United Kingdom

Futureproofing medical device supply using GS1 standards

Challenge

Due to NHS requirements and changes to the EU medical device regulations, PDI was required to ensure all products were issued with GTINs and that medical devices had unique device identifiers to comply with EU MDR.

Approach

The business implemented new equipment and processes to ensure compliance, and continue to service its international customer markets.

100%
products and devices with GTINs

90%
time saved on production lines

Introduction

PDI International (PDI) is a well-established healthcare supplier of medical devices both in the UK and internationally, and supplies goods to the National Health Service (NHS) in England. Due to NHS requirements and changes to the EU medical device regulations, PDI was required to ensure all products were issued with Global Trade Item Numbers (GTINs) and that medical devices had unique device identifiers to comply with EU MDR. Today, each of their product lines and trading units (circa 300+ items) has a GTIN in order to comply with regulatory requirements.

Background

PDI International (PDI) is a well-established healthcare supplier of medical devices both in the UK and internationally, and supplies goods to the National Health Service (NHS) in England. For the past 40 years, PDI has focused on helping to fight preventable infections, developing important infection prevention innovations including the first alcohol prep pad and disposable disinfectant wipes.

Manufacturing facility, Corby UK

Originally part of Nice-Pak, PDI used the European Article Number (EAN) for unique identification in order to distribute its products on the European market. However, when Nice-Pak and PDI became independent, PDI needed to differentiate products with a separate prefix to prevent any identification errors when trading.

Key drivers for change

Meeting NHS requirements

In order to supply products to the NHS, suppliers need to comply with the requirements of the NHS eProcurement Strategy. The strategy, which was released in 2014, mandates suppliers to uniquely identify products using GS1 Global Trade Item Numbers (GTINs) encoded into barcodes. The aims of the programme centred on ensuring supply chain integrity, improving product traceability, and making it easier for hospitals to source supplies at standardised prices (procurement efficiency).

PDI wanted to ensure products could be scanned at the point of care or use to support hospitals with Scan4Safety implementation. Scan4Safety is based in using GS1 standards to uniquely identify every person, every product, and every place to improve patient safety. The GS1 barcode is scanned to capture accurate data and improve product traceability. For hospitals to be able to scan products, PDI needed to ensure each item was barcoded correctly and accurately encoded with the necessary production information.

Medical device regulations

The introduction of the European medical device regulations (EU MDR) further supported the decision to use GTINs as they can also be used to comply with other global medical device regulations (such as US FDA requirements). Using the GTIN would enable PDI to continue to service its customers across the UK and its wider international customer markets without limitation.

To comply with requirements, PDI needed to allocate GTINs to products and encode the production information into GS1 2D DataMatrix barcodes for the necessary device classifications. However to mitigate any classification changes, the business decided to implement 2D DataMatrix barcodes across all medical devices.

Implementation and challenges

Over the four year transition period from Nice-Pak, PDI gradually allocated GTINs to all 115 individual product lines amounting to 300+ total products accounting for the units of use. All packaging artwork needed to be updated which required investment in new infrastructure across the production line. This required system, software, and hardware upgrades to manage changes to the barcode printing configuration.

Step-by-step plan:

1. GTIN allocation
   Contacted GS1 UK to obtain a new GS1 Company Prefix (GCP) for PDI products. Used the GCP to allocate GTINs to all necessary product lines and trading units – circa 300+ items.

2. Artwork changes
   Update all product packaging artwork to ensure space for the necessary barcodes, UDI information and required UDI human readable interpretation (HRI) to be printed.

3. System upgrades to support automation and standardisation
   Products were transitioned from linear barcodes on primary packaging to using 2D DataMatrix barcodes to meet regulatory compliance. System software had to be reconfigured to meet the desired adjustments. Three different types of software had to be introduced to instruct the software to print the 2D DataMatrix. This also had to account for different packaging types such as curved canisters. PDI use Bartender 2019 for the creation of the DataMatrix barcodes and these are then validated through the GS1 healthcare barcode scanner app (HBSA).

