GS1 Healthcare Reference Book 2014/2015

12 Implementation success stories

Towards a safer and more efficient healthcare with GS1

Welcome to the sixth edition of the GS1 Healthcare Reference Book which is a compilation of case studies where industry players share their experiences on how GS1 Standards truly make a difference in healthcare, all over the world.

Ten companies and organisations describe their successful implementation of GS1 Standards.

Acknowledgements

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INTRODUCTION

The Power of GS1 Standards in Healthcare

Industry aligns around one single set of global standards

To comply with all the latest regulations, healthcare organisations and governments are turning more and more to GS1. To cite only one of the most advanced system, in Turkey, the Turkish Drug and Medical Device National project, launched in 2006, required that every single medical device be registered in the main national database (TITUBB). **Today approximately 2.5 million medical devices have been registered in the database and 91.84% of the devices registered are marked with GS1 Standards.** In 2007, the Turkish Ministry of Health launched the Turkish Pharmaceuticals Track & Trace System (ITS) which defines the infrastructure to track and trace all units belonging to each pharmaceutical product in Turkey. GS1 Standards are here also required: all pharmaceuticals need to include a Global Trade Item Number (GTIN) encoded in a GS1 DataMatrix bar code to ensure the uniqueness of each single unit.

Equally, in Australia, healthcare companies are increasingly using GS1 BarCodes despite the absence of binding healthcare legislation in their market. **Today 97.05% of medicines carry GS1 BarCodes, and 75,49% of medical devices are marked using GS1 Standards.**

Many other governments are recommending the use of GS1 Standards. The UK Department of Health endorses GS1 Standards in its latest NHS eProcurement Strategy published in April 2014. The Saudi Arabia Food and Drug Administration requires the use of GS1 DataMatrix on pharmaceutical products by 2015. Last April, the Philippines Food and Drug Administration published a circular mandating the use of Global Trade Item Numbers on all FDA-regulated products.

Change has finally come, get ready for UDI!

The U.S. is the first country to have released a specific regulation on Unique Device Identification. On September 24, 2013, the United States Food and Drug Administration (FDA) published a final Unique Device Identification rule establishing an identification system for all medical devices sold in the U.S. The rule provides a standardised way to identify medical devices across all information

sources and systems, including electronic health records and devices registries as well as a Global Unique Device Identification Database (GUDID), which will serve as a reference catalogue for every device with an identifier.

Global GS1 Standards meet the government's criteria for UDIs and will help manufacturers to address requirements of the new U.S. FDA UDI regulation. **In that context, GS1 was the first organisation to have received accreditation, in December 2013, by the U.S. Food and Drug Administration (FDA) as issuing agency for unique device identifiers (UDIs).**

By unambiguously identifying medical devices, GS1 Standards benefit patients and the healthcare system. GS1 Standards assist healthcare organisations around the world to quickly and efficiently identify devices when recalled, improve the accuracy and specificity of adverse event reports and provide a foundation for a global, secure distribution chain.

Paving the way for healthcare providers

In order to achieve **full visibility** down to the patient, healthcare providers need to implement traceability systems too. That is why, GS1 created the Healthcare Provider Advisory Council (HPAC) which consists of thought leaders and early adopters of GS1 Healthcare Standards that support the adoption of global standards in healthcare institutions and retail pharmacies. In 2013, HPAC introduced two awards, the Provider Recognition Award and the Provider Implementation Best Case Study Award which were given this year to:

• Feargal McGroarty, St. James's Hospital, Dublin, Ireland and Kevin Capatch, Geisinger Health System, US (winners of the HPAC Provider Recognition Award).

• Michael Innes, Kaiser Permanente, Oakland, US and The Hong Kong Hospital Authority (winners of the HPAC Provider Implementation Best Case Study Award).

According to the 2012 McKinsey & company report - Strength in unity: The promise of global standards in healthcare – "implementing global standards **across the entire healthcare supply chain** could save 22-43,000 lives and avert 0.7 to 1.4 million patient disabilities." Let's work towards that promise.

Medical Devices

Traceability of surgical instruments in Argentina by FAICO

by **Hernán D. Fernández,** FAICO

Abstract

Currently, all surgical instruments of Instrumental Quirúrgico FAICO S.A.I.C are traced with the GS1 DataMatrix, which carries a Global Trade Item Number and a serial number, enabling each unit to be unique. The individual identification of the instruments gives legitimacy to the products, fights counterfeiting, brings more safety to the processes in the supply chain, and helps to manage instruments inside the sterilisation areas of healthcare centers.

FAICO is the first Argentine company manufacturing surgical instruments that incorporates traceability into all of its products with the aim of enhancing and optimising clinical safety for the patients.

Instrumental Quirúrgico FAICO S.A.I.C. (FAICO) is a company that manufactures and markets surgical instruments. With more than 68 years in the local and international market, the company has earned a reputation for having integrity and being trustworthy. Its commitment to adding value to its products and the continuous improvement of its services has prompted the company to develop tools to properly manage surgical instruments used inside healthcare centers.

In 2013, FAICO began to work on enabling traceability for all of its surgical instruments by identifying them with global GS1 Standards. At present, the extensive quantity of units marketed lack standardised identification with their characteristics only displayed on the primary package label, which is discarded when the product is used. The supply and demand chain for surgical instruments is complex and the intensive flow that exists inside different healthcare centers requires special attention in order to enable effective and safe management of these instruments.

As national and international health-control agencies adapt and improve health procedures, it is important to implement a robust track and trace system that complies with national, regional and international best practices. The objective is to protect and offer more safety to patients, in addition to detecting defective products and recalling them quickly from the market.

In order to implement proper traceability of any product, it is important to use global standards to uniquely identify all products. Standardised identification enables the development of a management service within healthcare centers,

Traceability is the ability to trace forward the movement along the different steps in the extended supply chain, and to trace backwards the history, the application or the localisation which is being considered.

Source: Global Traceability Standard in the Healthcare Sector (GTSH)

Engraving area

which in Argentina, until now, was something unknown and/or to which there was no access.

GS1 Standards identification numbers engraved on surgical instruments

FAICO has ordered that of its products to be identified with the two-dimensional (2D) GS1 DataMatrix bar code, which are read with a 2D or area imager bar code scanner. The printing area available for this bar code symbol is only approximately six mm^2 for each unit. Through this method, the engraving of virtually the whole universe of surgical instruments is possible. Each GS1 DataMatrix bar code identifies the surgical instrument with the following data:

- **The Global Trade Item Number** (GTIN), which is composed of a company prefix, (in its numeric structure, including the identification code of the country of origin (779 in Argentina), the Item Reference and check digit. When encoded in the bar code the GTIN is preceded by the Application Identifier (01).
- **A Serial Number,** which is a unique alphanumeric data string of up to 20 characters preceded by the Application identifier (21) is assigned to each individual product.

Engraved instruments

Engraving Laser

In order to achieve an optimal engraving of the GS1 DataMatrix bar code, FAICO implemented a review and an adjustment of every production and administrative process, while also incorporating latest-generation engraving technologies. This included developing internal software that manages different manufacturing processes, all the way up to the final delivery to the customers and assigning each surgical instrument the alphanumeric serial number.

Through Direct Part Marking (DPM) a GS1 DataMatrix bar code symbol is engraved on the surgical themselves.

FAICO also provides their software to healthcare centers that wish to implement their surgical management system internally.

As FAICO identifies each instrument, the management system can record every one of the stages or processes in which the instruments are involved.

Standardisation means optimised management of instruments

The main advantages obtained from the management system of surgical instruments include the following:

- **Estimation of a surgical instrument's useful life:** Early detection of useful life of surgical instruments is essential to ensure patient safety. A simple scan of the GS1 DataMatrix reads the unique code and connects to a database to obtain the exact date when the instrument first came in to use. Due to their frequent use, many instruments need to be repaired or disposed of when they can no longer fulfill their purpose. The traceability of surgical instruments enables FAICO to understand the cost of maintenance of an instrument during all its useful life in order to make the right decision of whether to keep it in stock or not.

- **Loss and/or theft of surgical instruments:** One of the problems discovered in many healthcare centers is loss of instruments due to theft or other means such as loss through outsourcing and/or lack of control in sterilisation areas.

- **Sterilisation follow-up processes:** Perhaps one of the most important advancements in the implementation of this tool is the follow-up of the sterilisation processes, which enables FAICO to know amongst other things which hospital is using an instrument or what they are doing with it.

- **Quick and accurate set up of surgical instrument sets through automatic reading of each surgical instrument:** The set-up of the different specialised sets is quickly achieved, avoiding errors or missing instruments. This process also facilitates a quick replacement process.

- **Control of instruments before and after surgical operation:** By reading the GS1 DataMatrix directly in the surgery room, all the pieces placed on the surgical instrument table can be controlled and all instruments are ensured to be returned once the operation is completed.

- **Accurate inventory management:** Surgical instruments engraved with a GS1 DataMatrix used together with the management software enables FAICO to register, unregister and record any inventory movement made.

Manufacturing companies and official control agencies assume the main responsibility when working together in the development of tools, procedures, and regulations to improve and optimise clinic and patient safety by incorporating useful techniques for the traceability of products and medical devices. FAICO has worked intensely to offer the health system an innovative management system for surgical instruments.

About the author

Hernán D. Fernández is the surgical instruments' director at Instrumental Quirúrgico FAICO S.A.I.C. He obtained his degree in International Commerce in the Facultad John F. Kennedy. Hernán started working for FAICO in 2009 and has more than 10 years of experience in executive positions in international companies. Currently, he leads FAICO's project to implement new technologies to enable the company's medical products to be traceable.

About FAICO

FAICO, founded in 1945 in Buenos Aires, Argentina manufacturers and markets surgical instruments. The company distributes its products all over Latin America and is certified under the Quality Management System ISO 9001:2000 and ISO 13485:2003.

Coloplast: the key to success in complying with the U.S. FDA Unique Device Identifications rule
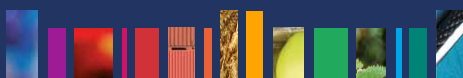
by **Bianca Maria Gravenhorst Greve,**
Coloplast

Abstract

Coloplast, a world leader in intimate healthcare products and services, has manufacturing facilities in five different countries. As a global organisation, Coloplast is required to react quickly to changing regulatory requirements. With many new regulations on Unique Device Identification (UDI) emerging, the company focuses its work on improving its labelling processes to anticipate future UDI rules.

Introduction

Coloplast operates globally and has manufacturing facilities in five different countries. Its portfolio of 20.000 Stock Keeping Units (SKUs) is varied and covers class I, II and III medical device products[1]. In the past few years, Coloplast has focused on improving its labelling processes to meet the increasing number of regulatory requirements for labels. However, as it had several labelling systems in various manufacturing facilities, it proved to be more challenging than expected.

In September 2013, the U.S. Food and Drug Administration (U.S. FDA) published its final rule on UDI, which establishes a unique device identification system for medical devices. UDI is a unique identification that includes a device identifier, e.g. Global Trade Item Number (GTIN), and production identifiers, such as batch/lot, expiration date, and manufacturing date.

According to the rule, whenever a device must bear a UDI, the labeller will need to submit the device information to an online database administered by the U.S. FDA, called the Global UDI Database (GUDID). The latter will serve as a reference catalogue for every medical device.

Compliance dates take effect over time using a risk-based approach starting with class III products, which have to comply with the regulation by September 24, 2014.

The road to implementation and gaps identified

In the beginning, the U.S. FDA UDI regulation was followed closely by the regulatory affairs department. It quickly became clear that, in order to comply successfully with UDI, a cross-functional team had to be established. A UDI core team was created in 2011 consisting of representatives from the following departments: Supply Chain, Regulatory Affairs, Quality, Engineering and Packaging & Labelling. During the project, the core team involved other departments when necessary.

That same year, to gain more insight into the complex UDI task, Coloplast participated in the Global GS1 Healthcare conference in Amsterdam,

Figure 1: Listen and respond to UDI requirements

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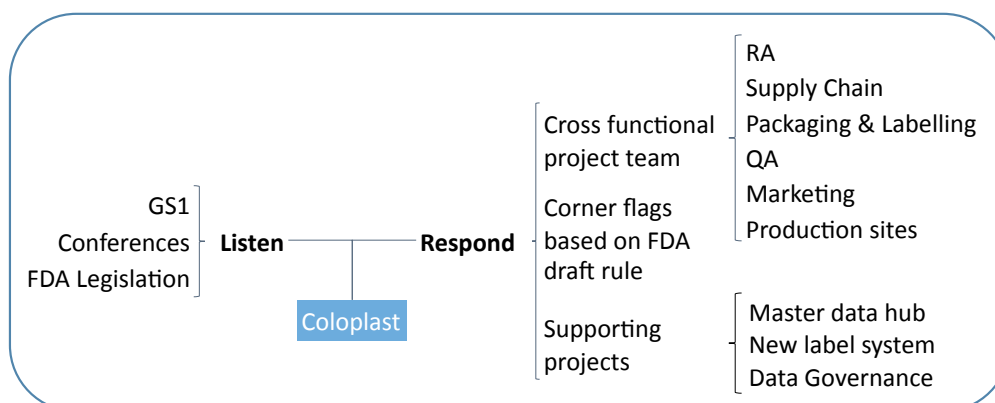
1   U.S. FDA medical devices are classified into three categories: Class I, Class II, and Class III, Class III being considered the highest risk devices.

which led to a close collaboration with GS1 Denmark. Quite early in the process, it was agreed with Coloplast's management that the UDI team had to make assumptions in defining what the rule might be demanding.

The team's first task was to make an interpretation of the draft rule and identify the impact the rule might have on Coloplast's daily operations and processes. During this process, the following main gaps were identified:

- Missing or wrong bar code data carrier types on the primary packaging.
- Poor bar code symbol quality, i.e. due to the printer or the material on which the bar code symbols was printed.
- Wrong date format printed on products and packaging.
- Difficulty in extracting various data for U.S. FDA's GUDID.

Coloplast first concentrated its efforts on products sold in the U.S. knowing that further regulations were expected in other regions.

In addition to closing the gaps that the team identified, the UDI team had to ensure that the following tasks were handled:

- Make a plan for when and how to implement UDI on the various products.
- Find sources for all data elements which must be uploaded to GUDID.
- Make data extractable from Coloplast databases.
- Ensure that data is uploaded to GUDID.

New label system and change of labels

Due to an increase in country-specific regulatory requirements for labels, it had become difficult to maintain label compliance. Therefore Coloplast decided to buy a new label system that would allow them to label its products in a more agile way. The system needed to allow easy design changes and provide the means to extract some of the data for the GUDID.

One of the UDI requirements is that a bar code symbol or Radio Frequency Identification (RFID) tag must be included on the different packaging levels. Coloplast was quite far ahead already in this regard as it has used GS1 BarCodes for the last 20 years. However, Coloplast mainly included bar codes on retail and shipping levels (i.e., GS1-128 and EAN-13). GS1-128 is used internally, whereas EAN-13 is provided as a service to the retail sales chain (e.g., pharmacies).

