GS1

The Global Language of Business

GS1 Healthcare Reference Book 2022-2023

Stories of successful implementations of GS1 standards

GS1

"
Safer, more efficient care starts with a simple scan. "

GS1 Healthcare would like to express its gratitude to the following organisations and experts who contributed to this edition of the GS1 Healthcare Reference Book:

- **Aspen Australia:** Michael Hadjion
- **Cruz Verde Columbia:** Adriana Montoya Cely
- **EFDA:** Heran Gerba Borta, Kidanemariam Gebremichael, Yeshialem Bekele
- **Galderma:** Ray Zhang
- **Geisinger Health:** Kevin Capatch
- **Hospital of Zhengzhou University:** Simeng Wang
- **Jawasoft:** Xuejing Wang (Chris Wang)
- **Johnson & Johnson:** Shekhar Nambi
- **Manchester University NHS Foundation Trust:** Mark Stevens, Jacob Parry
- **MC – Wells:** Beatriz Almeida
- **Movilitas:** Marco Steinkamp
- **NAFDAC:** Mr. John Kayode
- **Owens & Minor:** Vicky Lyle
- **Pfizer:** Nicola Michelle Barnes
- **PinkRoccade:** Remi Quak
- **TQ Pharma:** Dr. Farouq Murad
- **Zealand University Hospital:** Lars Østrup Leiding

We would also like to thank the GS1 Member Organisations (MOs) who helped facilitate the creation of this book:

- **GS1 Australia:** Margo Fraser, Marian Makram-Perkins
- **GS1 China:** Xue Wang (Shirley Wang), Flora Sue, Han Du
- **GS1 Colombia:** Orietta Paola Morales, José Mauricio Martínez
- **GS1 Denmark:** Jesper Kervin Franke
- **GS1 Germany:** Sylvia Reingardt
- **GS1 Jordan:** Areej Rawashdeh, Mai Ali
- **GS1 Nigeria:** Tunde Odunlami, Christine Oyewo
- **GS1 Portugal:** Maria Madalena Centeno, Sofia Perdigão
- **GS1 Singapore:** Andy Siow
- **GS1 The Netherlands:** Hans Lunenborg
- **GS1 UK:** Natasha Smith
- **GS1 US:** Adrian Bailey

Need to contact an MO? Visit the GS1 website: www.gs1.org/contact.

What's inside

GS1 standards are enabling the transformation of healthcare around the world

US
Geisinger Health has rolled out an inventory management system for medical devices, increasing accuracy, efficiency and productivity.

The Netherlands
Information on how hospitals are using GS1 standards and barcode scanning is being collated in GS1's Hospital Implementation Dashboard, helping share knowledge on best practice.

UK
Manchester University NHS Foundation Trust has implemented an inventory management system which helps track and trace supplies throughout the organisation. Money and staff time have both been saved, and unwarranted clinical variation cut.

Denmark
The Zealand University Hospital, on which construction is almost complete, will have an automated logistical infrastructure in place to ensure the right products are in the right place at the right time.

Germany
Acino, a pharmaceutical company, has introduced a track and trace system. Previously manual regulatory reporting and compliance processes have been automated, improving operational efficiency and traceability.

Portugal
Retailer MC has seen a 50% reduction in time spent receiving a case of products at its warehouse, and a 99% reduction in labelling errors, since introducing a labelling solution on cases and pallets based on GS1 standards.

Jordan
Teams at the Jordan Food and Drug Administration and at GS1 Jordan are working together to implement a national traceability programme for medicines. This will increase the ability to easily recall products and so improve patient safety.

Singapore
Johnson & Johnson supply chain has developed an app which enables patients to receive digital information about their medicine, based on GS1 Digital Link.

China
• The First Affiliated Hospital of Zhengzhou University has introduced new processes for the delivery, acceptance, warehousing and billing of medical devices, greatly improving stock management

• Galderma has implemented a single traceability system for its dermatology drugs and medical products, based on GS1 standards and increasing safety and efficiency.

Colombia
Staff at Cruz Verde have joined with those at GS1 Colombia to design and implement a model for product identification, with automatic and efficient information capture and transmission.

Ethiopia
Work is underway to ensure every medicine in the country has a unique identifier with a proper barcode. This will be a foundation of the country's fight against falsified and substandard medicines.

