



Bedside scanning and patient safety

Stryker's GS1 standards adoption journey

Stryker is one of the world's leading medical technology companies and offers a diverse array of innovative products and services in orthopaedics, medical, surgical, neurotechnology, and spine that help improve patient and hospital outcomes. Stryker is active in over 100 countries around the world.

By Mary Beth Krantz and Shannon Pfau



Problem

The advent of the US FDA's Unique Device Identification (UDI) Final Rule and the NHS eProcurement strategy meant that Stryker, as with all other medical suppliers, needed to update their product labelling to comply with these new regulations.

How was the problem solved?

Stryker saw this problem as an opportunity to standardise all of their product identifiers and barcodes. This approach makes life easier for their customers and increases efficiencies in the healthcare supply chain. Stryker recognised GS1 as the preferred standard for their customers and began implementation of GS1 standards across all 72,000+ Stryker products globally. This was a complex process, requiring hundreds of people, in multiple functions across all product and selling divisions.

An additional benefit of transitioning to GS1 standards, specifically GS1-128 linear or GS1 DataMatrix barcodes wherever possible, was to support a single scan on a product label.

The organisation first needed to identify the product data owners within the company, which was a vital step to ensure accuracy and consistency. Collaboration and consolidation of the information was required from:

- Regulatory (GMDN, authorized representative)
- Marketing (brand)
- Product development (dimensions, storage conditions)
- Supply chain (packaging level, unit of measure)

The Stryker teams developed sustainable business processes to harvest and consolidate these disparate product attributes into a new product master data system. This approach created one source of truth for Stryker product data.

Prior to the adoption of GS1 standards, the majority of Stryker products were labelled in production with HIBCC identifiers. An additional benefit of transitioning to GS1 standards, specifically GS1-128 linear or GS1 DataMatrix barcodes wherever possible, was to support a single scan on a product label. A phased approach was developed to introduce GS1 standards globally, making the transition more manageable. The first GS1 labelled products started shipping in September 2014 and the rest will be phased in over the next four years.

What are the benefits?

By adopting the GS1 standard, Stryker anticipates there will be many benefits both internally and to their end customers, including:

- Help reduce medical errors caused by the incorrect identification of products
- Simplify integration of device usage information into computer data systems
- Facilitate faster identification of medical devices associated with adverse events
- Enable more efficient solutions to reported problems and resolution of device recalls
- Provide an easily accessible source of definitive device identification information
- Help detect counterfeit devices
- Improve inventory management and supply chain efficiencies
- Facilitate development of electronic patient records
- Help identify similar or replacement devices in case of a shortage

Next steps

Stryker's implementation timeline is as follows:

Sept 24 2014	Class III (high risk) Medical Devices 61 Stryker products impacted
Sept 24 2015	All Other Implantable, Life Supporting, Life Sustaining Medical Devices 21,351 Stryker products impacted
Sept 24 2016	All Other Class II (critical) Medical Devices 17,000+ Stryker products impacted
Sept 24 2018	All Other Class I (non-critical) Medical and Unclassified Devices - 30,000+ Stryker products impacted
Beyond 2018 - remaining non-medical devices and products	



About the authors



At Stryker, **Mary Beth Krantz**, Director, Data Governance and Master Data Management, leads enterprise master data

and governance strategies to support corporate-wide initiatives. This includes the process of data collection, maintenance and governance of product and customer Master Data Management as well as leadership in overall data governance policies across the enterprise.



At Stryker, **Shannon Pfau**, Manager, Training and Organizational Change, leads the communication, training, and organizational change

efforts to support corporate-wide initiatives. This includes ensuring comprehensive internal and external communication is taking place, required training is being developed and conducted, and facilitating organizational change principles throughout the initiatives.

About Stryker

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