As the GS1-128 fulfils the U.S. FDA's UDI requirements, Coloplast did not have to make any changes to the bar code on the box labels. However, the company had an issue with its primary packaging level as a vast majority of labels did not contain a bar code or only contained an EAN-13, which is not always sufficient from a UDI perspective. As many of the products are very small, Coloplast opted for a GS1 DataMatrix on the primary packaging level.

Another UDI rule requirement is the date format used for printing the production identifiers like e.g. expiration date. To be in compliance with the U.S. FDA's UDI regulation, Coloplast needed to include a new date format YYYY-MM-

Figure 2: Project plan

UDI Preparation	Assess master data, packaging and labelling	UDI Implementation
• Assess device class and volume • Select bar code standard • Test quality of existing barcodes • Check for gaps in use of bar codes	• Identify data sources for all data for GUDID • Decide on data structure • Establish process for maintenance of base data • Determine how to apply UDI on all packaging levels	• Change design of labels • Implement new printers • Make data extractable • Create interface to internal and external databases • Manual upload of data to GUDID for class III products

DD – as previously it only included YYYY-MM. The change affected the design of the labels as some were quite small. In some cases, Coloplast had to rearrange all the information to fit in the additional day on the date format.

Ensuring the right quality of bar code symbols

The Coloplast UDI team, considering the importance of ensuring the quality of the bar codes, decided to assess its products and verify that they were GS1 BarCode-quality compliant. GS1 Denmark helped with the verification and concluded that the quality of some of the bar codes were suboptimal, mainly due to contrast issues.

Based on this result, Coloplast purchased a new bar code verifier and implemented a more thorough quality check of its bar codes. Furthermore, a standard operating procedure for how and when to verify bar codes was set up.

Data collection and submission

Coloplast needed to be able to submit all its device information to the FDA's GUDID Database for a total of 62 data elements. This was an additional challenge as the company had difficulties finding data sources from which it was possible to extract the data required. Coloplast is currently in the process of finding the most efficient solution to handle the data extraction.

The U.S. FDA provides two ways of submission to the GUDID: manually via a web form or electronically via an interface. Coloplast has 91 class III SKUs, which have to comply with the U.S. FDA's UDI requirements very soon (September 24, 2014) and has therefore opted for the web form approach.

"Implementing a single, global system of standards, such as the GS1 System, is fundamental to enable an efficient and effective implementation of UDI"

Bianca Maria Gravenhorst Greve, Senior Regulatory Affairs Manager

In the long run, Coloplast's aim is to find the most efficient way to upload its data electronically as it exports more than 2000 SKU to the U.S. In order to do so, the company is establishing a master data hub that will not only be used for UDI, but also for other internal and external product-related data requirements. Coloplast realised that robust data governance processes and policies would be needed to establish a master data hub.

Benefits of using the GS1 System to comply with the U.S. FDA's UDI regulations

Implementing a single, global system of standards, such as the GS1 System, is fundamental to enable an efficient and effective implementation of UDI:

- The GS1 Standards meet the U.S. FDA's UDI requirements by enabling interoperability and compatibility internally, externally and globally.
- The GS1 identifiers (e.g., GTIN and application identifiers) comply with the U.S. FDA device identifier and production identifiers.
- GS1 Standards increase the efficiency in meeting regulation requirements.

Conclusion

The journey towards achieving UDI compliance is long and complex. However, with some anticipation and the help of GS1 Denmark, Coloplast is on its way to success. Working cross-functionally and involving all the stakeholders has helped to successfully implement the new and improved processes. Furthermore, the implementation of the new label system has been beneficial as it created a more robust and flexible process to implement UDI. New projects have emerged as a consequence of UDI e.g. the need for robust data governance, increased need for verification of barcodes and change of processes.

Coloplast is now confident that it will meet the U.S. FDA's UDI rule deadline on September 24, 2014.

About the Author

Bianca Maria Gravenhorst Greve is Senior Regulatory Affairs Manager at Coloplast in Denmark. She has been with Coloplast since 2002. Bianca has a profound knowledge of medical devices and has worked intensively with labelling systems for several years. She is responsible for constantly improving labelling processes in order to ensure global compliance and making the processes smooth and lean.

About Coloplast

Coloplast, created in 1957, is today the world's leading supplier of intimate healthcare products and services. Coloplast develops products and services that make life easier for people with very personal and private medical conditions. Working closely with the people who use its products, Coloplast creates solutions that are sensitive to their special needs.

Its business includes ostomy care, urology and continence care, and wound and skin care. It operates globally, employing more than 8,500 people.

Coloplast has manufacturing facilities in China, Denmark, France, Hungary and the U.S. and is represented in 55 countries around the world.
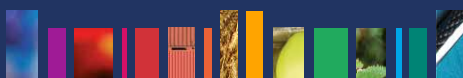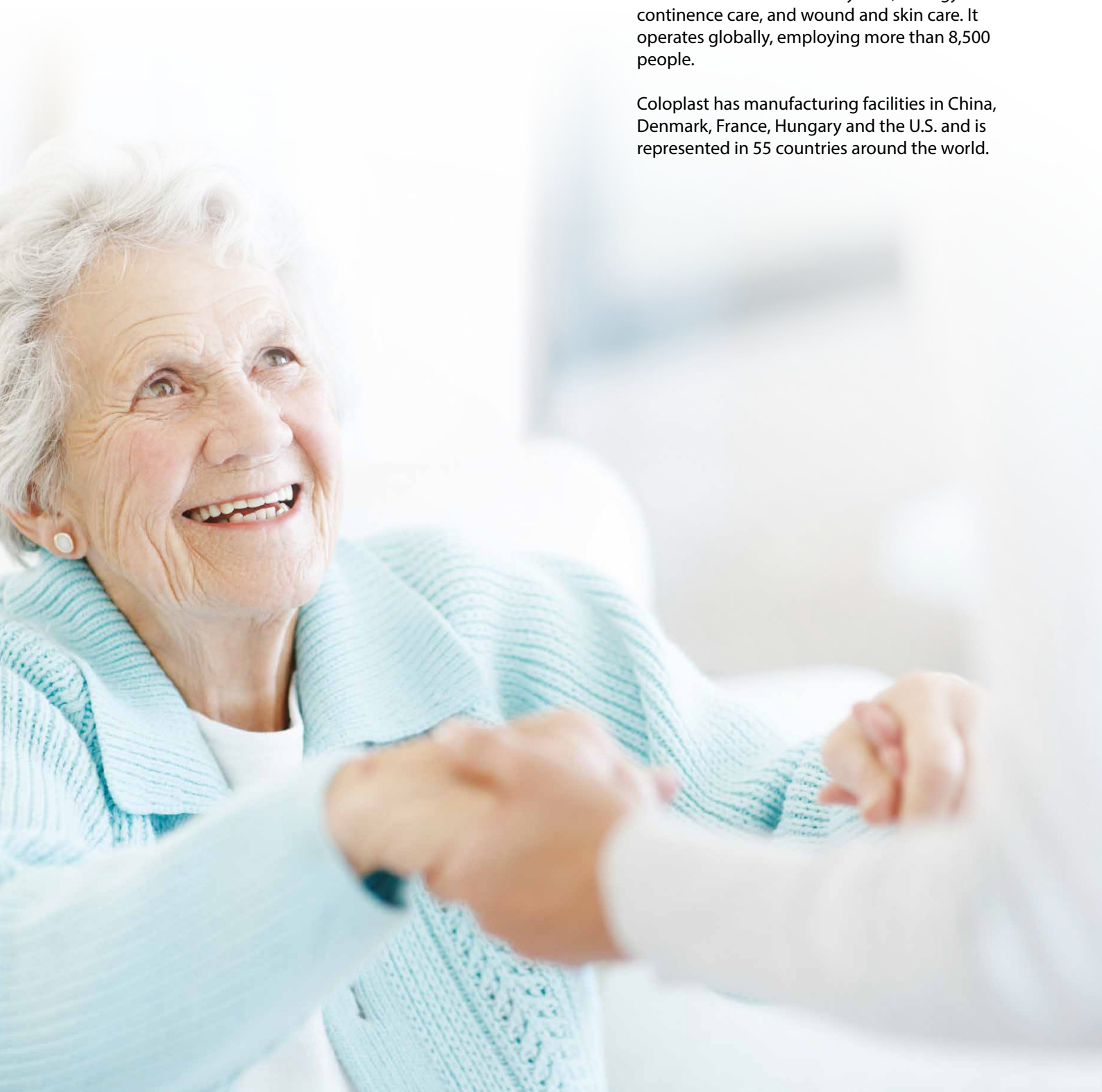
Management of Global Master Data using the Global Data Synchronisation Network by B. Braun

B. Braun's strong commitment to quality data

by **Holger Clobes,**
B. Braun

Abstract

B. Braun one of the world's leading medical device suppliers with 150 affiliate companies in over 50 countries, is faced with a number of regulatory and customer requirements for product information. These requirements relate to sharing complete and accurate master product information in a flexible way, while supporting patient safety. Today, B. Braun is faced with numerous challenges such as:

- lack of usage of a consistent master data exchange format (sometimes usage of word documents, excel, papers, …)
- suboptimal efficiencies, as customers don't currently synchronise master data with their suppliers, across borders or within their own regions
- high level of resources needed to upload and maintain B. Braun's product catalogue
- lack of unambiguous identification of physical or legal locations involved in transactions

In looking to address these issues, B. Braun wanted to ensure that the process was efficient, robust and comprehensive to meet customer needs of high-quality data. This would ultimately improve patient and clinician safety and lower healthcare costs.

At the same time, B. Braun acknowledged the value of using GS1 Standards to identify products within their supply chain to overcome these challenges and meet their customer's requirements.

Master Data Management: critical to comply with the Unique Device Identification system

On 24 September 2013, the United States Food and Drug Administration (FDA) published a rule establishing a unique device identification system for medical devices. Under the rule, the healthcare community and the public will be able to identify a device through a Unique Device Identifier (UDI) that will appear on the label and package of a device.

The UDI will provide a standardised way to identify medical devices across all information sources and systems, including electronic health records and devices registries.

In addition, device labelers will submit device information to the U.S. FDA database called the Global Unique Device Identification Database (GUDID). The GUDID will contain critical information about medical devices, and the UDI will provide the key for obtaining device information from the GUDID.

"B. Braun decided to perform the UDI submissions via a Global Data Synchonisation Network (GDSN)-certified data pool. The data pool creates the HL7 Structured Product Labelling (SPL) messages and submits the device information via the U.S. FDA's Electronic Submission Gateway into a global UDI database. In summary, the GDSN data pool was authorised to submit the UDI data on behalf of B. Braun."

Holger Clobes, **Head of Global eCommerce & Auto ID**

The U.S. Food and Drug Administration (FDA) UDI regulation was the first issued, but it is expected to be followed by other similar regulations in other countries across the world. Each UDI regulation is expected to include a database that will contain medical device product data, which is referred to as a UDI Database (UDID).

One of the most challenging areas related to implementation of a UDI regulation is the Master Data Management and Governance (MDM&G). MDM&G refers to a series of processes and protocols that should exist within an organisation to create, enrich, maintain and publish product information within and outside the enterprise.

Equally important is data quality management, which is a complementary cycle of activities aimed to ensure that the subject information is accurate, consistent and complete, thus meeting high standards of quality and reliability.

Web based tool

or

Bulk HL7 SPL

Global UDI Database

GDSN
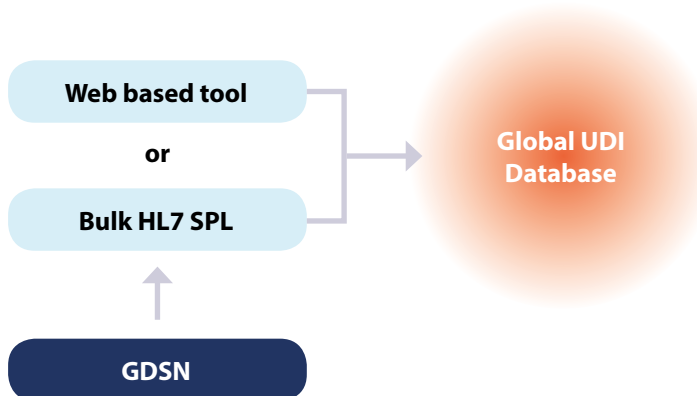
In short, the data created by the product manufacturer must meet the requirements of the intended use case. Medical device data, which would have to comply with a UDI regulation, is no exception.

Completeness, consistency, and accuracy of product data are the responsibility of the manufacturer. Each manufacturer should have an internal process to manage the data required by the regulator. This includes:

- data quality checks and procedures;
- data management process and policies;
- enterprise-wide data governance policies; and
- roles and responsibilities which outline who has the authority to create, modify and approve the data.

B. Braun decided to perform the UDI submissions via a Global Data Synchonisation Network

(GDSN)-certified data pool. The data pool creates the HL7 Structured Product Labelling (SPL) messages and submits the device information via the U.S. FDA's Electronic Submission Gateway into a global UDI database. In summary, the GDSN data pool was authorised to submit the UDI data on behalf of B. Braun.

Lessons learned during the pilot

B. Braun successfully piloted this UDI submission process early 2014 and began a production rollout in the U.S. The pilot results were leveraged to establish a methodology to facilitate a global rollout of GDSN. This will ensure that all of the company's divisions across multiple countries are using a consistent process for sharing product data.

Consequently, the implementation process now includes five areas of work, some occurring concurrently. These areas include:

1. Planning the overall GDSN initiative for the country involved
2. Preparing the data
3. Developing a sustainable process
4. Rolling out the GDSN.
5. Operationalising the process or developing the run model.

Implementing Global Data Synchronisation globally

Now that the UDI pilot is complete, B. Braun aims to leverage the GDSN to also synchronise data with their customers worldwide. This includes leveraging regulation and commercial needs to maximise the benefits enterprise wide and with its customers. To facilitate this process, an internal GDSN implementation guideline for enterprise-wide adoption was first created.

It was decided that a global Program Management Organisation (PMO) would be created to steer the programme. It will set the direction and timeline to govern the overall GDSN implementation across all of B. Braun's divisions and countries. Local B. Braun affiliates will support the implementation through their Data Management Organisation (DMO) representing the local organisation working on data management tasks.

