product data to effectively compete in healthcare."

Taking a one-to-many approach

B. Braun and Abbott both stress the importance of planning and testing as part of the learning curve and process. "It's important to recognise that UDI regulatory compliance is not simply a project—it's part of the bigger picture of the ongoing data management process," advises Depke. "Put in place the needed resources to focus on maintaining and taking full advantage of quality data for many years to come."

Both point to the value of having completed this work when preparing for future regulatory requirements. "We expect more UDI regulations are coming in just a few years from around the world—China, Brasil, Japan and more countries," says Zeinar. "Using the GDSN standard, we're in a good position to efficiently respond. It's a scalable, flexible solution that will help us meet other markets' requirements."

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   Auto-ID Affairs, B. Braun

Abbott estimates the GDSN-data pool solution will address 90 percent of other countries' regulatory UDI requirements in the future.

"We've learned a lot about how to best comply with the specific requirements for UDI regulation," says Depke. "It's taught us about how to anticipate future global UDI requirements, using the GDSN and GS1 standards."

Zeinar concludes, "By taking a 'one to many' approach with the GDSN-data pool option, in the long term, we expect to save time, work and costs—and most importantly have a positive impact on the markets we serve."

Visit **www.gs1.org/healthcare/udi** and contact your local Member Organisation; see **www.gs1.org/contact**.

About Abbott

Abbott is a global healthcare company devoted to improving life through the development of products and technologies that span the breadth of healthcare. With a portfolio of leading, science-based offerings in diagnostics, medical devices, nutritionals and branded generic pharmaceuticals, Abbott serves people in more than 150 countries and employs approximately 73,000 people. Visit Abbott at **www.abbott.com** and connect on Twitter at @AbbottNews.

About B. Braun

Founded in 1839, B. Braun is one of the world´s leading healthcare suppliers with approximately 54,000 employees. The B. Braun brand rests on three supporting pillars of values: innovation, efficiency and sustainability. Guided by its Sharing Expertise® promise, the company is committed to sharing medical knowledge and expertise for eliminating preventable treatment errors and enhancing patient, clinician and environmental safety with products, services and education focused on sharing best clinical practices. **www.bbraun.com**

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 the 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 US. **www.1worldsync.com**

About GHX

Global Healthcare Exchange, LLC (GHX) is driving costs out of healthcare by transforming the healthcare supply chain. Working with providers and suppliers, GHX is accelerating change by providing a faster, more efficient and collaborative supply chain that takes billions of dollars out of the cost of healthcare. **www.ghx.com**

About GS1

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