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Abbott drives global deployment of GS1 Standards to benefit customers and patients alike

Abstract

Abbott Laboratories (Abbott) was faced with numerous new regulatory and customer requirements for product identification and information. To ensure it was "easy to do business with," the company decided to implement GS1 Standards to efficiently manage and share accurate product data with regulators and trading partners. Abbott formed the Global Standards & Serialisation Office (GSSO), a corporate team of experts responsible for supporting its four businesses when implementing standards. This flexible model has enabled Abbott to implement and use Global Location Numbers (GLNs) for company locations and Global Trade Item Numbers (GTINs) for its products. Furthermore, Abbott has registered the vast majority of its GTINs and product attributes in the Global Data Synchronisation Network ™ (GDSN®) for accurate data sharing with trading partners.

Customers, such as group purchasing organisations (GPO), have responded positively since the GDSN helps streamline their ordering processes and minimise errors and rework. Using GTINs and the GDSN, Abbott is well positioned to support compliance with the U.S. FDA Unique Device Identification (UDI) regulation. By using GS1 Standards, Abbott also helps providers ensure patients receive the right products, strengthening patient safety practices.

Abbott
A Promise for Life

Abbott Laboratories is one of the world's leading, global healthcare companies. The company has four core businesses: nutritionals, diagnostics, medical devices, and established pharmaceuticals. With sales, research, manufacturing, and distribution facilities located throughout 150 countries, Abbott combines its diverse expertise with deep cultural insights to create products that meet local and regional health needs. About 70 percent of Abbott's sales come from outside the United States, making it a truly global company.

Abbott participates in both retail and regulated healthcare markets with multiple businesses that operate independently. Yet, all businesses are leveraging a similar approach to GS1 Standards when managing product data throughout the Abbott supply chain.

"The new reality of the world is that the data [commercial, clinical, regulatory] about the product is now as important as the product itself."

Mike Wallace, Director, Global Standards & Serialisation

A natural requirement

Abbott is no newcomer when it comes to using GS1 Standards. The company has used Universal Product Codes (U.P.C.'s) [1] on its nutritional products for more than 30 years, and its pharmaceutical business has been an early adopter of standards for regulatory compliance.

1 The U.P.C. (Universal Product Code) is a GS1 Standard for bar code symbology used exclusively for products scanned at retail point of sale and mainly in North America.

Yet, some of Abbott's businesses were using proprietary product identification schemes that were not compliant with new regulatory and customer requirements. Also, countries like Brazil, France, Germany and Japan, were starting to require the use of GS1 Standards. Abbott considered the business advantages of adopting standards company wide. Recognising the short- and long-term potential benefits, the company started implementing standards to be part of its normal business processes.

Expertise and flexibility

In late 2008, the company formed the Global Standards & Serialisation Office (GSSO), a corporate group that has enterprise-wide responsibility to facilitate the implementation of GS1 Standards and serialisation for all of Abbott's businesses.

A diagnostic assay for the hepatitis C virus (anti-HCV) uses a GS1 DataMatrix bar code and a 14-digit GTIN. The expiry date uses the ISO 8601 format (YYYY-MM-DD)

An initial step for the GSSO was the creation of a standard operating procedure stating the requirements for Abbott's usage of GS1 Standards, including the creation and management of GS1 Standard data for product and location identification. At the same time, the group recognised the autonomous nature of its businesses during this transition.

While the GSSO provides the "center of expertise", it also partners with and extends its knowledge to global associates within Abbott's businesses via educational opportunities. Each member of the GSSO serves as a liaison to a respective business within Abbott. As a corporate function, the GSSO brings repeatable methodologies and best practices to the businesses, ensuring the same problem isn't solved in different ways. In the end, this saves time and costs across the enterprise.

"We recognised the short- and long-term potential benefits of using GS1 Standards. By implementing the standards as part of our normal business processes, we are able to proactively manage the pace of change on our own terms as opposed to reacting to a mandate or crisis."

Mike Wallace, Director, Global Standards & Serialisation

Managing the pace of change

One of the GSSO's first steps was the identification and documentation of GS1 Global Location Numbers (GLNs) to meet the U.S. healthcare industry's 2010 "sunrise" deadline for location identification.