B. Braun is committed to undertaking this project in a collaborative approach. The global PMO consists of both B. Braun staff and, as
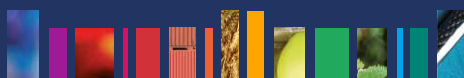
necessary, external support staff. The roles and responsibilities of the global PMO were defined as follows:

B. Braun Global Program Management Organisation (PMO)

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                    ┌─────────────────────────────┐
                    │   Global Executive Sponsor   │
                    └─────────────────────────────┘
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| External Resource Support Manager (partly) | Global GDSN Coordinator | Global Process Coordinator | Country Business Sponsor |
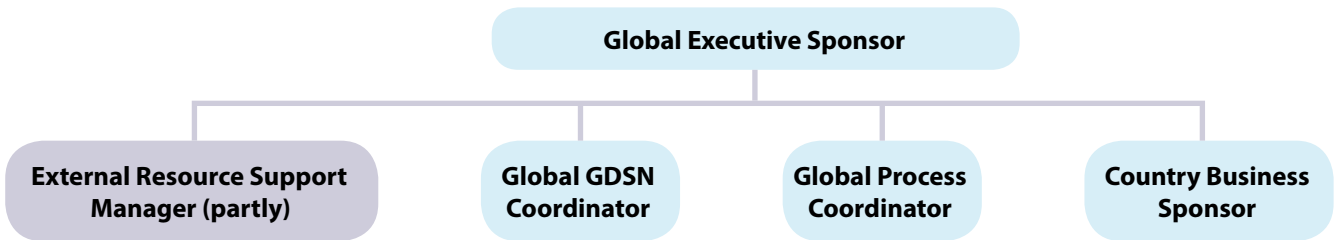
External partners (External Resource) are included in the project as support members of the PMO with the required expertise regarding GDSN implementation, GS1 standards, data pool provider, and middleware. The first countries to undertake the project will be those where customers are requesting specific and aligned data. At the same time, some countries will benefit from activities being undertaken by local healthcare-focused GDSN working user groups, steered by the GS1 member organisation in the affected country.

Success Criteria

As part of the project planning, success criteria were established such as:

- Implementation timeline
  - As part of the project plan, a realistic timeline should be developed to track to project milestones

- Other success criteria coexist depending on B. Braun affiliate needs and customer demands

  - Sales organisations/Product Category considerations
    - Number of items per sales organisation/category

  - Trading partner considerations
    - Number of items being traded with that trading partner(s)
    - Number of categories being traded with that trading partner(s)
    - Revenue share of that trading partner(s) compared to others in that country

Summary

The increase of legal and customer requirements stresses the importance of up-to-date and high-quality master data. The use of GDSN will undoubtedly help B. Braun meet the challenges they face as a complex, global organisation.

About the author
Holger Clobes is Head of Global eCommerce & Auto ID at B. Braun, one of the world's leading healthcare suppliers. He has been working at B. Braun for more than 30 years, with the last 17 working closely with GS1 Germany in the development and implementation of GS1 Standards.

About B. Braun
B. Braun is one of the world´s leading healthcare suppliers divided into four divisions: hospital, surgery, private practice (medical care and doctors´ offices) and extracorporeal blood treatment. Today the company has 150 affiliate companies in over 50 countries.

Abbott drives global deployment of GS1 Standards to benefit customers and patients alike

by **Mike Wallace,** Abbott Laboratories

Abstract

Abbott Laboratories (Abbott) was faced with numerous new regulatory and customer requirements for product identification and information. To ensure it was "easy to do business with," the company decided to implement GS1 Standards to efficiently manage and share accurate product data with regulators and trading partners. Abbott formed the Global Standards & Serialisation Office (GSSO), a corporate team of experts responsible for supporting its four businesses when implementing standards. This flexible model has enabled Abbott to implement and use Global Location Numbers (GLNs) for company locations and Global Trade Item Numbers (GTINs) for its products. Furthermore, Abbott has registered the vast majority of its GTINs and product attributes in the Global Data Synchronisation Network ™ (GDSN®) for accurate data sharing with trading partners.

Customers, such as group purchasing organisations (GPO), have responded positively since the GDSN helps streamline their ordering processes and minimise errors and rework. Using GTINs and the GDSN, Abbott is well positioned to support compliance with the U.S. FDA Unique Device Identification (UDI) regulation. By using GS1 Standards, Abbott also helps providers ensure patients receive the right products, strengthening patient safety practices.

Abbott
A Promise for Life

Abbott Laboratories is one of the world's leading, global healthcare companies. The company has four core businesses: nutritionals, diagnostics, medical devices, and established pharmaceuticals. With sales, research, manufacturing, and distribution facilities located throughout 150 countries, Abbott combines its diverse expertise with deep cultural insights to create products that meet local and regional health needs. About 70 percent of Abbott's sales come from outside the United States, making it a truly global company.

Abbott participates in both retail and regulated healthcare markets with multiple businesses that operate independently. Yet, all businesses are leveraging a similar approach to GS1 Standards when managing product data throughout the Abbott supply chain.

A natural requirement

Abbott is no newcomer when it comes to using GS1 Standards. The company has used Universal Product Codes (U.P.C.'s) [1] on its nutritional products for more than 30 years, and its pharmaceutical business has been an early adopter of standards for regulatory compliance.

"The new reality of the world is that the data [commercial, clinical, regulatory] about the product is now as important as the product itself."

Mike Wallace, Director, Global Standards & Serialisation

Yet, some of Abbott's businesses were using proprietary product identification schemes that were not compliant with new regulatory and customer requirements. Also, countries like Brazil, France, Germany and Japan, were starting to require the use of GS1 Standards. Abbott considered the business advantages of adopting standards company wide. Recognising the short- and long-term potential benefits, the company started implementing standards to be part of its normal business processes.

Expertise and flexibility

In late 2008, the company formed the Global Standards & Serialisation Office (GSSO), a corporate group that has enterprise-wide responsibility to facilitate the implementation of GS1 Standards and serialisation for all of Abbott's businesses.

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1   The U.P.C. (Universal Product Code) is a GS1 Standard for bar code symbology used exclusively for products scanned at retail point of sale and mainly in North America.

A diagnostic assay for the hepatitis C virus (anti-HCV) uses a GS1 DataMatrix bar code and a 14-digit GTIN. The expiry date uses the ISO 8601 format (YYYY-MM-DD)

An initial step for the GSSO was the creation of a standard operating procedure stating the requirements for Abbott's usage of GS1 Standards, including the creation and management of GS1 Standard data for product and location identification. At the same time, the group recognised the autonomous nature of its businesses during this transition.

While the GSSO provides the "center of expertise", it also partners with and extends its knowledge to global associates within Abbott's businesses via educational opportunities. Each member of the GSSO serves as a liaison to a respective business within Abbott. As a corporate function, the GSSO brings repeatable methodologies and best practices to the businesses, ensuring the same problem isn't solved in different ways. In the end, this saves time and costs across the enterprise.

"We recognised the short- and long-term potential benefits of using GS1 Stan- dards. By implementing the standards as part of our normal business processes, we are able to proactively manage the pace of change on our own terms as opposed to reacting to a mandate or crisis."

Mike Wallace, Director, Global Standards & Serialisation

Managing the pace of change

One of the GSSO's first steps was the identification and documentation of GS1 Global Location Numbers (GLNs) to meet the U.S. healthcare industry's 2010 "sunrise" deadline for location identification.

In 2011, the team initiated the assignment of GS1 Global Trade Item Numbers (GTINs) – unique identifiers for each product in the business units' portfolios, which was a major goal of the U.S. healthcare industry's 2012 GTIN Sunrise.

Another critical step was to load the GTINs and required healthcare product attributes in the 1WorldSync™ Data Pool for sharing product data in the GS1 Global Data Synchronisation Network (GDSN). The Abbott GDSN project team combined the implementation of the GDSN with the creation of GTINs to work simultaneously.

GS1 Standards and UDI

The U.S Food and Drug Administration (FDA) Unique Device Identification (UDI) regulation is at the forefront in the medical device market as companies need to transition from disparate medical identification methods to a standardised UDI system. Suppliers will be required to assign and apply a UDI to all medical devices.

Abbott's choice for the UDI's device identifier is the GS1 GTIN.

Suppliers are expected to provide their UDI data for access by the FDA in a single, global UDI database (GUDID) system. Since the GDSN is currently used by many trading partners, it can be leveraged as a "data feed" to the UDI database.

With its GDSN implementation, Abbott is well positioned to support this new regulation. In fact, Abbott's GSSO developed its GDSN implementation with the UDI in mind, merging its business requirements with the FDA requirements.

The GSSO also worked closely with 1WorldSync, its GS1 certified-data pool provider, to establish the FDA as a recipient of Abbott's device data. Leveraging the GDSN for UDI compliance was a strategy the company devised when it heard about the regulation. With GS1 Standards, Abbott has a common, single solution for UDI compliance.

The XIENCE Xpedition™ Everolimus Eluting Coronary Stent System is comprised of two main components: the drug-coated stent and the balloon expandable delivery system. The label displays a GS1-128 bar code including the GTIN (01) , Expiration Date (17), Lot Number (10) and an Internal Company Code (91).

In the upper right corner, the information is concatenated into one bar code and wraps around the spine of the box for quick scanning of inventory. The two bar codes on the lower portion of the label depict the same information as the one on the spine. ISO 8601 format is used for the expiry date (YYYY-MM-DD).

The team developed a common process, working with IT to stage each of Abbott's businesses when delivering product data.

To date, about 83 percent of Abbott's U.S.-based products, including medical devices, have their GTINs and other data attributes registered in the GDSN. Abbott's goal is 100 percent even as new products are introduced to the U.S. market. Over time, the company's plan is to share the GTINs and item data to all target markets, using a common framework, repeatable processes, and adhering to Global Data Synchronisation principles.

A three-way match

During the GDSN implementation process, the GSSO contacted Abbott customers to advise the company could now offer its all-inclusive product line from one source. The team received positive responses, especially from group purchasing organisations. The hospital GPOs realised that implementing the GDSN is an important step for them since it helps streamline their ordering process and minimise errors and rework.

Eventually, they will not need to maintain proprietary product numbers from every manufacturer. They can be assured that when ordering product A, they will receive product A, and not product B. By having and sharing standardised product identifiers, there is potential value for their order-to-cash processes.

Another example where GS1 Standards are making a difference involves one of Abbott's customers – a major healthcare provider using the GDSN. When ordering Abbott products, the provider issues the Purchase Order listing the products' GTINs, instead of proprietary part numbers or SKUs, since, as trading partners, both Abbott and the provider share product data via the GDSN. The provider receives the right products along with an accurate invoice, which also listed the products' GTINs. Abbott calls this a "three-way match" for efficient and accurate ordering, fulfillment and invoicing.

"Patient safety is one of the key drivers for Abbott's use of [GS1] standards."

Mike Wallace, Director, Global Standards & Serialisation

Also, when a customer requests an Abbott catalog, the salesperson can simply get the customer's GLN to give him access to not one, but all of Abbott's products in all businesses. Some of Abbott's GPOs and customers have commented that they appreciate knowing about all the company's product lines.

Caring for patients is one of Abbott's core values. For 125 years, Abbott has been about improving lives through medical science and the life-changing technologies it creates, and this same caring extends to how the company fulfills and distributes its products to ensure patients receive the right products in a timely manner.

About the author

Mike Wallace's role, as Director Global Standards & Serialisation, is to implement the adoption of GS1 global product and customer identification standards and an enterprise-wide approach to serialisation for Abbott. This will allow the corporation to cost effectively meet the growing and evolving customer and regulatory requirements. Mr. Wallace represents Abbott on the GS1 Global Healthcare Leadership Team and is serving as a tri-chair. For the past ten years, he has consulted with a cross section of groups across Abbott and the supply chain for healthcare and consumer packaged goods to prepare to implement these emerging standards and technologies.

About Abbott Laboratories

Abbott is a global healthcare company devoted to improving life through the development of products and technologies that span the breadth of healthcare. With a portfolio of leading, science-based offerings in diagnostics, medical devices, nutritionals and branded generic pharmaceuticals, Abbott serves people in more than 150 countries and employs approximately 70,000 people.
www.abbott.com

Cook Medical transforms its vision into greater patient safety with GS1 Standards

by **Chuck Franz,**
Cook Medical

and **David Reed,**
Cook Medical

Abstract

With worldwide manufacturing centers operating as separate entities, Cook Medical (Cook) decided to unify and standardise its business processes to better serve its customers and their patients as "one Cook Medical."

Cook Medical chose GS1 Standards, implementing Global Trade Item Numbers (GTINs) and Global Location Numbers (GLNs) to uniquely identify all of its worldwide products and locations. The company registered its GTINs and attributes in a GS1 Global Data Synchronisation Network™ (GDSN®)-certified Data Pool for sharing with healthcare systems. The company is now integrating these GS1 Standards into its processes for greater visibility while also leveraging them to support the U.S. Food and Drug Administration's (FDA) Unique Device Identification (UDI) ruling.

With GS1 Standards in place, Cook has improved the traceability of products as they travel through the supply chain for a highly effective track and traceability process. Internal benefits continue to emerge, including an improved customer-centric approach that enhances the Cook brand, and the promise of increased efficiencies as more healthcare systems and suppliers adopt standards-based trade.

"For us, using standards was principally about making patients safer—making sure the right product was delivered at the right time to the patient's bedside."

David Reed, Vice President of Operations and Healthcare Business Solutions

Shared vision

Cook Medical has been at the forefront of minimally invasive medicine since its founding in 1963 by founder, Bill Cook. From the beginning, Cook Medical worked closely with its customers - physicians and other healthcare professionals - to develop less invasive ways to treat patients.

Today's Cook Medical innovation process continues to put customers first; it always starts with listening to customers and asking questions to fully understand their needs. Solutions are developed together, whether a new product, technique, procedure, or even business process. Over the years, this model of innovation - listen, understand and collaborate - has led Cook to develop many new products.

Cook was the first company to package the three primary components for percutaneous (through the skin) catheterisation in one convenient set for cardiovascular procedures. In less than a decade, its growth trajectory went straight up, allowing the company to expand into Europe and Asia in the 1970s.

Today, Cook Medical is the world's largest privately held medical device manufacturer, producing over 16,000 devices globally. It has ten divisions based on the 41 medical specialties it supports, has manufacturing facilities in Australia, Denmark, Ireland and the U.S., and has nearly 2,500 employees in its U.S. headquarters alone.

1999	2001	2003	2005	2012	TODAY
376,000 SKUs representing 20,000 parts	Created global Cook product database	Implemented GS1 Standards on labels (GTIN-14 and other AIs)	Created Cook Americas customer service center (CMI) — Allows for one customer interface to do business with Cook	Validated and aligned packaging level indicators on labels — Published attributes to GDSN — Transacting with GTINs	Working towards full UDI compliance — Piloting GS1 Standards' use in Cook Manufacturing Supply Chain

Cook Medical timeline: implementing GS1 Standards

GS1 Standards prepare Cook Medical to comply with the U.S. FDA UDI ruling

> *"We're hearing that standards are making customers' lives better and this is better for patients. If there are benefits for both our customers and patients, then it's ultimately better for Cook."*

Chuck Franz, Vice President and CIO

The right thing to do

By the late 90s, Cook Medical's entrepreneurial culture had created separate, thriving companies that developed and commercialised life-changing innovations - in very different ways. Worldwide, the company had approximately 376,000 SKUs with each company using different interpretations of Cook Medical's approach for numbering the products.

