United States

Driving Unique Device Identification compliance puts focus on patient safety

Challenge

With a focus on improving patient safety, the US Food and Drug Administration (FDA) recognised the potential risks of not being able to accurately identify each medical device out in the world. As a result, Unique Device Identification (UDI) was introduced. Additional countries have also enacted regulations. For UDI to be effective, it necessitates a harmonised and consistent approach.

Approach

Johnson & Johnson Supply Chain (JJSC) has a comprehensive UDI program enabling it to meet compliance milestones. Collaboration, data management and product identification are key components. JJSC supports the use of GS1 standards and assigns Global Trade Item Numbers (GTINs) to Johnson & Johnson company medical devices.

Complying with UDI regulations puts the focus on patient safety

75,000

device records submitted to FDA's GUDID by J&J companies

84%

of records submitted to GUDID utilised GS1 as issuing agency

Universal adoption allows healthcare providers to use UDI data

Patient Safety

UDI regulations being introduced around the world have resulted in key benefits focused on patient safety and hospital effectiveness. Common components of these regulations include labelling, a publicly accessible data repository and direct marking on reusable medical devices.

Johnson & Johnson Supply Chain embraces product identification and traceability as it has numerous benefits for patients, customers and the industry. JJSC has enterprise, supply chain product identification and traceability programmes and a comprehensive UDI programme, enabling it to meet compliance milestones. Collaboration, data management and product identification are key components.

Tom Jones

"Guided by Our Credo, we put the needs and well-being of the people we serve first. Complying with UDI regulations puts the focus on patient safety. Widespread adoption of GS1 standards to support UDI requirements aids the industry and protects the patient," says Vivek Nadadur, Senior Director of Digital Identification & Traceability.

Collaboration

In 2013, when the US FDA published its UDI regulation establishing a common, worldwide system for product identification for all medical devices sold in the United States, the JJSC dedicated UDI team, along with multiple functions, created an approach that would meet compliance milestones and could be leveraged to meet future regulations from around the globe. Compliance requires collaboration across multiple functions. Given the typical regulatory components of data submission, labelling and direct marking, there must be a coordinated effort with participation from Regulatory Affairs, Information Technology, Quality, Supply Chain and engagement of the commercial organisation for that market.

JJSC's first objective was to review and interpret the regulations on what it means to be compliant. Next, the team developed the data submission infrastructure, enabling all Johnson & Johnson companies to consolidate and submit their device records to the health authority in a consistent manner. Working closely with the company's medical devices, consumer health, and pharmaceuticals segments ensured a consistent interpretation of the regulation. Segment leaders worked with their respective companies to execute the appropriate actions, including the significant efforts associated with data collection, evaluation and, where appropriate, remediation of barcodes and labels, and similar activities associated with direct marking requirements.

It Takes a Unified Effort

Regulatory Affairs
Interpretation of regulations
Primary conduit to Health Authorities

Information Technology
Apply technology to meet requirements
Develop the data submission infrastructure

Quality
Establish policies and procedures to sustain compliance

Supply Chain
Execute data collection, evaluation and remediation of barcodes and labels

Commercial
Provide customer perspective as we pursue compliance

Operating Companies
Execute strategy labels, direct markings, data

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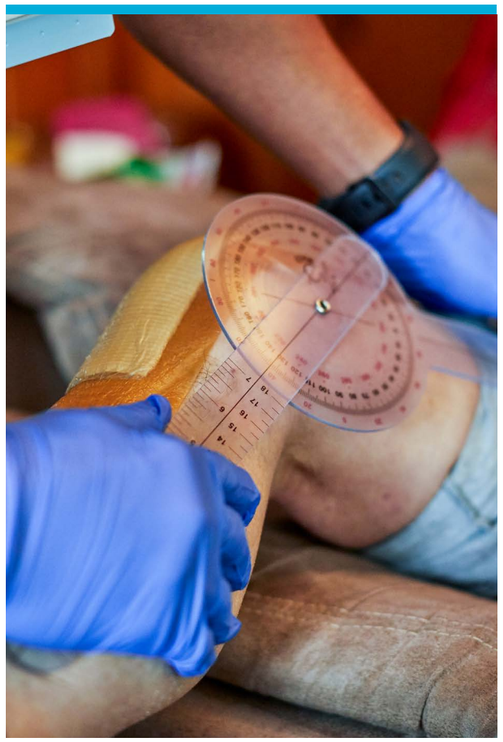
Vivek Nadadur
Senior Director of Digital Identification & Traceability
Johnson & Johnson Supply Chain