Nigeria
A successful pilot with Covid-19 vaccines has helped lay the ground for pharmaceutical traceability for all drugs by 2024.

Australia
Pharmaceutical firm Aspen has implemented a GS1 standards-based serialisation system, enabling full regulatory compliance across multiple nations.

2022: The change that remains

Almost three years on from the appearance of a novel coronavirus that swept across the world, the issue of what has permanently changed and what is returning to a pre-Covid 'normality' remains the source of considerable debate. Can the spirit of innovation which flourished in response to the early waves of the pandemic continue?

It is a spirit which has further advanced the use of GS1 standards in healthcare. Faced with unprecedented challenges, health organisations around the world have more strongly and urgently embraced the idea of tracking and tracing items and activity.

Unprecedented demand for personal protective equipment in the early waves of the pandemic, for instance, demonstrated the value of being able to more precisely manage consumables. The rollout of vaccines showed how important it is to be able to track vital medical supplies and so use them in the most effective way possible. And as antivirals become part of treating those at highest risk of serious illness from Covid-19, the need to be able to quickly identify and remove counterfeit drugs from supply chains also becomes clearer.

This year's GS1 Healthcare Reference Book therefore reveals how barcode scanning is becoming an increasingly central plank of healthcare processes in countries around the world.

Making the best use of precious resources

It includes several case studies detailing how hospitals are using GS1 standards to better manage stock.

At The First Affiliated Hospital of Zhengzhou University in China, for instance, full tracking of high value medical devices has been introduced. An updated system can automatically capture product information from GS1 barcodes, all of which can be easily retrieved and reviewed subsequently.

It's a similar story at Manchester University NHS Foundation Trust. This is one of the largest healthcare providers in the UK, providing services from 10 separate sites. Obtaining full visibility of supplies across the organisation has traditionally been very difficult, leading to inefficiencies: over-ordering of inventory was common and clinical staff had to spend many hours performing manual stocktakes. Now GS1 barcodes are simply scanned when products arrive at the hospital, and again when they are used. This provides an instant and precise picture of what equipment is available, where and in what quantities.

Supporting the development of new treatments and keeping patients informed

As this year's Reference Book reveals, GS1 standards are also supporting the effective testing of entirely new products. The pharmaceutical company Pfizer has introduced a single GS1 standard barcode to all its clinical trials products.

In the first instance, this is helping those at Pfizer's packaging and distribution centres to ensure the right products go to the right sites in the right quantities. But, in the longer term, those at the company envisage the same barcode will also be used by hospitals to help with the administration of clinical trials medicines – and even by the patients taking part in trials. The vision is that patients would be able to scan a code using their phone which would then present information about, for instance, how and when to take the drug and how to store it.

This is already happening with some commercially-available products. In Singapore, Johnson & Johnson has introduced a mobile application which patients can download. Scanning the barcode or entering the Global Trade Item Number (GTIN) links the user to a secure online system and directly to important, updated and regulated electronic product information.

Fighting falsified and substandard medications

This sort of facility can also help identify medicines that are falsified or substandard. In Ethiopia, for example, work is underway to ensure each and every medicine in the country has a unique identifier with proper barcode. Scanning this will immediately authenticate the medicine. This will make it possible to track and trace products through the supply chain, but also to quickly identify any medicine which is fake or substandard.

And in Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) has launched a five-year plan to implement traceability of all pharmaceutical products in the country. Based around scanning of GS barcodes, the idea is to be able to precisely track every medicine, from arrival in the country to administration.

Covid-19 vaccines offered the opportunity to pilot the new traceability plans, and means it is possible to see details of vaccine batches in the country – including manufacturer and expiry dates – and also to follow the journey of any batch.

Continuing along the path

In short, the accelerated innovation seen during the initial phases during the pandemic has greatly advanced the use of GS1 standards in healthcare. It is a journey not yet complete – there is more to be done, and this Reference Book hopes to contribute to that by sharing best practice and lessons from implementation. But it is increasingly true that, around the world, safer, more efficient care starts with a simple scan.