It wasn't easy for Cook to conduct business with its customers around the globe. Moving products through its global supply chain was getting increasingly complex, and tracking products was not as efficient as the company wanted it to be. As a result, Cook decided to unify its business as "one Cook Medical" to better serve customers and patients.

The future today

With GS1 Standards, Cook Medical is prepared to comply with the FDA UDI rule requiring manufacturers to label their products with unique device identifiers. In fact, Cook participated in the FDA UDI pilot in 2012 to help the government agency assess the ruling.

The UDI provides a common language for trading partners to use about products that travel through the supply chain. The UDI system is comprised of a UDI code, application of the UDI to device labeling and packaging, and a related database, the FDA Global Unique Device Identification Database or GUDID.

As government gets into the electronic act with national product catalogs and the GUDID, Cook is excited about how much simpler the industry can make the transaction of devices

For Cook, using standards was principally about making patients safer - making sure the right product was delivered at the right time to the patient's bedside. While Cook's customers did not mandate the use of GS1 Standards, the company was starting to hear from them that a standards-based approach was going to become the preferred, or possibly only way of doing business with them.

Cook also recognised the significant efficiencies a shared system of standards could bring to the industry. Based on all these reasons, Cook decided to make standardisation a priority for its business. And as a global company, Cook felt it made sense to select GS1 Standards as the most-used worldwide.

A global language

In 2001, Cook Medical took its initial step to transition from separate product portfolios to a single global product catalog.

The Cook IT team then worked closely with the company's quality team and manufacturing entities to identify each of its products with a GS1 Global Trade Item Number® (GTIN®) encoded in a GS1-128 bar code for labels. Global Location Numbers (GLNs) were assigned to customer "touch points" such as orders and distribution centers, returns, and Cook Medical Inc.

One of the hurdles the team had to tackle was all the different entity "standards" in place - the different bar codes, lot numbers and ways of labeling products that had evolved from internal decisions and requests from government.

Cook found this first implementation in 2003 was no small task, but it had to get done. The company was laying the foundation for traceability and greater efficiencies in its supply chain.

Shared conviction

Implementing GS1 Standards on labels also provided a major prerequisite for the creation of Cook's customer service center in North America. Launched in 2005, the center is a shared services operation, providing customers with a single point of contact for questions about any Cook device manufactured anywhere the world.

With GTINs and GLNs assigned, a company-wide, cross-functional team was created to help Cook's managers integrate the use of GS1 Standards into business transactions and supply chain processes such as recalls. The team started by focusing on the non-clinical side of the supply chain to make sure Cook products could easily travel from manufacturing centers to customer locations. This meant completing milestones such as ensuring every product bar code was "readable" for scanning at points-of-delivery and that GTINs were marked on appropriate packaging levels like cases and pallets.

In approximately five years, Cook completed this phase for North America-manufactured products only. What carried the team was a shared conviction in the benefits for both customers and patients.

The team's goal was to be prepared for the healthcare industry's "2012 GTIN Sunrise." This industry-led initiative defined objectives for healthcare suppliers and providers on the internal use of GTINs as well as sharing GTIN product data and attributes with trading partners via a GS1 GDSN-certified Data Pool.

Through the Data Pool, the GDSN connects Cook and its subscribing customers to the GS1 Global Registry® for immediate electronic sharing of standardised, up-to-date, accurate product information. Currently, Cook's product information is shared with 28 customers.

Before orders can be placed, Cook products are assigned GTINs and only loaded into the GDSN after the GTIN attributes have been verified. To date, Cook has loaded 17,179 GTINS into the GDSN for 13,673 available products. With 16,940 total available products, Cook has published 80 percent of its products in the GDSN. And nearly 95 percent of the published products' measures are verified, meaning all dimensions and weights have been validated.

Cook Medical recognised by Healthcare Transformation Group (HTG)

In a global business like Cook Medical, the move to standards is a multi-year undertaking and the full benefits will only be realised when standardised data consumption reaches critical mass. The evolution has begun in North America, due to the importance of supply chain efficiencies driving down overall healthcare costs, and the greater safety afforded by traceability, including expeditious product recalls.

In 2010, five major healthcare systems – Geisinger Health System, Intermountain Healthcare, Kaiser Permanente, Mayo Clinic and Mercy – formed an action-oriented collaboration called the HTG to share best practices and drive needed positive change across the healthcare supply chain.

By communicating in the marketplace through one voice, the HTG aims to drive the adoption of GS1 Standards by suppliers for improved supply chain efficiencies and enhanced patient safety.

During its 2013 Summit, HTG presented Cook Medical with its inaugural HTG Excellence Award that honors a supplier who serves as a leader in the adoption of GS1 Standards.

"We didn't need to develop a business case to make the decision [to adopt standards]. We knew it was the right thing to do, so we took action. For our global company, it only made sense to select GS1 Standards that are most-used world-wide."

Chuck Franz, Vice President and CIO
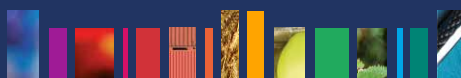
"For our business, the move to use global standards was a good decision, because the benefits continue to play out."

David Reed, Vice President of Operations and Healthcare Business Solutions

Shared insights

With years of experience, the Cook Medical team offers advice for others considering the move to standards:

Start. Just make the decision to start. It sounds simple, but it can be hard to do. Accept the fact that not everyone is going to be convinced that implementing standards is the right thing to do, but it is.

Prioritise. Once the decision to start is made, narrow the scope to prioritise and decide what to do first. Remember that taking small steps is still making progress.

Decide. Make decisions based on assumptions and understand there are external forces that cannot be controlled. Make the best decision and adjust later, if necessary. But keep going.

Commitment. From a technology process standpoint, the transition to standards is not really costly. The "cost" comes from the significant time, effort and commitment it takes from the company's resources.

Purpose. Be mindful of the reasons for taking action: patient safety is paramount, and the efficient movement of products through the healthcare system benefits everybody.

About the authors

Chuck Franz is the Vice President and Chief Information Officer for Cook Group. Chuck graduated with a BS in Computer Science from Indiana University, and joined Cook as a software engineer in 1984. Over the past 29 years he has worked in a variety of roles in information technology, operations and management at Cook Group companies. Chuck has served as an operations manager for Cook Incorporated, operational liaison, President of Cook Vascular, President of Cook Urology and interim President of Cook Australia. He has been in his current role since 2005.

David Reed is currently Vice President of Operations, Vice President of Healthcare Business Solutions and Corporate Compliance Officer for Cook Medical Incorporated, a pioneer of many of the devices now commonly used worldwide to perform minimally invasive medical procedures. With over 30 years of life science industry expertise including time as a Sales Representative, National Sales Manager and Vice President of Sales, Mr. Reed has spent the last nine years in an operational role at Cook Medical

overseeing the start up and implementation of the North American customer and distribution services business. Included within the scope of this Cook entity are the areas of customer service, sales operations, and supply chain activities. Additionally he leads Cook's Healthcare Business Solutions team which focuses on the business and supply chain processes within healthcare. Mr. Reed holds an MBA from California Miramar University and serves as a member of the Indiana University Kelly School of Business Supply Chain and Global Management Academy Advisory Board.

About Cook Medical

Since 1963, Cook Medical has worked closely with physicians to develop technologies that eliminate the need for open surgery. Today we are combining medical devices, biologic materials and cellular therapies to help the world's healthcare systems deliver better outcomes more efficiently. We have always remained family-owned so that we have the freedom to focus on what we care about: patients, our employees and our communities. www.cookmedical.com

Pharmaceuticals
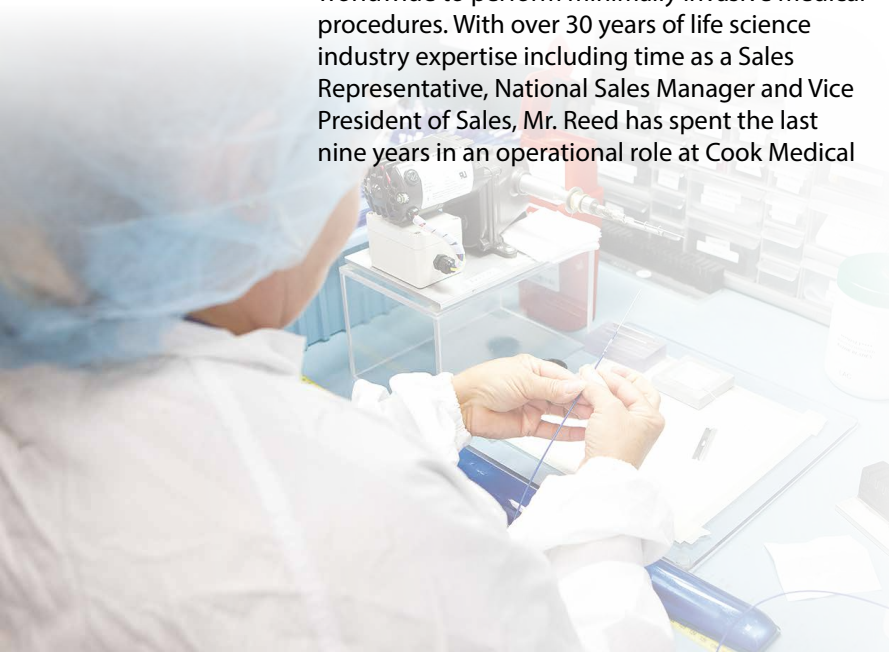
Programa Remediar: bringing essential drugs to patients and optimising the supply chain in Argentina with GS1 Standards

by **Mauricio Monsalvo,**
Ministry of Health, Argentina

Abstract

In Argentina, the Programa Remediar is the programme that supplies medication guaranteeing free healthcare coverage to more than 16 million patients. The Programa Remediar not only issues public tenders for the purchase of the drugs it distributes, but has also become the main logistics operator for public health in the country, using GS1 Standards to efficiently manage the programme. The latter was mandated by the National Administration of Drugs, Foods and Medical Devices (ANMAT) Traceability System in 2011.

Programa Remediar

In 2002, Argentina started implementing the Programa Remediar to supply free medications to people with scarce resources and lack of medical coverage.

Since its creation, the Programa Remediar has managed to distribute free drugs monthly to over 7,000 primary healthcare centres all over the country, providing kits composed of a selection of essential medication, covering the needs for 80% of Argentina's primary centres. By guaranteeing the coverage of more than 16 million users of the public health system, Programa Remediar became the most important programme for drug purchasing and distribution in Latin America.

In this capacity, it provides access to 54 essential drugs, which are purchased in bulk by the National Ministry of Health. The drugs contained in the kits reach the pharmacies of primary healthcare centres directly, bypassing municipal and/or provincial intermediate warehouses.

In order to obtain cut-rate products, Programa Remediar manages the specifications and public tenders for each of these drugs. This methodology aims to ensure the visibility and quality of drug supply from procurement to delivery to the primary centres, all the way to dispensing the medication for treatment.

Implementing GS1 Standards to comply with Argentina's National Traceability System

Following the implementation of Argentina's National Traceability System, introduced in 2011 by the National Administration of Drugs, Foods and Medical Technology of Argentina (ANMAT), each drug or device must be marked with an individual and unambiguous identifier in order to track and trace the item all along the distribution chain – from production or import to the patient. The National Traceability System requires all drugs to be identified through the application of an unambiguous code, according to the recommendations of GS1 Standards.

National and international suppliers need to register and, in real time, update the database by registering unambiguous codes assigned to each product as well as the date of each logistic operation to comply with the requirements. There are specific procedures regarding the identification and marking of secondary packaging that suppliers must follow. The secondary packages are colour-coded according to the Anatomic Therapeutic Chemical (ATC) classification, and include a GS1 DataMatrix containing a Global Trade Item Number (GTIN), lot number, expiration date, an internal code assigned by the Programa Remediar as well as a serial number (where applicable).

As part of its successful implementation, Programa Remediar became the logistics operator for all public health programmes supplying pharmaceutical products and medical supplies.
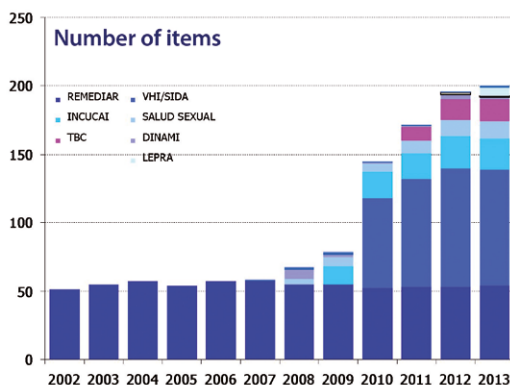
Figure 1: Progress of units distributed by Programa Remediar

Traceability and logistics

The National Administration of Drugs, Foods and Medical Technology of Argentina's (ANMAT's) National Traceability System brought efficiency and visibility to the supply chain, but at the same time represented a challenge for the public health sector. In response to the system's requirements, Programa Remediar had to adapt its processes and IT systems to fully comply with the regulation.

To allow the tracking and tracing of each individual drug, two systems were implemented: the Monitoring System of Healthcare Supplies and the Integrated System of Healthcare Information of Argentina. These two systems were made compatible with the requirements established by the drug traceability system determined by the National Administration of Drugs, Foods and Medical Technology of Argentina.

Programa Remediar also developed a web interface to allow the different health programmes distributed by Argentina's health agencies (National Aids Agency, Ablation and Transplant National Institute, Sexual Health National Programme, National Agency for Sanitary Emergencies and others) to send online distribution requests to the Programa Remediar, replacing the use of paper, optimising shipments' preparation process and tracing products in real time.

The ultimate goal of these systems is to register the patient's medical consultations, link the information to the lot/batch number of the drug dispensed to patients, and to transfer this information to the drug traceability system established by ANMAT.

The complexity of adapting the existing system required the effort from a multidisciplinary team, with representatives from different departments such as the:

- information systems;
- logistics and drug management unit;
- audit and quality area; and
- tracing and evaluation unit.

Benefits of GS1 Standards: efficiency, safety, speed

The implementation of GS1 Standards enables Programa Remediar to improve efficiencies at each level of the supply chain, including the following:

- Delivery of drugs: supplies are identified and scanned at the unloading dock to reduce errors and verify that the delivery corresponds to the order.
- Drug shipping: Drug delivery labels are scanned to guarantee they are despatched according to their content.
- Information flow: The flow of information is guaranteed whilst efficiently using the human resources.

About the author
Mauricio Monsalvo has worked on the coordination of the Programa Remediar at Argentina's Ministry of Health. Mauricio graduated from the University of Political Science in Morón. He has a Master's degree in Social Research Methodology from the Universitá di Bologna and a Master's degree in Epidemiology Public Health at the Oswaldo Cruz Foundation (Fiocruz/ANLIS).