4. Standardisation and barcode compliance
   Set up technical specifications so the information pulled through is accurate and standardised across all products i.e. expiry date preset to the correct formatting i.e. YYYY-MM-DD for consistency. Ensure barcodes are scannable and that all 2D DataMatrix barcodes meet the requirements outlined in the GS1 General Specifications.

5. Upgrade printing capabilities
   All printers were upgraded to ones with capacity to combine HRI information along with the barcode and UDI symbols onto products. This ensured that the human readable information, such as lot number and expiry dates, could be linked to the data encoded in the barcode for compliance. Critical stage for consideration as PDI have varying packaging requirements including varnished containers, soft packaging, and curved canisters.

Production Facility, Corby UK

6. Update technical guidance
   All guidance documents for line operatives were updated to outline the new automated processes. For example, operatives are no longer required to manually print the expiry date labels on to products. Now when the works order number comes through e.g. for X quantity of Y product, the order number automatically pulls through product code and GTIN, and automatically fills the day's date and product expiry date.

The challenges

- Updating all product lines with new GTINs as part of the transition process
- Financial outlay to cover all updates to printers, systems and software
- Ensuring all software upgrades could accommodate the changes to ensure compliance
- Change of quality assurance processes in the factory to validate barcode quality
- Confirmation on a decision for date of implementation

Core benefits

- 100% products now use a GS1 GTIN
- 100% medical devices use a GS1 2D DataMatrix barcode
- 90% time saved during labelling processes
- Standardised formatting across all products for compliance i.e. expiry date presentation YYYY-MM-DD
- Reduced risk manual errors due to automated processes – improved quality assurance
- Compliant with international medical device regulations
- 100% compliant for NHS tenders and other customers that request GTINs

PDI has been able to reduce the number of variables due to fewer manual touchpoints throughout the production process. This has helped to engineer out the risk of manual errors to reduce the frequency of any packaging defects.

Where line staff used to manually add and check the batch number and expiry date, it is now automated due to the new infrastructure. It now takes significantly less time to check for consistency and compliance.

As more NHS and international customers ask for the GTIN, PDI can be confident that all products are 100% compliant for any market across all product lines.

Conclusion and next steps:

PDI continues to focus on future proofing its systems and processes to ensure the organisation remains compliant with NHS requirements and any global medical device regulations.

To improve quality assurance the business is also reviewing its barcode verification process to introduce either in-line or post-production validation. This will help to ensure all barcode quality specifications are met and that each product can be scanned appropriately at the point of care or use.

PDI is currently exploring more ways to use GS1 Location Numbers (GLNs) to support processes. GLNs are already in place at the Corby site but are considering implementing GLNs into the Milan site and individual warehouses for stock management and order picking. There is also the option to scan products onto the line to determine what stock is outstanding to drive efficiency improvements for inventory management and order processing.

About the author

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With a background in pharmaceutical quality control and method development analysis, Elan joined PDI in an analytical capacity, working with the formulation team, initially conducting various testing methodologies, thereafter, transitioning into the Quality team where she led on the re-design and management of the Quality Management System, including validation and statistical analysis.

An opportunity presented itself to further develop a commercial skillset allowing for a transition into the role of Product Manager, where an understanding of full product lifecycle was developed.

During the 10 years at PDI, and the experience of the full product life cycle acquired across several departments combined with the understanding of internal processes, procedures and products has allowed for the natural next step to Regulatory Manager.

About the organisation

PDI International (PDI) is dedicated to leading the fight against preventable infections and promoting health and wellness in healthcare, hospitality and our communities. Driven by a commitment to research and development, sustainable innovation and industry-leading partnerships, our range of Sani-Cloth®, Prevantics® and Hygea solutions for Environmental Cleaning and Disinfection, Skin Decontamination and Patient Care are trusted by healthcare professionals around the world.

pdi-intl.com/healthcare