Government Initiatives

New government initiatives for monitoring and enhancing supply chains are being created. As a neutral facilitator between healthcare stakeholders and regulators, GS1 plays an important role by enabling the harmonised implementation of regulatory requirements around the world. This is in everyone's best interest, because globally consistent policy frameworks supported by GS1 standards are good for patient safety, increasing productivity, combatting counterfeits, and streamlining business and clinical processes.

Nigeria

Tracking the distribution of Covid vaccinations

Challenge

The arrival of vaccinations against Covid-19 represented a big step forward in managing the pandemic. Countries around the world have been seeking ways to easily and constantly monitor the amount of vaccine available to citizens, to ensure efficient and fair distribution of these medicines. As a relatively new treatment – with side effects and efficacy still being closely tracked – it is also important to know which batches of which medicines are where, not least in case of recall.

Approach

Nigeria already had a plan to implement pharmaceutical traceability for all drugs by 2024, with part of it involving a series of pilots focused on specific products. Covid-19 vaccines were chosen to be one of those pilots. It means that all batches of vaccines arriving in the country have been scanned on arrival and again later in the distribution chain. This means it is possible to understand exactly which supplies have been received and where they are.

A pilot based in pharmacovigilance

In September 2019, Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) launched a five-year plan to implement traceability of all pharmaceutical products in the country. Based around scanning of GS1 standard barcodes, the idea is to be able to precisely track every medicine, from arrival in the country to administration.

Four months after the plan was launched, the World Health Organisation announced a novel virus had been detected in Wuhan in China and, three months after that, declared a global pandemic. A year later, the first doses of Covid vaccine would arrive in Nigeria and – with it – the chance to implement a high-profile pilot of the country's traceability plans.

Pilots are a key part of the country's pharmaceutical traceability plan. The arrival of the vaccines, however, offered an early opportunity for a first pilot.

"As a regulatory agency in Nigeria, NAFDAC has the responsibility to ensure that we closely monitor the distribution of these vaccines," says John Olusola Kayode, the agency's assistant chief regulatory officer.

"That's especially for reasons of pharmacovigilance, because safety, efficacy and adverse effects of the vaccines are still being documented. To support our pharmacovigilance efforts, we needed to ensure that in Nigeria we had data to be able to show, real time, where the vaccines have been, where they were going.

"We also needed to be able to use the data to assist the agency in case there were regulatory recalls. Covid-19 vaccines were being distributed for the first time, and it's possible that there could be a need for us to recall one or two batches."

To meet this need, GS1 barcodes are being used. Global location numbers (GLNs) have been registered within the supply chain, which are embedded in a barcode. Scanning this barcode records the location. The barcode containing the GTIN on the vaccine batch is then scanned. This links information on that batch to the location at which it has been scanned.

"Scanning for commissioning event at national level upon arrival of the vaccines and scanning in-country for inspection of the vaccines at sub-national levels was done using the NAFDAC Ports Clearance System," explains John, "while other scanning events were done with a mobile application built on GS1 standards."

Powerful proof of concept

As data began to be collected, NAFDAC started to build a dashboard on which to display it. Now in place, it enables users to see all details of vaccine batches in the country – including manufacturer and expiry dates – and also to track the journey of any batch. "You're able to see, across the country, where the batches are," says John.

There are now moves to introduce a similar setup for drugs used to treat HIV/AIDS and tuberculosis, as well as anti-malarials. According to John, the existing Covid-19 dashboard is proving a powerful encouragement for those efforts.

"There is a lot of enthusiasm now with antimalarial commodities, because we are not just telling them we want to conduct a traceability pilot – we are also showing them what the Covid-19 vaccine pilot looked like. They are so happy and excited that with a click of a button they will know where all the batches are.

"Pilots show that traceability is realistic, it's visible, it's practicable, it's doable," he says.

Gaining support

He believes that fostering support and political will is crucial to successfully implementing a traceability project. "The commitment of the director general of NAFDAC was one of the key factors in ensuring there was engagement at the highest levels," says John.

"The importance of stakeholder collaboration throughout the supply chain cannot be overemphasised. You have to let everyone in the chain understand the reason you are doing what you are doing, and the importance of what you are doing, because you have to get their buy-in. Without their buy-in, you can write regulations and put everything in place but nobody's going to be compliant."