He has assisted many research projects and publications focused on the safe use of drugs.

by **Stéphane Aubert,**
UCB

and **Sébastien Godfroid,**
UCB

Patient Safety and the Challenge of Serialisation at UCB

Abstract

Because of numerous cases of falsified medicines on the market, governments and companies are making patient safety a priority in the pharmaceutical supply chain.

Product traceability increases the capability to check the authenticity of a product, reduces the risk of counterfeit products being dispensed, and ultimately, ensures delivery of the right product to the patient. Hence, in 2010, UCB initiated a serialisation programme, which was aimed at preparing the company to comply with the different regulatory requirements emerging worldwide, enabling complete and accurate identification of the products from early stages of manufacturing through the entire supply chain.

The serialisation programme includes unique identification of products through serialisation at the trade item level and integration of various partners using effective communications and data exchanges. A complete integrated IT architecture that leverages GS1 Standards, such as the Global Trade Item Number (GTIN), Serial Shipping Container Code (SSCC), combined with harmonisation of processes and data management, is expected to deliver more than the required outcome.

Inspired by **patients.**
Driven by **science.**

The concept of serialisation

Pharmaceutical serialisation has been on its way for a long time. There is uncertainty, though, with the timing and the exact compliance requirements. These have grown, mostly as a result of regulatory push, leading to enforced legislation imposed on various stakeholders.

Serialisation at the item level is one measure enforced by governments and legislation to implement complete and accurate traceability. Any trade item is assigned a serial number, which enables its unique identification within the supply chain. Companies must now prepare to generate, receive, distribute and manage unique serial numbers at a global level.

To date, two traceability models are emerging:

- The U.S. Federal Drug Supply Chain Act (November 2013): products are serialised, aggregated and authenticated when a change of ownership occurs. Traceability data is shared between trading partners along the supply chain
- Europe: the "authentication model" relies on item-level serialisation, registration of product in a national or regional database, and then authentication at the point of dispense.

At UCB, the decision was taken to implement item level serialisation with the required information to be printed in human readable format and encoded either in a linear bar code or a two dimensional (2D) bar code, such as the GS1 DataMatrix, depending on the legislation.

The basis of the work has been the European Stakeholder Model - see diagram below.

The European Stakeholder Model

Overall Goal - Improve patient safety
Reduce the risk of counterfeit products being dispensed, detect expired products automatically, perform product recalls more effectively and efficiently, deliver the right product to the right patient.
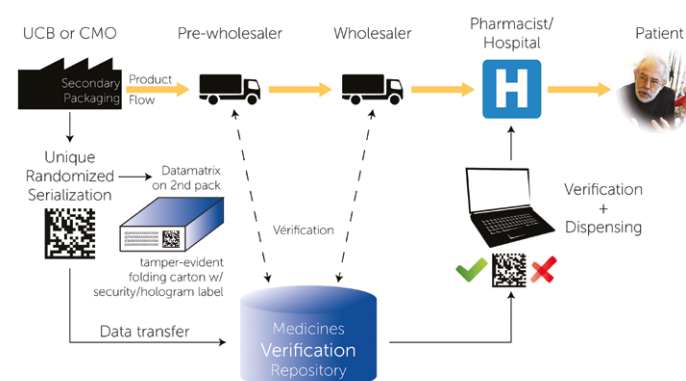
Initiating the serialisation programme

The serialisation programme kicked off in 2010. Its goal was to prepare UCB to effectively respond to the upcoming regulations requiring serialisation and track and trace capability filtering in from all over the world.

The changes in the European Union's (EU) legislation and the potential initiatives in the U.S. have increased the focus on the areas of serialisation, Change of Ownership (CoO) and track and trace. Therefore, UCB needed to make some assumptions about the legal requirements and most plausible implementation deadlines for compliance. Work was done to identify how these types of requirements would affect UCB's processes and what solution might be best implemented to respond to regulations.

The first point for consideration was that complete identification and full traceability of products impact the supply chain from start to finish. Packaging plants need to adapt their production lines to be able to generate and print information on the material and all logistics, and distribution transactions need to be considered to ensure proper management of associated information. In addition, external stakeholders, such as Contract Manufacturing Organisations (CMOs) and third-party logistics providers (3PLs), also had to be included in the programme since information passes on along with the physical material flow.

Structure of the programme

The preliminary investigation led to an overall blueprint of the programme, covering processes mapping and functional description of the

solution. SAP being UCB's corporate Enterprise Resource Planning (ERP) application, the selected approach was to extend the existing system and integrate serialisation functions.

From January to August 2013, a pilot was conducted to confirm the design and the capability of the solution to ensure that it could effectively support the company's processes. The scope of the pilot included packaging and logistics processes and was implemented at UCB's U.S. facility. As UCB's datacenter is physically located in Belgium, it also demonstrated system performance and robustness.

Given the successful evaluation and outcome of the pilot, the programme was then launched in a productive environment. Subsequent implementations at other sites are now also planned based on local regulations, with possible functional extensions required by specific processes and needs.

Using GS1 Standards

UCB did not have to conduct any deep analysis to decide on the standard to use to identify its products. GS1's Serial Shipping Container Code (SSCC) were already implemented to identify the logistic units (i.e., transport cases or pallets).

In addition, with regards to track and trace, GS1 Standards were the natural choice to use as they are commonly recognised as the most widely used supply chain standards and supported by many regulators. Since SSCCs were applied on its shipper cases and pallets, UCB was able to focus its effort on serialising trade item GTINs.

The use of globally-recognised standards was also enforced to support standardisation and allow integration between sites and external partners.

Key success factors

From a **regulation perspective,** the programme started at a time when very little information was available on the requirements and key assumptions had to be made on points such as information to print, bar code format and contents, aggregation, and randomization. At the same time, UCB wanted to design a global solution that would be flexible enough to respond to changes and adapt to different local requirements.

From a **technology perspective,** the solution had to cover many processes, including packaging execution, logistics, distribution, and external connectivity with UCB's partners (CMO, 3PLs, etc.).

It had to consider a scaleable architecture to adapt to various sizes of plants and, at the same time, be able to comply with evolving regulations.
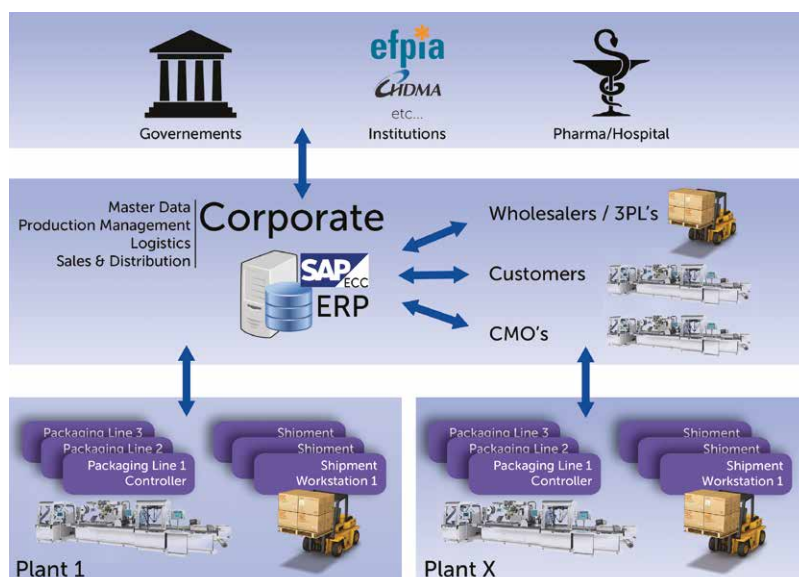
UCB's global solution design

Data management was also a key concept to take into account. Ensuring detailed identification and traceability of products requires proper definition of items in the systems, and local mechanisms for identification were already in place well ahead of the serialisation programme. Equally, although EU countries are striving towards harmonised standards, some countries still have their local codification. European decisions will be crucial in this matter.

The global implementation of the programme required the collection and combination of the point of view and knowledge of the local organisations. So, whilst UCB globally-defined a detailed process to gather all possible technical and regulatory requirements, it was shared with the local affiliates and the final solution was designed based on their feedback.

It was also decided that the global organisation at UCB, in charge of the Global Master Data Management, would be responsible for defining the strategy and rules for product coding and characteristics. Meanwhile, local affiliates and sites were responsible for implementing these rules and sharing product data accordingly.

As a result, GTINs are now managed at the global level in a harmonised way and maintained in the ERP system, the corporate repository of all unique codes. Existing GTINs are collected from affiliates all around the world, allowing to identify and create missing codes to fill the gaps.

The information is stored in a single, secured system and is accessible by the entire company. This centralised and controlled information repository allows high-quality data to be transmitted to UCB's partners. One scan of a bar code will tell them what is to be shipped and to be received. Every single box is already recorded in the aggregation scheme, making human errors less possible.

From the organisation's viewpoint, UCB's pilot made it apparent that the programme did not solely impact the packaging and labeling processes. It also illustrated that it is crucial to involve other internal departments, such as technical operations, corporate management, packaging plants, supply chain, quality assurance, distribution networks, IT, engineering, as well as external partners like CMOs, 3PLs, and suppliers. The pilot also showed that effective governance and strict rules in terms of project management and execution are paramount.

Consequently, the organisational structure of the programme now considers various levels of decision and execution. Steering committees endorse the implementation strategy in terms of prioritisation, scope and investment, and support project execution by assigning resources and acting as decision body when escalation occurs.

High level of dependency across various business domains and locations (globally and locally) requires strong integration to ensure alignment. Communication is maintained through regular project, programme and steering committees, which include internal staff as well as external suppliers.

Benefits

As this programme relates to compliance, not delivering a solution on time can lead to the inability to distribute UCB products to various markets, resulting in numerous patients not receiving their treatments. This alone is reason enough to justify the investment made.

However, various additional opportunities were identified to deliver added value to the organisation, further leveraging this investment:

- Cleansing of data through standardisation of processes
- Master product data harmonisation and simplification at both global and local levels
- All data supporting serialisation processes and automation are now managed through the global ERP system as per UCB's global rules instead of being based on local equipment with no view or control of the rest of the teams
- Automating data transfer to allow the operators to focus on the core manufacturing process and to minimise the risk of errors from manual data entry. Similarly, the integration with external partners will also be extended to other types of information for other processes, leading to a complete and more efficient end-to-end integrated supply chain.

Beyond product safety, identification will also allow to track additional information assigned to the products within the supply chain, such as temperature and humidity, associated with position and timestamps. Furthermore, collecting this data will allow tighter control and faster response to exceptional events. UCB trusts that further benefits will be visible and other opportunities will arise from the extensive use of the programme.

Conclusion

The challenge of serialisation is to adapt processes at all stages of the internal and external supply chain, to identify and track products at item level, and develop a solution allowing for the integration of various partners through effective communications and data exchange.

Patient safety is a common concern shared by all stakeholders in the pharmaceutical industry. As legal requirements still need to be formally clarified, the industry needs to make assumptions to move forward.

Success of serialisation implementation relies on a continuous collaboration and alignment between all partners, such as industry professionals, solutions providers and regulators.

Maintaining constant and open discussion through various forums or organisations like the European Federation of Pharmaceutical Industry Associations (EFPIA) or GS1 will ensure overall consistency, alignment of reasonable requirements, and the implementation of effective solutions to ultimately ensure patient safety.

About the authors
Stéphane Aubert is Director IT – SAP logistics Execution at UCB. He has been with UCB for about 20 years, where he has managed various IT projects and solutions, mostly focused on manufacturing and logistics. Since 2010, he has also been leading the IT portion of the serialisation programme.

Sébastien Godfroid is Artwork Process & Packaging Technology Manager at UCB. He has previously worked for different companies in areas such as clinical trials and regulatory affairs (international labelling). In June 2013, he joined UCB's Global Products Master Data & Artworks team, where he focuses on the serialisation programme.

About UCB
UCB in Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With over 8,500 people in approximately 40 countries, the company generated revenue of EUR 3.4 billion in 2013. UCB is listed on Euronext Brussels (symbol: UCB).

by **Ms. S. C. Chiang,**
Hospital Authority, Hong Kong

WINNER of HPAC Award

Modernising the pharmaceutical product supply chain in Hong Kong public hospitals

Abstract

The Hong Kong Hospital Authority is a statutory body that manages all the public hospitals and affiliated institutions in Hong Kong, totalling 42 public hospitals, over 27,000 beds, 48 specialist out-patient clinics and 73 general out-patient clinics. In 2010, the Hospital Authority began its Supply Chain Modernisation project with the aim to achieve two main goals: firstly, to enable the track and trace capability in its handling of the large volume of pharmaceutical products through the adoption of industry standards including unique item identification as well as electronic data messaging protocols; secondly to achieve operational efficiency in the supply chain management process.

These goals, with the full collaborative support from the major pharmaceutical distributors, were successfully achieved in 2013. The entire implementation process of the Supply Chain Modernisation project had benefited from the professional technical advice from GS1 e.g. in the use of GS1 Standards and their support providing the appropriate training. The project has provided significant improvement in the workflow efficiency with much enhanced pharmaceutical product traceability and has paved the way to benefit medication and patient safety in the clinical care process.

Manual processes created a challenge

In 2012, the Hospital Authority Hong Kong's drug expenditure amounted to near HK$4 billion in pharmaceutical products. However, the entire supply management process was based on traditional manual workflow procedures, e.g. majority of the procurement and goods receipt processes were paper based. There was a lack of efficient and accurate means of recording the movement of different batches and expiration dates of the goods into and out of the pharmacy warehouse with high degree of questionable traceability.

To address these fundamental issues of concern, the Hospital Authority began an initiative in 2010 called the Supply Chain Modernisation (SCM) project, to revamp these related processes in order to:

• automatically check products received against ordered ones to improve accuracy and efficiencies; and

• automatically track and trace pharmaceutical products from the point they are received to the point of distribution to prevent expired medications from being dispensed.

Ensuring operational efficiencies and patient safety through adoption of GS1 Standards

The Hospital Authority adopted the following GS1 Standards to help achieving the aims of the SCM project to track and trace pharmaceutical products:

• the Global Trade Item Number (GTIN) to identify every pharmaceutical product package;

• the Global Location Number (GLN) to identify every medication supplier and different delivery locations for their hospitals; and

• the Serial Shipping Container Codes (SSCC) to identify the logistic units in each goods delivery from the suppliers.

When cartons of products carrying the GS1-128 BarCode is scanned by Hospital Authority staff at the goods receipt process, vital information such as the GTIN, batch number and expiration date is provided via wifi access through the scanner. Since these products are delivered to different points-of-use throughout the Hospital Authority's operations, the Supply Chain Modernisation project provides an accurate tracking of products from one location to another through the use of the GLN.
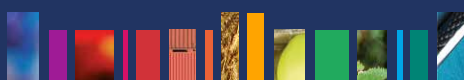
PHARMACEUTICAL SUPPLY CHAIN MODERNISATION
Make Traceability Possible

DID YOU KNOW?

