Case study

BRIDGE WP6 project - Pharma Traceability Pilot

As part of the BRIDGE (Building Radio frequency IDentification solutions for the Global Environment) project, GS1 together with leading healthcare sector companies and solution providers have demonstrated full item-level traceability in a live operating environment using GS1 standards through its participation in the Pharma Traceability pilot.

Introduction

The BRIDGE project is part funded by the EU and involves several business application work packages that aim to research, develop and implement tools to enable the deployment of RFID and EPCglobal applications in Europe.

The key objective of the pilot was to implement a complete supply chain traceability system for pharmaceutical products to improve patient safety and increase supply chain efficiency. Additionally this would facilitate the development of related supply chain applications such as electronic pedigree, authentication, recall, inventory management and financial reconciliation.

The operational pilot, completed in May 2008, is the only one of its kind in the world to involve the trialling of such a comprehensive standards-based tracking and tracing system within a live, end-to-end supply chain spanning drug packaging, their distribution, right through to their receipt at the hospital pharmacy.

A range of technologies and standards were implemented to allow 15 different types of drugs to be tracked from the start of their journey at the packaging plants – one in Ireland, one in the Netherlands - to the end, at Barts' and The London NHS Trust.

Pilot participants included drugs companies Althone Laboratories, Actavis and Sandoz; distributors Kent Pharmaceuticals and CPG Logistics; Dutch contract packer Tjoapack; transport provider Movianto; wholesaler UniChem, the customer/recipient Barts and The London NHS Trust; equipment and printing solution vendor Domino Printing Services; technical design and software developers Melior Solutions, EPCIS database provider VeriSign Inc, project management and business consultancy JJ Associates, and GS1 UK provided consultancy on standards and RFID.

Implementation of GS1 standards

Data Matrix symbology was used on all levels of product packaging from individual items to product bundles, cases, pallets and transport lorries. It was chosen for its cost effectiveness, robustness and ability to carry a 4-string data structure. The structure used in the pilot comprised the GTIN (Global Trade Identification Number), serial number, expiry date and batch number.

In addition, EPC Gen 2 standard UHF Radio Frequency Identification (RFID) tags were affixed on cases and pallets in hybrid labels which included printed GS1 bar codes. Selected pallets were also fitted with active devices to allow GPS tracking across the international supply chain. Every single pack of every product being tracked was assigned a unique serial number. Using this and the process of aggregating the contents to other unique serialised packaging levels allowed for full traceability of every single item throughout the supply chain from the packaging line to the final destination. Printing and QA systems were installed to enable the required codes to be assigned, printed and checked within the production line.

The pilot involved the full adoption of GS1 standards including the use of GLN (Global Location Number) and GRAI (Global Returnable Asset Identifier) numbers for physical assets and locations. EPCglobal's data exchange standard, EPC Information Services (EPCIS), was also implemented to capture data at each 'handover' point in the journey. EPCIS enables trading partners to share information about their products or items moving in the supply chain such as 'what, when, where and why'.

The pilot process

Prior to the pilot commencing, all participants received in-depth training on the systems they would be responsible for, or operate. During the pilot's operation, all technology partners provided on-site and phone-based application support, recording issues and rectifying glitches. The step-by-step pilot process can be found below:

Step 1 At the patient pack level, each item was coded with a unique SGTIN (serialised Global Trade Item Number) together with the expiry and batch information in the form of a 2-D Data Matrix code.

Step 2 Packs were aggregated into a case coded with an SGTIN, correctly identifying the contents as a grouped trade item. The case label was a hybrid, or multi-format type, capable of storing the SGTIN code and expiry/batch information as a Data Matrix code, GS1-128 linear barcode and human readable text. The SGTIN was also encoded into the RFID tag. This ensured that the case label would be readable no matter what system was used downstream.

Step 3 The cases were then scanned as they were aggregated onto pallets. The RFID tag was also scanned to provide alternative data that could be compared to the data read by bar code scanners. This would later allow full evaluation of the technologies used in this process. Each pallet was given an SSCC (Serial Shipping Container Code) identifier which was encoded on the pallet label as a 2-D Data Matrix code, GS1-128 barcode and onto an EPC Gen 2 standard UHF RFID tag.