In 2011, the team initiated the assignment of GS1 Global Trade Item Numbers (GTINs) – unique identifiers for each product in the business units' portfolios, which was a major goal of the U.S. healthcare industry's 2012 GTIN Sunrise.

Another critical step was to load the GTINs and required healthcare product attributes in the 1WorldSync™ Data Pool for sharing product data in the GS1 Global Data Synchronisation Network (GDSN). The Abbott GDSN project team combined the implementation of the GDSN with the creation of GTINs to work simultaneously.

GS1 Standards and UDI

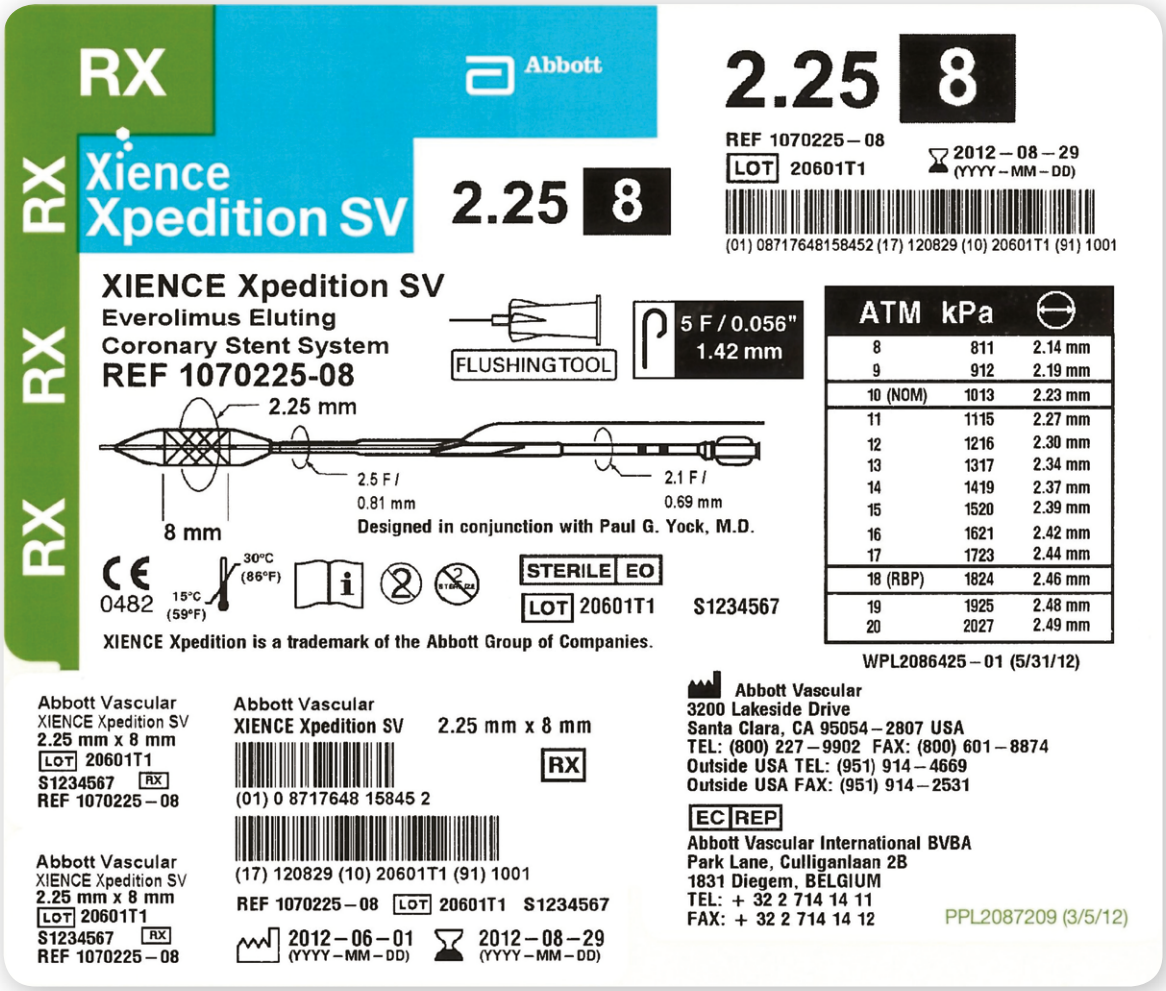
The U.S Food and Drug Administration (FDA) Unique Device Identification (UDI) regulation is at the forefront in the medical device market as companies need to transition from disparate medical identification methods to a standardised UDI system. Suppliers will be required to assign and apply a UDI to all medical devices.