Starting from June 2012, Hospital Authority (HA) pharmacies are able to *track and trace* pharmaceutical products from external vendors into the pharmacy stores in a *more accurate and efficient way*.

HOW DOES THIS WORK?

Suppliers

GS1 Standards EANCOM®

Supplier — ezTRADE — HA

Electronic Advanced Shipping Notice (ASN)

Entire shipment with bar coded Serial Shipping Container Code (SSCC) on each logistic unit

At Pharmacy Stores

ASN
- SSCC
- country of origin & manufacturer
- expiry date

① Process

Before goods arrive
- Vendors send ASN to HA.
- Prior validation of manufacturer, country of origin, quantity, etc.
- Online provision of lot no. & expiry date.

When goods arrive (at staging process)
- Scan SSCC bar code on logistic units to verify Purchase Order (PO).
- PO details displayed in scanner for inspection.
- Confirm receipt & instant update into system.

② Process

醫院管理局
HOSPITAL AUTHORITY

Stock into stores
- Pack-unpack containers to separate items.
- Scan product barcode (GTIN) with lot no. & expiry date and confirm quantity.
- Stock to pre-defined location in stores.

③ Process

④ Process

Drug distribution
- Enable lot-control with track-and-trace functionality.

Drug Traceability ↑
Accuracy ↑
Efficiency ↑
Streamline Operation ↑
Patient Safety ↑

30 Vendors support

42 Hospitals benefitted

82% Order line automated

To facilitate the accurate and efficient exchange of information between the Hospital Authority and the suppliers, information such as purchase orders, purchase order responses, despatch advice and invoices, are sent and received using defined Electronic Data Interchange (EDI) protocols such as GS1 EANCOM®, the GS1 Standard for electronic business-to-business exchanges, were deployed.

The EDI processes and the improved Supply Chain process includes the following steps:
- The Hospital Authority sends the EDI purchase orders to the suppliers
- Upon receipt of these orders from the Hospital Authority, the suppliers pack up the required products and attach SSCC labels that contain GS1-128 BarCodes onto these shipments
- Suppliers then send an electronic despatch advice to the Hospital Authority for advance validation by the purchasing units.
- Upon delivery of the products at the Hospital Authority's warehouses, pharmacy staff scans the bar codes from the SSCC labels to retrieve information which was received in advance from the electronic despatch advice to make sure all the product data for the goods delivered, matches with the electronic information source.
- Pharmacy staff also checks to ensure the right products were delivered and counts the quantities delivered to ensure the delivery quantities are correct. After validation, the product data retrieved from the despatch advice through the scanners are confirmed and fed back through the wifi connection into the Hospital Authority's system.
- Suppliers then send electronic invoices to the Hospital Authority's finance department to settle the payment process.

Successful implementation

To minimise the risks from the project implementation and to test out these solutions, an extensive pilot project was undertaken and conducted in two phases. In Phase 1, products were tracked from distributors into Hospital Authority pharmacy stores. In Phase 2, products were tracked from pharmacy stores to the dispensing stores.

From January 2011 onwards, with professional advice and business support from GS1 Hong Kong, the Hospital Authority successfully engaged an initial batch of 13 vendors who are the major suppliers of pharmaceutical products in its Supply Chain Modernisation project pilot accounting for more than 70% of the Hospital Authority's purchase volume. The Phase 1 of the project was successfully implemented in all the pharmacy stores and warehouses at 41 public hospitals in Hong Kong by June 2013.

The Hospital Authority then engaged a second batch of 13 vendors who constituted another 16% of their purchase volume. This second wave of implementation was completed in April 2014.

Benefits of GS1 Standards

The Supply Chain Modernisation project was initiated in response to important quality care aspects in the healthcare industry – safety and efficiency. In implementing the project, the Hospital Authority revamped the entire processes which made use of GS1 Standards. **Along with its suppliers, the Hospital Authority is now able to harness supply chain visibility through the use of GS1 GTINs for products, SSCCs on logistical units, GLNs for delivery locations, and despatch advices for delivery notifications.**

• The adoption of GS1 Standards and implementation of the new process resulted in the realisation of a full range of benefits. Hospital Authority Hong Kong has enhanced the speed of their operations by replacing manual processes with automated ones,

• Hospital Authority Hong Kong has improved the accuracy of the information captured in their trading documents during the procurement cycle

• Hospital Authority Hong Kong has automated the validation of the goods delivery thus making the operations faster and more accurate.

With the appropriate technology and systems in place, the Hospital Authority was – and continues to be – able to improve the quality and safety of the healthcare services it provides.

Next steps

By April 2014, the project covered 86% of the Hospital Authority's purchase volume of pharmaceutical products, with altogether 26 vendors participating. The Hospital Authority now intends to extend its Supply Chain Modernisation project further to more pharmaceutical products and suppliers.

Since many local suppliers have yet to be part of the Hospital's automated procurement process, it has worked with GS1 Hong Kong on educating them on the concept, processes and benefits of using GS1 Standards. Practical examples from the Supply Chain Modernisation project are shared with these suppliers, as well as with healthcare professionals and organisations in Hong Kong and abroad.

In the longer term, the Hospital Authority plans to develop a system with enhanced level of pharmaceutical product traceability – beyond the pharmacy and dispensary level to the point of patient care for every product and every patient. However, such a system would require the pharmaceutical products to be repackaged in such a way to facilitate the transfer of information such as the product identity, the expiration date and the batch number from the product to the tracking system at individual item levels to ensure that the right medication is administered to the right patient. The benefits are invaluable – it will help enhance pharmaceutical traceability and safety throughout the supply chain process for the patients and general population.
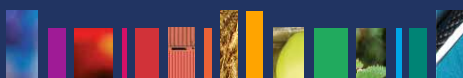
About the author

Ms. S.C. Chiang is the senior pharmacist with the Hong Kong Hospital Authority in charge of the development and implementation of the Supply Chain Modernisation project. Ms. Chiang began in the pharmacy industry and was one of the first pharmacists to develop a dispensing and labeling system, which was eventually used in all public sector pharmacies. She was also the first pharmacist to introduce automated dispensing technologies. Ms. Chiang obtained her Bachelor of Pharmacy from the University of Bradford, England and obtained a Master of Health Administration from the University of New South Wales, Australia.

About the Hong Kong Hospital Authority

The Hospital Authority is a statutory body that is responsible for managing Hong Kong's public hospitals and their services to the community. The Hospital Authority is accountable to the Hong Kong Special Administrative Region Government through the Secretary of Food and Health, who also formulates health policies and monitors the Hospital Authority's performance.

At present, the Hospital Authority has a workforce of around 64,000 people, managing 42 hospitals and institutions, 48 specialist out-patient clinics, and 73 general out-patient clinics. Between them, they provide 27,000 beds, or about 4 beds for every 1,000 members of the public.

"The Supply Chain Modernization (SCM) project has adopted the GS1 Standards and this has turned out to be a successful healthcare system initiative that we have implemented recently to enable automation in the pharmaceutical procurement process and track-and-trace capability in the supply chain process in our hospitals, which is essential for the achievement of medication safety, supply chain eciency, and traceability,"

Ms. S.C. Chiang, Senior Pharmacist, Hospital Authority Hong Kong.

by **Arnaud Septer,**
Mediq Systemfarma

and **Chris
Sindhunata,** SPITS
Alkmaar

DDS Pharmacies optimise clinical care and improve elderly patient safety through GS1 Electronic Data Interchange

Abstract

By using global standards for electronic business messaging for rapid, efficient and accurate automatic transmission, the use of GS1 Standards has helped pharmacists, general practitioners and nurses in the Netherlands to safely treat patients who live in nursing homes or at home. The newly implemented GS1 eCom Standards improved the ordering process between the dispensing pharmacies and the patients' community pharmacy, paving the way for new patient safety and logistic opportunities.

The Unit Dose Dispensing System

The unit dose system of drug distribution is a pharmacy-coordinated method of dispensing and controlling medication in organised healthcare settings [1]. Unit dose dispensing systems are in place to provide patient-specific, individually packaged medications, which minimise nurse/caregiver product manipulation. These unit doses of medication are dispensed with individually labelled bar code packaging to enable nurse scanning of the medication at the bedside prior to administration.

The DDS pharmacies

In the Netherlands, Dose Dispensing Systems (DDS) are increasingly implemented in healthcare facilities. DDS support pharmacies with the distribution of patient specific medication at home, in nursing homes, institutions and hospitals.

Small packs are filled with one or multiple tablets for oral use and are prepared for each patient. These individual packs are prepared for a week's worth of medication. Each pack contains medication for one intake time and carries the following printed information:

- patient data to identify the right patient,
- date and intake time,
- name of medication and number of tablets, and
- description of tablet appearance.

Due to aging population, unit dose dispensing is becoming increasingly important in the Netherlands, in both (elderly) home care and in institutions. According to the total number of "invoices" to the insurance companies, in 2009, only 26% of all invoices were for a unit dose dispensed medicine. This percentage has grown to 40% in 2013 [2].

The process in a DDS-enabled pharmacy: from goods receipt to production of week packs. Source: Alliance Healthcare Nederland

1 American Society of Hospital Pharmacies http://www.ashp.org/
2 SFK   http://www.sfk.nl/

Still, a drug can be very effective, but will be of little use if not taken properly. Medication management becomes more important as people grow older and stay in their homes until an advanced age. Older people at home or in nursing homes often take multiple tablets at multiple times during a day, which can cause confusion about when to take which medication and in what dose.

This is where a DDS can help. Numerous studies concerning unit dose DDS indicate that they are:

- safer for patients, reducing the incidence of medication errors, and
- more efficient and economical for the organisation dispensing them.
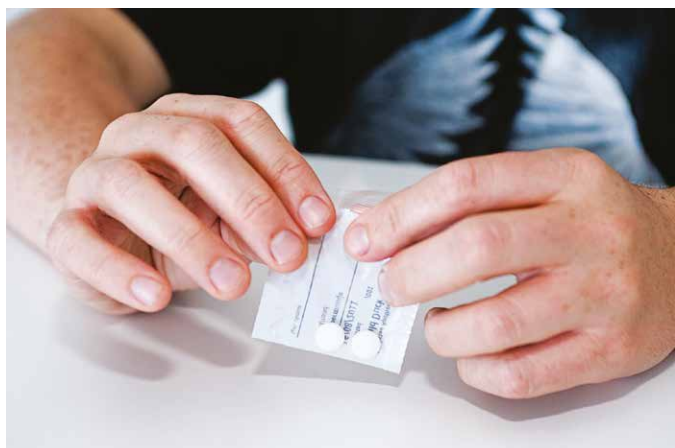
Figure 1: patients labels e. Source: Mediq Systemfarma

Medimo, an electronic dispenser of packs for patients treatment at home. Source: Mediq Systemfarma

Community pharmacies make use of DDS by ordering from specialised pharmacies called DDS pharmacies. In the past, the ordering process had limited functionality and did not rely on GS1 Standards.

Pharmacies and DDS pharmacies expressed the need to enhance their functionality to better support their processes. At the same time, new developments such as the Medimo, an electronic dispenser of packs for patients at home, generated the need to improve the current electronic message used in the ordering process.

GS1 Standards will optimise patient identification and delivery process

GS1 develops and maintains the most widely-used supply chain standards system in the world, including Electronic Data Interchange (EDI) standards – also known as GS1 eCom. EDI allows rapid, efficient and accurate automatic electronic transmission of agreed-upon business data between trading partners.

EDI now allows for a DDS order and DDS order response, based on the GS1 eCom standards for order and order response with the use of Global

Trade Item Number (GTIN) identifying each drug and Global Location Number (GLN) identifying the physical location of the drug and/or the legal entities (nursing home, pharmacy).

More functionalities have been introduced in the new ordering process. For example, the opportunity to add extensive patient and medication specific information supports administration of medication. Also, specific delivery information, such as "Delivery through back door" or "Please ring bell for a long time" makes deliveries easier and ensures the patient receives his medications on time.

Some medication need a certain method of administration, such as laying down for a time period after taking it or ensuring the medication is taken with liquid, so another important functionality was added to the ordering process: the ability to include dosage and recommendations for safe use.

An additional improvement linked to the implementation of EDI is that it offers more space for patient name and address information making the information complete on the address label.

Furthermore, new developments in the market around DDS, such as Medimo, an intelligent electronic dispenser of unit dose packs for patients at home have increased the need to implement GS1 Standards to uniquely identify the products and patients and have accelerated the requirements.

The order response is also a new feature in the process, which provides pharmacies with information on the delivery of the ordered medication. The DDS pharmacy communicates to the community pharmacy which medication will be delivered and which cannot be delivered if the medication is out of stock. This results in less manual processes (such as telephone calls) and improves efficiencies.

In addition, the order response contains information per patient on the medication to be delivered, for example the number of tablets that need to be taken at specific times and dates, and, if necessary, a reason for a substitution.

Staged implementation at DDS-pharmacies network

Through a collaborative effort launched in 2012, the DDS Pharmacies Network asked GS1 Netherlands to implement GS1 Standards for the ordering process to be used between community pharmacies and DDS pharmacies. The goal was to establish "a communication standard for the whole care chain" to support efficient, better and safer patient care.

A pilot of this effort will run during the fourth quarter of 2014, with broad implementation in the Netherlands expected to be completed in 2015.

About the Authors
Arnaud Septer has been a pharmacist since 1999. He has previously worked as a community pharmacist in three different Dutch pharmacies. In 2010, Arnaud moved on to work in a DDS pharmacy, Mediq Systemfarma, Sliedrecht. His job responsibilities at Mediq Systemfarma are IT (pharmaceutical), quality assurance and procurement.

Chris Sindhunata graduated from the University of Amsterdam and has been a pharmacist since 1987. During the first 20 years of his career, Chris worked in a community pharmacy in Alkmaar. In 2002, he co-founded and became the managing director of the DDS pharmacy SPITS, also located in Alkmaar. He is also the pharmacist of the 24/7 pharmacy and chairman of the communication health IT network, OZIS.

About the DDS Pharmacies Network
The DDS pharmacies network is a cooperation between the seven largest DDS pharmacies: Pharmacy Voorzorg, Mediq Systemfarma, Pharmacy Spits, Pharmacy 5 Sterren, Brocacef Maatmedicatie, Verpakapotheek and Baggerman Farma Consult B.V. The Network reflects the common interests of the different pharmacies. It also develops and creates quality norms, expedites improvements of current processes, and innovates by enhancing knowledge of the pharmaceutical industry.