Step 4 Upon despatch, each pallet's SSCC was scanned onto a vehicle. A unique GS1 GRAI (Global Returnable Asset Identifier) number was also assigned and scanned to each pallet to enable it to be tracked throughout the supply chain. For those pallets implanted with a GPS tracking device, the devices' unique codes were linked to the EPCIS system via mobile tracking and read at regular intervals to check their progress which was recorded as part of the chain of custody process.. Data was sent back to a central server which was displayed on a map to enable live tracking.

Step 5 At each stage of the journey to the wholesaler, pallets were scanned as they were removed from one vehicle and scanned again as they were loaded onto the next vehicle. This was carried out using mobile phones, loaded with decoding software that scanned the Data Matrix code and sent the data via SMS to an EPCIS database, so that each transaction or movement was recorded.

Step 6 When the pallets reached the wholesaler they were scanned with a bar code scanner and the data was sent to the respective EPCIS database. Then each pallet was moved through an RFID portal, data from which was stored separately to enable easy comparison between the two methods.

Step 7 Warehouse staff picked the required products for delivery to St. Barts and the London NHS Trust and scanned the products into a tote box, which was uniquely identified using a GRAI code. The tote was labelled, bearing a Data Matrix code and an SSCC label applied on the folded lid to act as an anti-tamper device. As they were loaded for delivery, each tote was scanned again.

Step 8 Once at the hospital pharmacy, staff scanned the SSCC code to record receipt of the goods and all contents were checked against the tote manifest which was generated from the EPCIS record.

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Pilot conclusions

The data collected during the pilot is currently being evaluated and the key learnings are being developed by the pilot participants. Overall, the pilot was a success and it demonstrated that the technology required to implement a full international supply chain traceability system is available today.

Good communication and collaboration between trading partners was vital to the success of the pilot. This was supported by the use of open systems information standards and hybrid data carriers (GS1 Data Matrix and RFID) which maximised system interoperability.

The implementation of the 4-string data set (product code, serial number, expiry date and batch number) and the EPCIS system delivered complete traceability. As each participant in the supply chain recorded the movement of the products in and out of their custody, the data that was sent to their respective EPCIS databases which formed the necessary traceability information. Cumulatively, and in a live scenario, this could deliver significant efficiencies and reduce costs. Complete traceability also supports future recall capabilities, inventory management and financial reconciliation, which will generate further process efficiencies.

With errors in medication administration and the problem of counterfeit drugs entering health services both increasing, it's essential that technologies which can track drugs and monitor their progress throughout the entire supply chain are implemented as soon as possible. Getting the correct, authentic drugs to patients quickly and accurately is an essential component in reducing medical errors and increasing patient safety. Implementing systems that support the traceability of products also help ensure product recalls are effected thoroughly and swiftly, preventing patients being exposed to sub-standard, or dangerous drugs.

The real-world nature of the pilot of course highlighted issues that will require solutions prior to future implementations. For example, the complexity of coding and printing within the production line environment requires meticulous planning and packaging design may have to take into consideration the space required to print Data Matrix symbology. Staff training and robust intuitive applications will also play a crucial role in the success of any traceability solution implementation.

Regardless of these concerns, traceability systems will have an incredibly positive impact on improving patient safety and reducing the scourge of counterfeit drugs.

"With the ability to fully track and trace the drugs that we order from our suppliers, we can feel confident that the medication we administer to our patients is safe and authentic. The added benefits of capturing and recording drug expiry dates and batch numbers can also help increase the hospital's efficiency, enabling improved inventory management and quicker response times to product recalls," **commented Patrick Martin, Senior Principal Pharmacist at Barts and The London NHS Trust.**

For more information about this pilot and to access all the reports pertaining to the BRIDGE project visit: www.bridge-project.eu/ www.bridgewp6.eu

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