Abbott's choice for the UDI's device identifier is the GS1 GTIN.

Suppliers are expected to provide their UDI data for access by the FDA in a single, global UDI database (GUDID) system. Since the GDSN is currently used by many trading partners, it can be leveraged as a "data feed" to the UDI database.

With its GDSN implementation, Abbott is well positioned to support this new regulation. In fact, Abbott's GSSO developed its GDSN implementation with the UDI in mind, merging its business requirements with the FDA requirements.

The GSSO also worked closely with 1WorldSync, its GS1 certified-data pool provider, to establish the FDA as a recipient of Abbott's device data. Leveraging the GDSN for UDI compliance was a strategy the company devised when it heard about the regulation. With GS1 Standards, Abbott has a common, single solution for UDI compliance.



The XIENCE Xpedition™ Everolimus Eluting Coronary Stent System is comprised of two main components: the drug-coated stent and the balloon expandable delivery system. The label displays a GS1-128 bar code including the GTIN (01) , Expiration Date (17), Lot Number (10) and an Internal Company Code (91).

In the upper right corner, the information is concatenated into one bar code and wraps around the spine of the box for quick scanning of inventory. The two bar codes on the lower portion of the label depict the same information as the one on the spine. ISO 8601 format is used for the expiry date (YYYY-MM-DD).

The team developed a common process, working with IT to stage each of Abbott's businesses when delivering product data.

To date, about 98 percent of Abbott's U.S.-based products, including medical devices, have their GTINs and other data attributes registered in the GDSN. Abbott's goal is 100 percent even as new products are introduced to the U.S. market. Over time, the company's plan is to share the GTINs and item data to all target markets, using a common framework, repeatable processes, and adhering to Global Data Synchronisation principles.

A three-way match

During the GDSN implementation process, the GSSO contacted Abbott customers to advise the company could now offer its all-inclusive product line from one source. The team received positive responses, especially from group purchasing organisations. The hospital GPOs realised that implementing the GDSN is an important step for them since it helps streamline their ordering process and minimise errors and rework.

Eventually, they will not need to maintain proprietary product numbers from every manufacturer. They can be assured that when ordering product A, they will receive product A, and not product B. By having and sharing standardised product identifiers, there is potential value for their order-to-cash processes.

Another example where GS1 Standards are making a difference involves one of Abbott's customers – a major healthcare provider using the GDSN. When ordering Abbott products, the provider issues the Purchase Order listing the products' GTINs, instead of proprietary part numbers or SKUs, since, as trading partners, both Abbott and the provider share product data via the GDSN. The provider receives the right products along with an accurate invoice, which also listed the products' GTINs. Abbott calls this a "three-way match" for efficient and accurate ordering, fulfillment and invoicing.

Also, when a customer requests an Abbott catalog, the salesperson can simply get the customer's GLN to give him access to not one, but all of Abbott's products in all businesses. Some of Abbott's GPOs and customers have commented that they appreciate knowing about all the company's product lines.

Caring for patients is one of Abbott's core values. For 125 years, Abbott has been about improving lives through medical science and the life-changing technologies it creates, and this same caring extends to how the company fulfills and distributes its products to ensure patients receive the right products in a timely manner.

About the author

Mike Wallace's role, as Director Global Standards & Serialisation, is to implement the adoption of GS1 global product and customer identification standards and an enterprise-wide approach to serialisation for Abbott. This will allow the corporation to cost effectively meet the growing and evolving customer and regulatory requirements. Mr. Wallace represents Abbott on the GS1 Global Healthcare Leadership Team and is serving as a tri-chair. For the past ten years, he has consulted with a cross section of groups across Abbott and the supply chain for healthcare and consumer packaged goods to prepare to implement these emerging standards and technologies.

About Abbott Laboratories

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 70,000 people.
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