The Covid-19 project has helped build that support, and helped overcome some challenges. Lack of scanners meant that many of those within the vaccine supply chain had to use their personal phones to scan barcodes. That sometimes caused issues, because the cameras on those devices weren't necessarily very powerful.

But following the success of the vaccine pilot, donor agencies have agreed to provide funding. "We have two donors – the World Health Organisation and the United States Agency for International Development – that each agreed us to give 74 scanners, so a total of 148 scanners. We also have funding from The Global Fund to extend our traceability to malaria, tuberculosis and HIV drugs. They have also funded the procurement of a large number of scanners across the supply chain.

"Before the Covid vaccine pilot, much of that funding was not really forthcoming," explains John. "But when the donors saw that this was viable, they saw this was important for them to support."

About the author

John Olusola Kayode
Assistant Chief Regulatory Officer, National Agency for Food and Drug Administration and Control (NAFDAC)

John Olusola Kayode is a microbiologist, data scientist and public health professional with specialty in medical statistics who currently leads the technical team driving the implementation of traceability for pharmaceuticals in Nigeria. He is also part of the team leveraging innovative technologies to improve regulatory outcomes for NAFDAC. John is a seasoned data analyst with competence in development and deployment of data products, IT-related systems and use of field detection devices, some of which are currently deployed for NAFDAC to improve regulatory control, support product traceability and market surveillance.

About the organisation

Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) regulates and controls the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, medical devices, packaged water, chemicals and detergents. The agency was officially established in October 1992. It is made up of 14 directorates.

www.nafdac.gov.ng

Ethiopia

Laying foundations to fight substandard and falsified medicines

Challenge

Substandard and falsified medicines represent a real and growing risk to patient safety. The sheer complexity of the pharmaceutical supply chain makes it a difficult issue to stamp out. At best, any patients who ultimately use a substandard or falsified medicine will find it does not treat their condition. At worst, these products can cause actual harm.

In Ethiopia, a national study conducted in 2013 suggested 7.8% of medicines in the country were substandard, meaning they failed to meet quality standards and specifications. Various data since then has also identified products which are falsified, meaning they deliberately misrepresent their identity, composition or source.

Approach

In Ethiopia, work is underway to ensure each and every medicine in the country has a unique identifier with proper barcode. Scanning this will immediately identify the medicine. This will make it possible to track and trace products through the supply chain, but also to quickly identify any medicine which is fake or substandard.

The rise of substandard and falsified medicines

Back in 1985, the World Health Organisation (WHO) held a conference which served to draw attention to an emerging problem: that of substandard and falsified medications.

Four decades on, it is an issue which has become a significant concern. Such products are now found across the globe. Many are so-called 'lifestyle' drugs: the likes of hormones and steroids. But there are also medicines used to treat potentially life-threatening conditions, notably malaria and HIV/AIDS. That means substandard and fake medicines are a pressing concern on the continent in which that 1985 conference was held – Africa.

In Ethiopia, it is envisaged that traceability will play a crucial role in minimising the harm that can be caused by such products. In 2019, legislation was passed requiring all those involved in the country's pharmaceutical supply chain to use unique identifiers encoded in barcodes based on global standards. Scanning of these will make it possible to track and trace the journey of medicines through the Ethiopian healthcare system – and, importantly, to immediately identify any product that is illegitimate.

The legislation followed a national study in the early 2010s which suggested 7.8% of medicines

in the country were substandard, meaning they failed to meet quality standards and specifications. Marketing surveillance since has also identified some products which are falsified, meaning they deliberately misrepresent their identity, composition or source.

The importance of standards

The infiltration of substandard and falsified medicines in the country has been combatted through regulatory mechanisms. That has included federal, regional and district regulation of medicines. There have also been efforts to bolster the ability to test for poor quality medicines. The laboratories run by the Ethiopian Food and Drug Authority (EFDA) became certified under ISO/IEC 17025:2005 as able to test medicine quality.

Such efforts were important, but unable to entirely address the issue. "Using those mechanisms alone it was really difficult to identify substandard and falsified medicines. In addition, full traceability with proper exchange of information among the supply chain stakeholders is crucial," explains Kidanemariam Gebremichael, lead for the country's pharmaceutical track and trace project.

