



Suppliers and GPOs

Teleflex harnesses strong partnerships for patient safety

Teleflex needed to implement a data management solution to comply with the US Food and Drug Administration's (FDA) Unique Device Identification (UDI) regulation. The company created a cross-functional team, including GS1 Solution Providers, 1WorldSync and LANSA. A multi-phased project was launched that identified and integrated device data from diverse systems across the company and included processes to assign and validate each device's Global Trade Item Number® (GTIN®) and attributes on their way to the FDA's Global UDI Database (GUDID). Teleflex also achieved full Global Data Synchronisation Network® (GDSN®) operability for trusted data-sharing with trading partners. Now, Teleflex can provide accurate, complete and validated product data to regulatory bodies and trading partners alike, including healthcare providers.

By Mark Hoyle



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Understanding what it takes

Teleflex is a global provider of medical technologies designed to improve the health and quality of life for patients. The company's diverse portfolio of medical devices spans the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care.

When the US Food and Drug Administration finalised its ruling for a unique device identification system, Teleflex commenced working to comply with all designated deadlines.

“Even before the UDI regulation, Teleflex had primarily used GS1 standards,” says Mark Hoyle, Technical Director for UDI Compliance at Teleflex. “We were expanding the use of GS1 standards within our product lines exclusively. Given the UDI ruling, we accelerated our plans.”

Originally Hoyle joined Teleflex to oversee international packaging, drawing on his background in qualification, validation and automation. Transitioning to UDI compliance for Teleflex was a natural undertaking in view of his prior experience in this arena.

“There’s close alignment between packaging and product identification,” Hoyle says. “The automated processes of device assembly married with packaging and labelling for primary, secondary or tertiary packaging levels involves all aspects of electronic data management and physical application in a validated manner.”

Hoyle also had prior experience with GS1 as the Co-Chair of its GS1 Healthcare initiative. “Working with GS1 and other members of the healthcare sector, we collaborated with the FDA and helped shape GS1 Healthcare GTIN Allocation Rules, leading to the eventual UDI regulation,” says Hoyle. “So I came to Teleflex with a solid understanding of ‘what it would take’ to successfully implement a UDI strategy, with an additional goal of meeting customer expectations in data publication.”

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According to Hoyle

Hoyle wanted to adopt a forward-looking strategy that would go beyond the immediate UDI requirements. “I felt strongly that Teleflex should be positioned to fulfil future regulatory needs around the globe,” advises Hoyle. “At the same time, I wanted to plan for the key requirements of our customers that were using or planning to use the GDSN to exchange information with us throughout the supply chain.”

Following a rigorous analysis and comparison of options, Teleflex chose to work with 1WorldSync as its GS1-certified data pool provider, and LANSAs’s Product Management Information (PIM)

system for business process integration and data synchronisation software.

“Healthcare as a sector is on a steep learning curve when it comes to automating its UDI processes in a standards-based way,” explains Hoyle. “We needed to build a team with the necessary skillsets to help us develop a strong foundation. LANSAs brought a wealth of experience in creating data management solutions and a willingness to partner with us.”

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“Our goal was to build a single point of truth for the FDA’s GUDID that could consume information from our enterprise resource planning (ERP) and product lifecycle management (PLM) tools,” continues Hoyle. “1WorldSync offered a singular solution that we can leverage with all future regulatory demands, in addition to the FDA. With one global solution, there’s less opportunity for misinterpretation. Harmonisation is more easily controlled, and divergence based on the target market is better managed. It’s a clean solution.”

United team for united effort

The Teleflex team was comprised of a central core UDI team with expertise in project management, regulatory issues and IT. The team was supported by the labelling group to manage the intricacies of artwork design that would allow packaging real estate to accommodate the GS1 standards-based barcode symbologies.

“1WorldSync supported project management efforts that furthered interactions between LANSAs’s technical development and the overall processes being delivered,” says Hoyle. “LANSAs was a critical member of our team in helping to design and implement the process requirements for product data input and validation, as well as making needed modifications as they arose.”

An extended team of Teleflex professionals—including IT data analysis and data management support—joined with business unit team members, research and development, engineering, regulatory and quality assurance managers to coordinate a successful implementation.

“I was extremely keen to ensure that we didn’t see this merely as a customer/supplier relationship, nor as a hard start/stop initiative,” says Hoyle. “We established a strong partnership between LANSA, 1WorldSync and Teleflex because we were developing an embryonic technology, and we needed to be mindful of the platform expansions and the exponential growth that is already emerging.”

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Assess, assign, validate

As the first major step in the implementation process, the team conducted an assessment of the current situation—identifying where data resided in the various Teleflex organisations. While this may seem straightforward, Hoyle explains the challenging nature of the activity. “For more than 70 years, Teleflex has grown tremendously through acquisitions, which equates to the existence of many different business systems and integration points throughout the company.”

The second major work effort focused on creating the product data—the GTIN and attributes for each device—along with interfaces for input. “Our task focused on integrating all of the different systems in a centralised way to assign GTINs based on the different global company prefixes that we manage,” says Hoyle. “The goal was to provide a complete, accurate and consistent way of presenting data attributes that would conform to UDI regulatory requirements and GDSN requirements.”