Data management

The data management effort was significant, especially since prior to the US FDA's UDI regulation, many associates typically did not think of their products in terms of device class.

By creating an organisational working structure in 2013 to interpret and collect the required data, JJSC was able to leverage that network to comply with the requirements of subsequent regulations. Many of the data fields required by regulations from European Union, Korea, China and Saudi Arabia were similar, if not exact, to the fields submitted to the US FDA's Global Unique Device Identification Database (GUDID).

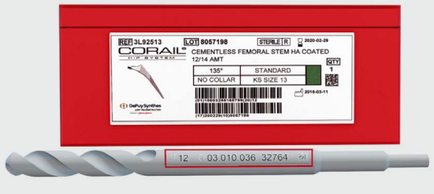


Product identification

Johnson & Johnson companies support the use of GS1 standards and have adopted the GS1 standard for their barcodes. Global Trade Item Numbers (GTINs) have been assigned to medical devices and are labelled with GS1 barcodes. The popularity of GS1 as an issuing agency is evident from the submissions to GUDID. A recent search of the GUDID suggests that over 84% of the records submitted utilised GS1 as the issuing agency.

Patients, customers and the industry benefit from using GS1 standards.

- **GS1 standards help to more accurately identify medical devices that are received, dispensed and recorded in patient records.**
- **The GS1 barcode is accepted by all countries with UDI regulations, and manufacturers have more flexibility in distributing the same product to multiple markets.**
- **Universal adoption allows healthcare providers to use UDI data in their procurement systems, inventory management systems, electronic health record systems and implant registries.**
- **Product availability is enhanced with the ability to leverage inventory across multiple markets. It's easier to avoid stockouts and ensure that the appropriate device is available, when needed.**
- **GTINs across multiple regions enable device manufacturers to more easily identify products and batch numbers in the event of any product concerns.**



Lessons learned

A comprehensive UDI strategy, a collaborative multi-functional team and the adoption of GS1 standards help to enable successful regulatory compliance. UDI helps healthcare professionals identify products in a consistent manner.

Most importantly, the implementation of UDI improves patient safety, ensuring the right product is at the right place, for the right patient. With GS1 standards, JJSC is ready to enhance product identification and improve patient safety around the world.

Initially UDI commenced in 2013 in the United States. It's now grown to approximately 40 countries.

About the author

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Johnson & Johnson Supply Chain

Tom Jones is a Digital Identification & Traceability Director for Johnson & Johnson Supply Chain. He leads the enterprise efforts for unique device identification and serialisation. Mr. Jones worked in information technology, business intelligence, and supply chain at the company, and has held multiple programme leadership roles at Ethicon Endo-Surgery, LLC, the DePuy Synthes Companies, and within the supply chain organisation.

About the organisation

Johnson & Johnson Supply Chain includes three business sector supply chains—Consumer Health, Medical Devices and Pharmaceuticals—that cover planning, sourcing, internal and external manufacturing, as well as the Supply Chain Strategy, Innovation & Deployment organisation and the Deliver organisation, which manages distribution and customer service. Additional enterprise-wide functions that are part of the Johnson & Johnson Supply Chain include Quality & Compliance, Environmental Health, Safety & Sustainability and Engineering & Property Services, and Procurement.

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