Kent Pharmaceuticals: a live pharmaceutical serialisation and verification system
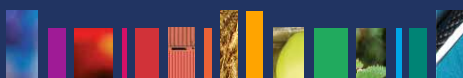
by **Jason Webb,**
Kent Pharmaceuticals

Abstract

In the UK, out-of-hours patients could not always receive the medication they needed during their consultation. These patients had to rely on the few medicines their general practitioner was carrying and had to wait until the pharmacy opened to receive their full medication. As a provider of pharmaceutical supplies to out of-hours doctor services, Kent Pharmaceuticals developed a system using GS1 Standards to ensure a safer and more efficient medicines management solution.

Introduction

Traditionally, out-of-hours doctors were expected to rely on the few medicines they were able to carry in their doctor's bag to meet the demands of patients requiring treatment outside normal surgery hours. It was not uncommon for patients to be provided with "one or two tablets in a brown envelope to tide them over" until they could visit a pharmacy and receive the necessary treatment in the usual way. In 2000, the Carson Review: "Raising Standards for Patients – new Partnerships in Out-Of-Hours (OOH) Care", made a number of recommendations aimed at improving both the safety and efficiency of OOH dispensing including:

• Recommendation Nineteen:
Other than in exceptional circumstances, patients should be able to receive the medication they need at the same time and in the same place as the out-of-hours consultation.

• Recommendation Twenty:
The existing remuneration and contractual arrangements for out-of-hours providers and pharmaceutical services should be reviewed and, where appropriate, modified to allow for the provision of all appropriate medicines in the manner set out in Recommendation Nineteen.

The implementation of these two recommendations clearly necessitated a root-and-branch review of how medicines were made available to doctors and nurses providing out-of-hours care.

> *"For the efficiency savings, I find about booking-in of stock 40%-60% quicker. This will go up again once I am able to log a whole box in with just one scan. Dispensing stock is much quicker with the 2D scanner as I am able to do multiple drugs within a fraction of the time. I would say dispensing stock is now over 60% faster."*
>
> **Sarah Workman,** Medicines Management Team at East Berkshire Primary Care Out-of-Hours Services

Kent Pharmaceuticals, a UK pharmaceutical manufacturer and wholesaler who supplies to of out-of-hours doctor services, partnered with Advanced Health & Care (developers of Adastra) and Melior Solutions Ltd. (Melior). They employed the GS1 System of Standards to provide the fundamental keys to enable the accurate identification of all pharmaceutical product packs, efficient capture of the required information and the ability to share and verify this information.

Applying GS1 Standards

The Adastra clinical patient management system is designed specifically to manage episodes of care in unscheduled settings such as out-of-hours services. The system monitors in real-time any drug issued by the clinician for his patient, as well as allows drivers or clinicians to check the availability of cars stock at the start of a visit to a patient and then monitors in real-time any drug issued by the clinician for his patient. This information, along with the relevant details of the consultation, are transmitted electronically to the 'in-hours' general practitioner system before 9.00 a.m. the following morning.

Kent sources the products from their own production or from other manufacturers. All products destined to be used in the out-of-hours service were then relabelled to indicate that they belonged to the service. This re-labelling requires (according to GS1 Healthcare Global Trade Item Number (GTIN) allocation rules) a new GTIN for each product and Kent Pharmaceuticals accordingly allocated these numbers using their

GS1 prefix. Each pack was relabelled with a GS1 DataMatrix and was marked with the following information on the secondary packaging:

- Global Trade Item Number (GTIN);
- serial number;
- batch/lot number; and
- expiration date.

During the re-labelling process, the Melior system scans and verifies each printed code for accuracy and uniqueness. The information contained in the GS1 DataMatrix on the re-labelled products is then uploaded via simple software tools to a secure external data repository (the Kent Secure Server). The data repository is equipped with secure web service connections used by Adastra when checking and verifying packs.

When the re-labelled product is received by the out-of-hours services, each pack is scanned in turn. The data from the scan activity is sent to the data repository where it is checked for validity, the status of the pack updated and a detailed response is then returned providing Adastra with further pack information that is used by Adastra when adding the product to stock.

The solution was piloted and assessed in two critical business processes:

1. Inventory management (goods receipt and stock management) - To assess the scanning and verification of the stock received from Kent and the movement of stock around the out-of-hours providers,

2. Medication Dispensing - To assess the feasibility of clinicians scanning the product, as well as the verification of the product, which ensures the product being prescribed is the right product going to the right patient, and embedding the batch number and expiry details into the patients records.

Matching the product prescribed and dispensed through standardised identification reduces dispensing errors.

Kent and Melior deployed and tested the solution, which consisted of a mix of standard commercial off-the-shelf products and customised products over a six-month period prior to release. Further enhancements are being discussed to permit the tracking and handling of bulk aggregated product using Serial Shipping Container Codes (SSCCs), which would further enhance the efficiency of the goods-in process.
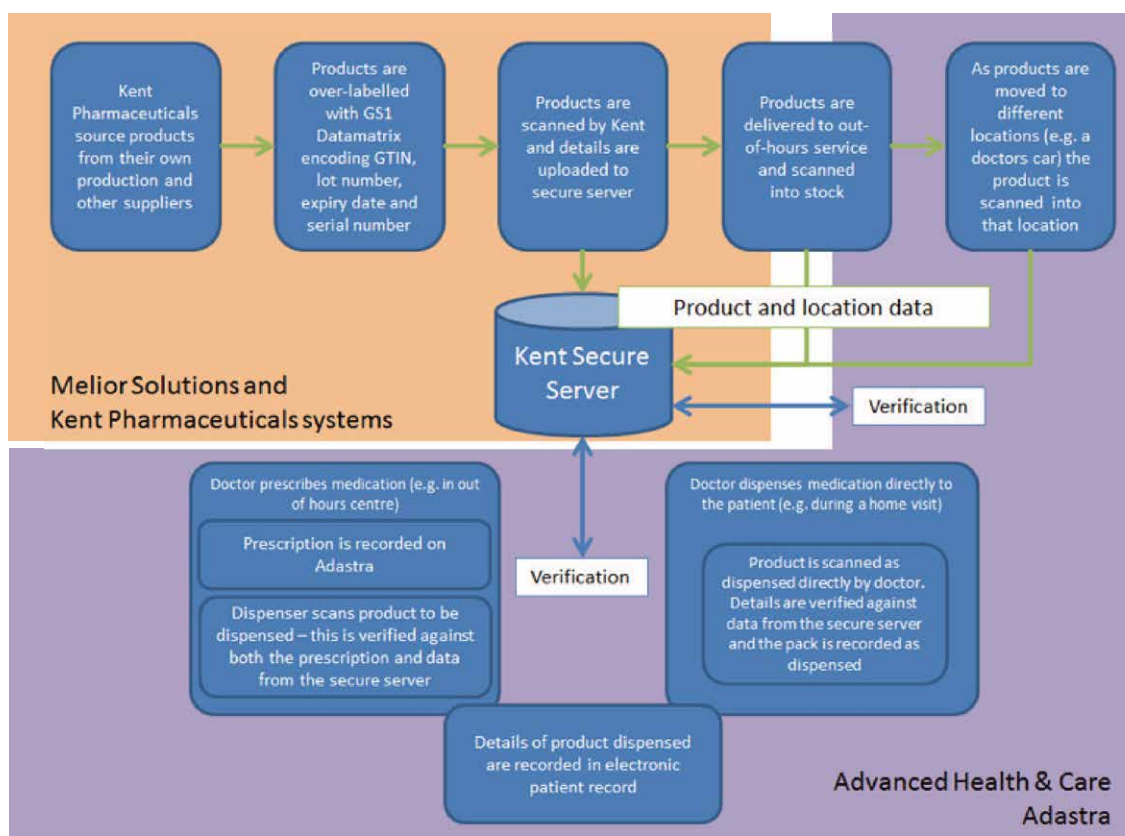
Benefits of using GS1 Standards

By 2013, the system has scanned and verified over 15,000 packs of medicine from the point of relabeling to the point of dispensing. The average time taken by the Kent server to verify a pack was less than 50 ms.

In short, the benefits of the system are:
* improved patient safety through authentication at point of dispensing and tracking of expiry dates;
* reduced risk through elimination of manual entry of stock in database;
* improved tracking system (products are tracked from reception of good to the patient);
* improved recall management (products are located immediately in the event of recall); and
* improved stock efficiency/savings through quick scanning of dispensing stock.

About the author
Jason Webb has been in the pharmaceutical industry for 19 years, starting his career in a manufacturing role before moving into a management role within a parallel import company. In 2005, Jason moved to Kent Pharmaceuticals Ltd. as Contracts Manager and, in 2009, was appointed Public Sector - Sales & Marketing Manager, which is a role he continues with today.

Jason is also Project Manager for the implementation of 2D coding within Kent and is also co-chair of the GS1/Department of Health Working Group on 2D coding within secondary care.

About Kent Pharmaceuticals
Kent Pharmaceuticals, a UK pharmaceutical manufacturer and wholesaler which offers a wide range of manufacturing, importing, re-packaging, sourcing and delivery services to healthcare providers in the UK, supplies to out-of-hours (OOH) doctor services.

Established in 1986, Kent Pharmaceuticals prides itself on dedicated service excellence. Its position as Britain's largest independent generic pharmaceuticals manufacturer and wholesaler has been significantly enhanced following the merger with Fannin Pharma. Kent Pharmaceuticals is now part of DCC Vital.

DCC Vital is a leader in the sales, marketing and distribution of pharmaceuticals and medical devices in Britain and Ireland servicing hospital, pharmacy and homecare channels, as well as specialised logistics provider in the UK through Squadron Medical and TPS.

Key Initiatives

Australian healthcare industry Data Crunch

Quantifying the benefits of accurate data in an electronically enabled supply chain

by **Dr Caroline Chan,** RMIT University

and **Mark Brommeyer,** NEHTA

Abstract

The Australian healthcare industry data crunch was commissioned by industry under the auspices of the National E-Health Transition Authority (NEHTA) Supply Chain Reform Group (SCRG), and developed in partnership between GS1 Australia, the Medical Technology Association of Australia (MTAA), NEHTA and Royal Melbourne Institute of Technology (RMIT). The report highlights the outcomes that can be gained from an in-depth study about data quality, using analysis of key business processes to identify potential benefits.

This is done by studying five scenarios within three business cases – procurement, external logistics and reimbursement of prostheses. The report identifies the benefits to all parts of the supply chain from bringing healthcare product data quality up to best practice. The aim of the Healthcare Industry Data Crunch report is to focus industry attention on the need for continual data quality improvement in healthcare [1].

Introduction

The Australian healthcare sector is a AUD$120 billion-plus growing industry [2], and with a rapidly growing population where 13.5% of residents are over 65 [3], the country can ill afford inefficient healthcare supply chain practices. The healthcare supply chain itself is complex, involving various players, with the ultimate objective of delivering the right product to the right patient at the right time. Accurate healthcare supply chain data is essential to achieve this objective.

The importance of quality product data in the Australian healthcare supply chain has been well understood for many years. As a result, data synchronisation was a primary focus in the NEHTA SCRG starting with the deployment of the National Product Catalogue (NPC) in 2006. Hosted on GS1net, GS1 Australia's Global Data Synchronisation Network (GDSN) compliant platform, the NPC uses the GS1 Global Trade Item Number (GTIN) as the primary identifier for all products at all levels of packaging.

The NPC now contains more than 300,000 records and is being used by more than 400 healthcare industry organisations operating in Australia, encompassing global and local suppliers, distributors, public and private sector hospital networks, and retail pharmacy chains. Using the NPC, suppliers have the ability to provide standardised, consistent data in an automated way to trading partners across Australia including all healthcare jurisdictions, private sector networks, wholesalers and distributors, as detailed in Diagram 1.

Diagram 1: National Product Catalogue data flows
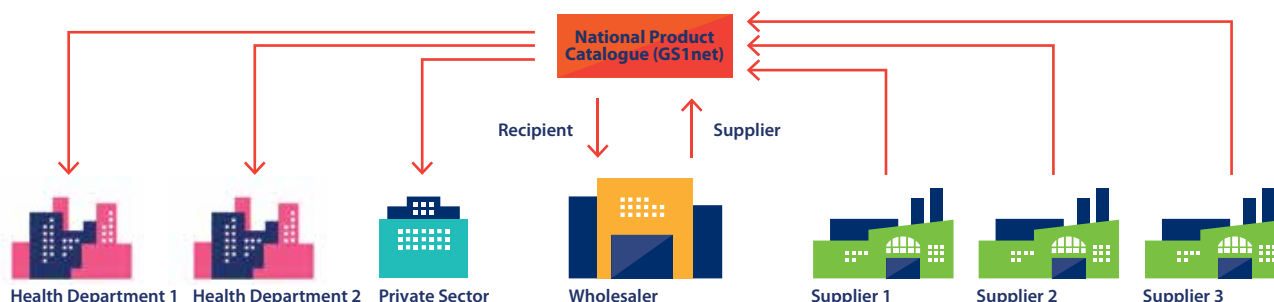
1   This case study is a summary of the full report, available from http://www.gs1au.org/industry/healthcare/

2   Refer: http://www.aihw.gov.au/australias-health/2012/spending-on-health; Note all monetary values quoted in this report are AUD

3   Refer: http://www.abs.gov.au/ausstats/abs@.nsf/mf/3201.0

Seven years after the deployment of the NPC, the healthcare sector has seen a slowly increasing consistency and accuracy of product data. As a result, the industry is well positioned for a step-change to drive data quality further.

The participants

Four Australian state government jurisdictions and three suppliers participated in the study. Participants represent all functions within the healthcare supply chain. The supplier and jurisdiction sizes varied, ensuring all organisations were represented on both sides of the trading relationship.

Study participants

Role	Approx. number of orders / month	NPC status4
Buyer	3,235	Integrated [4]
Buyer	850	Integration project in progress
Buyer	900	Integration project in progress
Buyer	12,500	Integrated
Supplier	4,500	Data loaded
Supplier	47,000	Data loaded
Supplier	3,500	Data loaded

These organisations currently trade with each other to varying degrees, as detailed in Diagram 2. Each buyer represents up to 20% of their supplier's total sales volumes, ensuring the data crunch analysis and results have representative relevance.
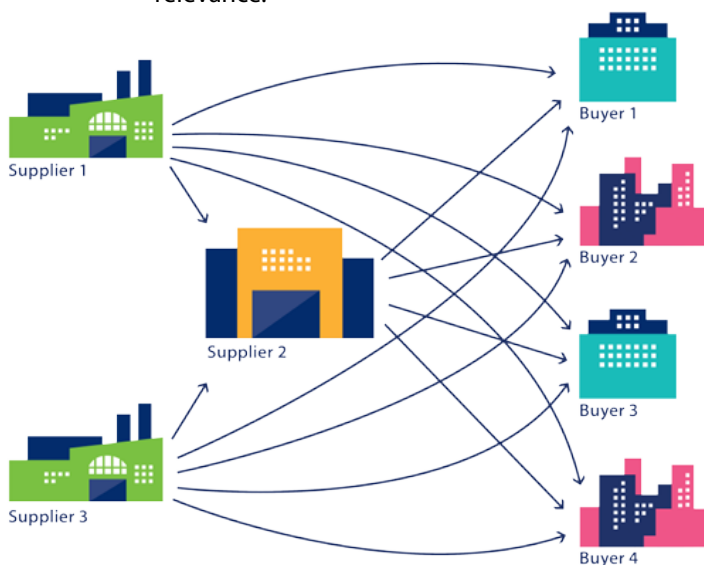
Diagram 2: Data Crunch participant trading relationships

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4 Integrated means the supplier automatically pushes electronic messages containing changed data or new products to the NPC and the buyer receives automatic updates (via electronic messaging) of this changed or new data.