LANSA became the single point of GTIN assignment, building the structure and hierarchies that followed GS1 Healthcare Allocation Rules. “At the same time, LANSA built customised rules that would uniformly manage the provision of correct information for new product creation and build,” says Hoyle. “This would ensure accurate and automated GTIN assignment in our systems.”

For every level of packaging, Teleflex leverages GS1 standards-based information encoded in GS1 DataMatrix barcodes.

The third step in the implementation process was to systematically validate data. Device GTINs and attributes were staged and automatically checked through loading and registration via the 1WorldSync data pool with publication to the GUDID, confirming the data at each step based on validations applied by LANSA, 1WorldSync and the FDA. “Based on these stages of validation, we achieved high confidence surrounding the format of data compliance on submission to the GUDID,” explains Hoyle.

“ Making considered decisions upfront by understanding the present and future vision is critical; you will reap many benefits downstream. These benefits will be realised through accuracy and efficiency along the supply chain, ultimately leading to improved patient care.”

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People, partners, processes

Hoyle attributes the success of the UDI project at Teleflex to people in the organisations that worked side-by-side to develop an industry-changing solution. “We have an excellent technical team at LANSA and a great project management function with 1WorldSync. Within Teleflex, people showed an understanding not just about the needs of the industry but the needs within the partnership, resulting in excellent collaboration.”

With the UDI solution now in place, Teleflex has started the next phase of its journey, expanding its use of the LANSA team members as they are always looking for better ways and opportunities to automate business processes and improve the data that is being delivered.

“The second part of our success is the standards-based process itself,” adds Hoyle. “We have a fully customisable PIM system in which we have information control, and the ability to configure it in such a way that allows it to fit other needs of our organisation and business practices.”

In addition to picking the right partners to work with, Hoyle would advise others to take time to develop the right strategy.

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Using GS1-128 barcodes, Teleflex encodes valuable product information on each product package.

Win-win for patient safety and operations

Hoyle considers the company’s investment in time, resources and money well worth the return in patient safety and other benefits.

“One of the difficulties for healthcare—or for any industry for that matter—is how to measure the return-on-investment when implementing standards and new processes,” Hoyle says. “Yet, once you start moving down the implementation path, you can quickly identify the improvements to your internal operations: distribution control, speed and efficiency, through to order fulfilment. You start to recognise all of the operational benefits. Couple this with delivering patient safety objectives and it’s a win-win. The benefits are all there.”

Hoyle concludes, “Our commitment to patient safety and the importance of UDI in achieving this goal is something we hold in the highest regard. When we deliver our products to our customers, we are also delivering patient safety in the form of UDI, enabling accuracy, efficiency and traceability. That’s not just a regulatory box to check or a supply chain process to complete — it’s a real and positive impact for real people.”

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About the Author



Mark Hoyle has been working for major multinationals for 33 years, specifically pharmaceutical and medical device companies and currently holds the position of Technical Director for UDI implementation globally at Teleflex. He has co-chaired the GTIN Allocation

Rules for Healthcare working group for GS1, producing the baseline on which to manage the standard for healthcare. Mark is one of the founding members and former co-chair of GS1 Global Healthcare and is still an active participant, shaping and modelling the healthcare objectives for product identification and data sharing between trading partners and regulators using the GDSN (Global Data Synchronisation Network).

Mark is fully committed to global harmonisation, striving to deliver and educate both internally for Teleflex and externally as necessary. He and his team have delivered a global and adaptable solution for UDI enabling growth and varied requirements to be fulfilled in this ever-changing world of UDI expansion and usability.

About Teleflex

Teleflex is a global provider of medical technologies designed to improve the health and quality of people's lives. Teleflex applies purpose driven innovation to identify unmet clinical needs to benefit patients and healthcare providers. The company's portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care.

www.teleflex.com

About LANSA

LANSA is a leading provider of business process integration and data synchronisation software. LANSA's product suite spans the entire supply chain process with solutions for GDSN participation, Product Information Management and data quality. LANSA is a solution provider for many GS1 Member Organisations worldwide and a leading 1WorldSync solution provider. LANSA is working with market category leaders include COTY, Del Monte Foods, Godiva, Hain Celestial, Hunter Fan and Pernod Ricard. Established in 1987, LANSA supports thousands of companies around the world with its products and services.

www.datasyncdirect.com

About 1WorldSync

1WorldSync is the leading multi-enterprise product information network, helping more than 23,000 global brands and their trading partners in 60 countries to share authentic, trusted content with customers and consumers, empowering them to make intelligent choices and decisions concerning purchases, lifestyle and well-being. 1WorldSync's Product Information Cloud platform was designed for businesses to exchange enriched product data and digital content, creating a mission-critical foundation for connected commerce. 1WorldSync is jointly owned by the member organisations of GS1 Germany and GS1 US.

GS1 is the preeminent global organisation for the development of global standards, for identifying, capturing and sharing product information.

www.1worldsync.com