Business processes analysed

Procurement
The majority of procurement activity currently undertaken in the Australian healthcare sector relies on identification of products using the vendor item code and unit of measure. The vendor item code is the supplier's internal reference number or internal product number allocated to identify a particular product. Net content and unit of measure describe the amount of the product contained in a package.

Vendor item code data was provided in all data files. Results showed a minimum match of 28.6% and maximum match of 100%. Net content and unit of measure data was also provided in all files. Matching varied from 0% to 99.6% for the two fields. Anecdotal feedback indicates this is significant improvement on pre-NPC accuracy.

Participants advised that when the vendor item code and unit of measure are used during manual procurement processes, associated data fields, such as price and description, are often double-checked. However, when a GTIN is used to identify a trade item (product) at a specific level of content (i.e. a different and unique GTIN is allocated to each product at each level of packaging, refer to Diagram 3), double checking of the vendor item code and unit of measure is no longer needed.
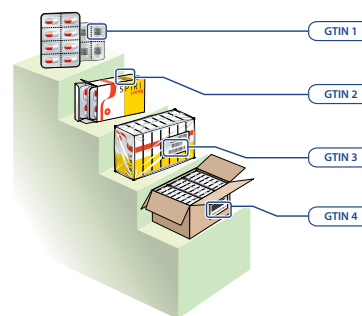
Diagram 3: Example healthcare product hierarchy

Participants indicated that their suppliers' customer service teams normally receive orders, review the total value and associated vendor item code, then divide the total by the number of items ordered to determine which unit of measure is being ordered.

AUD 8.8 million pa

Potential cost per annum of manual checking of unit of measure

Incorrect units of measure result in either undersupply or oversupply of goods. Undersupply could mean that hospital stores are unable to supply wards, which can potentially affect patient care levels. It was reported that at least once a month there is a need to place an emergency delivery order due to undersupply. This incurs priority shipping costs at approximately AUD$1,000 for each shipment to a regional location.

At a conservative estimate, considering both regional and metropolitan hospitals, catering for urgent deliveries due to undersupply has the potential to add AUD$4.37 million per annum to Australian healthcare supply chain costs.

This cost does not include the time and effort required of staff to address the initial error and arrange the urgent order. Nor does this take into account the impact of stock unavailability delaying medical procedures and impacting patient care.

External logistics

Shipping goods between trading partners requires all parties to have accurate weights and dimensions for the products being shipped. These weights and dimensions can also be used for activities such as warehouse management, optimal shipment and transport packing, imprest layout planning and Occupational Health & Safety (OH&S) compliance.

The gross weight of the product, the dimensions, height, width and depth of the trade item [5] were studied.

Findings indicated some participants could not provide product gross weight and dimensions data.

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5   Refer: GDSN Package Measurement Rules, GS1 Standards Document Issue 1.11.1, Jun-2011.

6   Refer: http://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslist.htm

Participants advised that due to lack of accurate weights and dimensions, logistics units are packed 'as best as possible', recognising that there is a lot of expensive 'fresh air' (partially filled cartons) being shipped.

Each part of the healthcare supply chain is currently measuring the same products to collect weights and dimensions data. One participant hired a weight and dimensions measuring device for one month to measure, at carton level, the top 1,000 products traded by their business. Not only did they incur significant equipment hire and staff time costs, the measurements cannot be taken as absolutely correct as measuring weights and dimensions is considered an 'expert' task.

Based on information provided by participants, the need for even 50 industry supply chain partners to independently source product weights and dimensions for the same items, adds AUD$6.98 million per annum to industry costs.

The overall labour costs across the sector would be much higher, and the logistics of moving items to measuring equipment is also complex and expensive.

Reimbursement of prostheses

As specified by the Private Health Insurance Act 2007, mandatory benefits for prostheses included on the Prostheses List must be paid by private health insurers to hospitals using these items. The Prostheses List contains the benefits applicable, and lists more than 9,000 products [6]. All are identified with a Prostheses Rebate or Billing Code (PRC), often assigned at the supplier product family level, rather than to individual products. Both public and private hospitals require a link between products (identified by their GTIN) and their PRC to ensure the correct claims.

PRC data was provided by three participants [7]. Results showed some positive matching (one file matching 41.5%), but overall results were considered inconclusive [8]. Participants indicated that accurate communication of the link between the GTIN and the PRC between suppliers and buyers is a significant issue.

The effort for hospitals across Australia in keeping the product to PRC relationships up to date manually is not only onerous but prone to error, as demonstrated by existing poor data-matching levels. All of this is done manually via phone calls from hospitals to sponsor (supplier) organisations. One participant claims their hospitals spend up to one hour per week per hospital phoning suppliers to verify codes.

> When extrapolated across the Australian healthcare sector, time to make phone calls to suppliers to clarify PRCs has the potential to add AUD$1.26 million to hospital resourcing costs. Sponsors (suppliers) will bear similar resourcing costs, so the financial impact would double.

The manual process of keeping the link between products and their PRC up to date often also means that rebatable items are not identified, leading to loss of revenue for the hospitals. One health services organisation had identified a variance between claimable products purchased and used, and those products actually claimed in the 2011– 2012 financial year. This equated to AUD$175,000 of lost revenue.

It is important to note that there are a large range of non-joint related prostheses, including stents, pacemakers and defibrillators. There would be additional savings should these product categories be studied.

AUD 8.75
million pa

Potential lost revenue from unclaimed joint replacement prostheses

Overall business implications

The five scenarios quantified in this study identified a potential total saving of AUD$30 million per annum for the Australian healthcare supply chain.

Another five areas of saving were also identified through the study but not qualified:

- Time and effort required of staff on both sides to address the initial error and arrange the urgent delivery
- Reverse logistics in the case of oversupply
- Rejection of prostheses claims due to inaccuracies, coupled with the cost of the supplier companies providing on-site staff to verify claim information
- Lost revenue from inaccurate linking of data to patient for non-joint related prostheses claims
- Stock being unavailable for patient care and associated costs of delayed or cancelled procedures

>AUD 100
million pa

Conservative potential savings from improved data quality for all business processes met by the NPC data set

The future

All participants in this project have communicated their vision for the future involving an electronically enabled healthcare supply chain.

"Prior to the NPC, the industry kept applying short-term fixes to try to resolve their product data accuracy. Each short-term fix adds hidden resource costs and complexity. The introduction of the NPC means that half-efforts and short-term fixes can't be used anymore. This ensures that best practice is implemented – a significant and positive change for the sector."

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7   It should be noted that this field only applies to a subset of products from some participants.

8   There is potential for incomplete data, as some products requiring a prostheses rebate code may not have had this included in the data files provided.

There has also been quantification of the time taken to advise trading partners of a single new product via various mechanisms, as detailed in Chart 1:
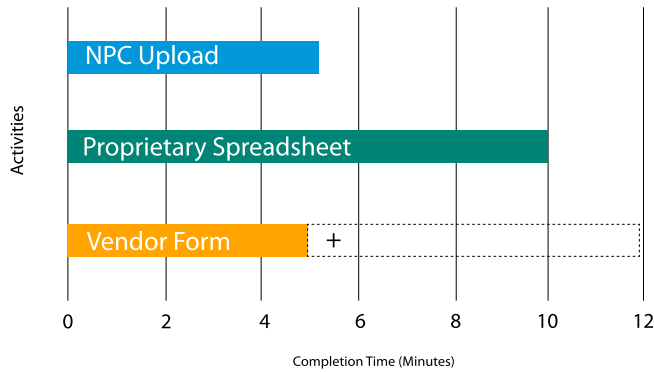
Chart 1: New product communication activities

- Uploading the same data to the NPC – initially 5 minutes to complete (including data validation); this provides communication to all key trading partners at once avoiding re-creation of data for different trading partners
- Completing a proprietary spreadsheet – 10 minutes (per buyer)

- Communication via a vendor form – 5 minutes to complete + time to email by each vendor for each customer.

The work involved in loading and maintaining the NPC, which provides accurate data to all public and key private sector buyers, is less than that for other methods of data communication.

The healthcare industry Data Crunch

The aim of the Healthcare Industry Data Crunch report is to focus industry attention on the need for continual data quality improvement in healthcare. The benefits of accurate data are confirmed via a number of scenarios. Clearly, the costs of inactivity and accepting poor-quality data as the norm are unacceptable.

> The project participants call on all Australian healthcare companies to adopt the National Product Catalogue and work together to improve product data quality for supply chain efficiency and to improve patient safety.

About the authors

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by **Steve Graham,**
Department of Health

UK Department of Health's eProcurement Strategy makes NHS more efficient and safer

Abstract

In August 2013, the Department of Health published Better Procurement, Better Value, Better Care, which established a new Procurement Development Programme for the NHS England (National Health Service). This document contains the commitment that "we will mandate, through contracts, the use of GS1 Coding in the NHS." The purpose of the Programme is to help NHS trusts stabilise their non-pay spending so that they spend no more than they currently do by the end of 2015-16, thereby realising £1.5bn of procurement efficiencies.

To ensure that the £1.5 bn new efficiencies are sustained and further improved upon, the National Health Service England (NHS) has developed an NHS eProcurement Strategy, which will establish the global GS1 coding and PEPPOL (Pan-European Public Procurement Online) messaging standards throughout the healthcare sector and its supporting supply chains. Compliance with these standards will enable NHS trusts to control and manage their non-pay spending by:

- using master procurement data
- automating the exchange of procurement data, and
- benchmarking their procurement expenditure data against other NHS trusts and healthcare providers.

> *"Everyone providing to the biggest public health-care system in the world will be required to identify their products and services using GS1 identification keys and then to share master product data with the NHS through a GS1 compliant datapool."*

Steve Graham,
Department of Health

Cover page of NHS procurement report - April 2014

Previous efforts to improve eProcurement in the NHS have been patchy due to a lack of central direction. The NHS has now mandated the use of the GS1 and PEPPOL standards by amending its standard contract to require compliance with the eProcurement strategy. It also requires suppliers to place their product data in a GS1 certified data pool through an amendment to the NHS terms and conditions for the supply of goods and the provision of services. In effect, everyone providing goods and services to the biggest public healthcare system in the world will be required to identify their products and services using GS1 identification keys and then to share master product data with the NHS through a GS1 compliant datapool.

Raising standards

To embed these standards across the NHS, a national infrastructure will be established to support the strategy, which will be interoperable with existing and future local eProcurement systems so that NHS trusts can locally select their preferred technology partners.

The national infrastructure will encompass a GS1 certified NHS datapool, which will become a single national repository of master product data. Suppliers will place their master product data into any of the GS1 certified source data pools around the world. The data required by the NHS will be brought into the NHS datapool using the GS1 Global Data Synchronisation Network.

The NHS datapool will feed master product data to individual NHS trust systems via a single national product information management system. This will enable trusts to pull the master product data they require from the NHS datapool into their local systems.

To help trusts to further improve their non-pay spending, a single, national spend analysis and price benchmarking service will also be established. This service will provide high quality expenditure data so trusts can identify opportunities to continuously improve their procurement performance.

To encourage and monitor trusts' and their suppliers' adoption of GS1 Standards, **the NHS will create a national framework for GS1 certification services. All trusts and their suppliers will be certified as GS1 Ready, GS1 Implementing or GS1 Compliant.** It is expected that suppliers certified as GS1 compliant will be at a competitive advantage in tendering and selection processes and that GS1 compliant trusts will be able to demonstrate greater efficiency as a result of adoption of GS1 Standards.

The NHS strategy draws from experience in the global healthcare sector and from the banking, manufacturing and retailing sectors. Importantly, there is nothing in the strategy that has not already been done in part somewhere, either in the NHS, in another sector or in another country. What is new, however, is bringing all these elements together in one cohesive strategy to improve supply chain efficiency and patient care through a modern, effective and efficient NHS procurement function.

These local systems will link to PEPPOL "access points", which will transfer purchase order and invoice messages between NHS trusts and their suppliers using the PEPPOL messaging standards, enabling interoperability between systems without manual intervention, thereby automating the exchange of procurement data. Recent work in Denmark has confirmed the inter-compatability of PEPPOL with GS1 EANCOM and GS1 XML.

Global outlook

The strategy also drives patient safety benefits. Providers of NHS funded healthcare, including the independent sector, must be able to electronically track and trace individual medicines and medical devices to a specific patient. Bar codes based on the GS1 Standards can be read at any point in the healthcare supply chain so that a product subject to a safety alert can be quickly located and recalled.

This strategy is an important element of a wide ranging programme of work to deliver between £1.5 billion and £2 billion of savings by the end of 2015-16 to keep a balanced NHS budget and to continue to provide a quality service for patients by protecting the front line. It will also support business to innovate, and help to make the NHS a more transparent and better place in which to do business.

"The Department of Health's new eProcurement strategy is an important element of a wide ranging programme of work to deliver between £1.5 billion and £2 billion of savings by the end of 2015-16"

Steve Graham, Department of Health

About the author

Steve Graham leads on NHS eProcurement policy at the Department of Health in England. He has developed a new NHS eProcurement Strategy for the English National Health Service that has received ministerial approval and was published in May 2014. He previously led the Innovative Technology Adoption Procurement Programme for the Department of Health, which focused on increasing the adoption of medical technologies to improve patient outcomes whilst reducing costs. The Programme was transferred to the National Institute for Health and Care Excellence.

As an MCIPS-qualified procurement professional, Steve has led national, regional and local procurement teams in the NHS, and has set up and managed several regional NHS procurement organisations. He has managed warehousing and distribution operations, and led the procurement of complex medical devices and technologies, particularly in the cardiac and disability sectors

About the NHS

Founded in 1948 and primarily funded through central taxation the NHS is the largest public sector healthcare provider in the world. With an annual budget in excess of £110Bn and employing 1.4M people, it is an integral part of the life and health of everyone in the United Kingdom. Now devolved into four independent systems covering England, Scotland, Wales and Northern Ireland, the financial pressures faced by the NHS will be familiar to healthcare providers around the world. NHS England is rising to the challenge of increasing demand for health services and increasing pressure on budgets by seeking to make the NHS more efficient and less bureaucratic by delivering better value and better care. Procurement efficiencies are a critical part of this programme.

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