That's why pharmaceutical manufacturers are now being asked to share their product and lo-

cation master data with the Ethiopian Food and Drug Authority. This is core information such as the name of a product, strength, dosage form, expiry date, batch/lot number, its ingredients, location information of the manufacturer. The idea is to make sure that the same information is available about all medicines used in the country and, ultimately, to ensure supply chain efficiency, patient safety and data visibility.

Progressing towards full traceability

The country has already made good progress on its traceability plans since the passage of initial regulation. This has included:

• Establishing a traceability office to support the work.

• Establishing a national steering committee to drive traceability activities and oversee implementation of the initiative. Chaired by Heran Gerba, the director general of EDFA, it includes representatives from government agencies, professional associations, development partners, and supply chain stakeholders.

• Developing and endorsing laws and implementation strategies.

• Developing and issuing various guidance detailing how the traceability system will operate.

• Conducting awareness sessions with stakeholders including government, private sector and the general public.

• Developing the requisite foundational technology to support the traceability system. This includes iVerify, an application developed for the general public to be able to verify authenticity of medication. The iVerify app is linked to a database of authentic medicines maintained by the EFDA.

• Communicating with manufacturers and starting to receive master data, an important foundation for traceability.

In March 2021, the EFDA published the Pharmaceutical Products Traceability Master Data Guideline, which serves as a guide for supply chain actors and stakeholders to share master data using standardised data attributes. In December 2021, it published the Pharmaceutical Products Barcoding Guidelines and guidance on Global Trade Item Number (GTIN) and Global Location Number (GLN) allocation.

The EFDA, with support from the United States Agency for International Development (USAID) Digital Health Activity, is also developing a suite of systems to support traceability initiatives. This includes a National Product Catalogue (NPC) tool with an associated mobile application. The

tool, designed as an information repository for managing master data, acts as a single source of information. Manufacturers and other pharmaceutical supply chain stakeholders will be able to share master data on the platform, and other local systems will use the tool to ensure standardisation in product nomenclature.

The NPC tool is integrated with existing electronic regulatory information systems such as i-Import and i-Register, which will automatically feed information about drugs approved by the EFDA into the NPC.

Another system under development is i-Clearance, which will be used to manage the clearance of pharmaceuticals from the port of entry. The tool will enable manufacturers to share pre-shipment information, including GTIN, expiry date, batch/lot numbers, and serial numbers and will make this information available to supply chain stakeholders prior to the arrival of the product in Ethiopia.

Patience and communication is key

Those working on the project in Ethiopia say patience is required in implementing pharmaceutical track and trace projects. "Manufacturers are requesting time and we give them time to arrange their packaging and labelling to our requirements," says Mr Gebremichael. "We are expecting them to label their products according to our requirements, but we're not stringently going after enforcement yet because we and they need to have platforms correctly structured and in place."

Communication about what is needed and why is crucial, he says, but this can present additional challenges in Ethiopia. "In most cases, we communicate through the agents that are available in Ethiopia because most of the manufacturers are overseas and we cannot approach them directly. So we approach the local agents, the importers in Ethiopia, but most of the time they are not clear on the traceability system and there are also communication gaps between the local agents and the manufacturers."

The importance of engagement

It's why a conference held in Addis Ababa in 2018 is cited as having been vital to advancing the case for traceability. The African GS1 Healthcare Conference brought together 350 participants in all, with 24 African countries represented as well as some other nations. The idea was to share knowledge on the overall implementation of traceability and on how using standardised barcodes throughout the healthcare supply chain can improve safety.

"The local manufacturers, local importers and the other local participants were excited and felt it should be implemented," remembers Yeshialem Bekele, track and trace project coordinator at Ethiopia's Food and Drug Authority.

"It increased the involvement of the stakeholders, especially supply chain stakeholders, and they were interested to engage in the project," adds Mr Gebremichael.

"I think engagement of all stakeholders is very important in implementing track and trace. We have to engage government institutions, espe-cially those like the Ministry of Finance, Innovation and Technology and communication. Private institutions, including the manufacturers, importers, even the low-level institutions should also be engaged. The media should be engaged."

This too takes patience. It is part of the reason that Ethiopia's plan envisages seven years between the original intention to introduce a traceability system and its full implementation. But the communication that has taken place so far has led to a dedication to complete the journey.
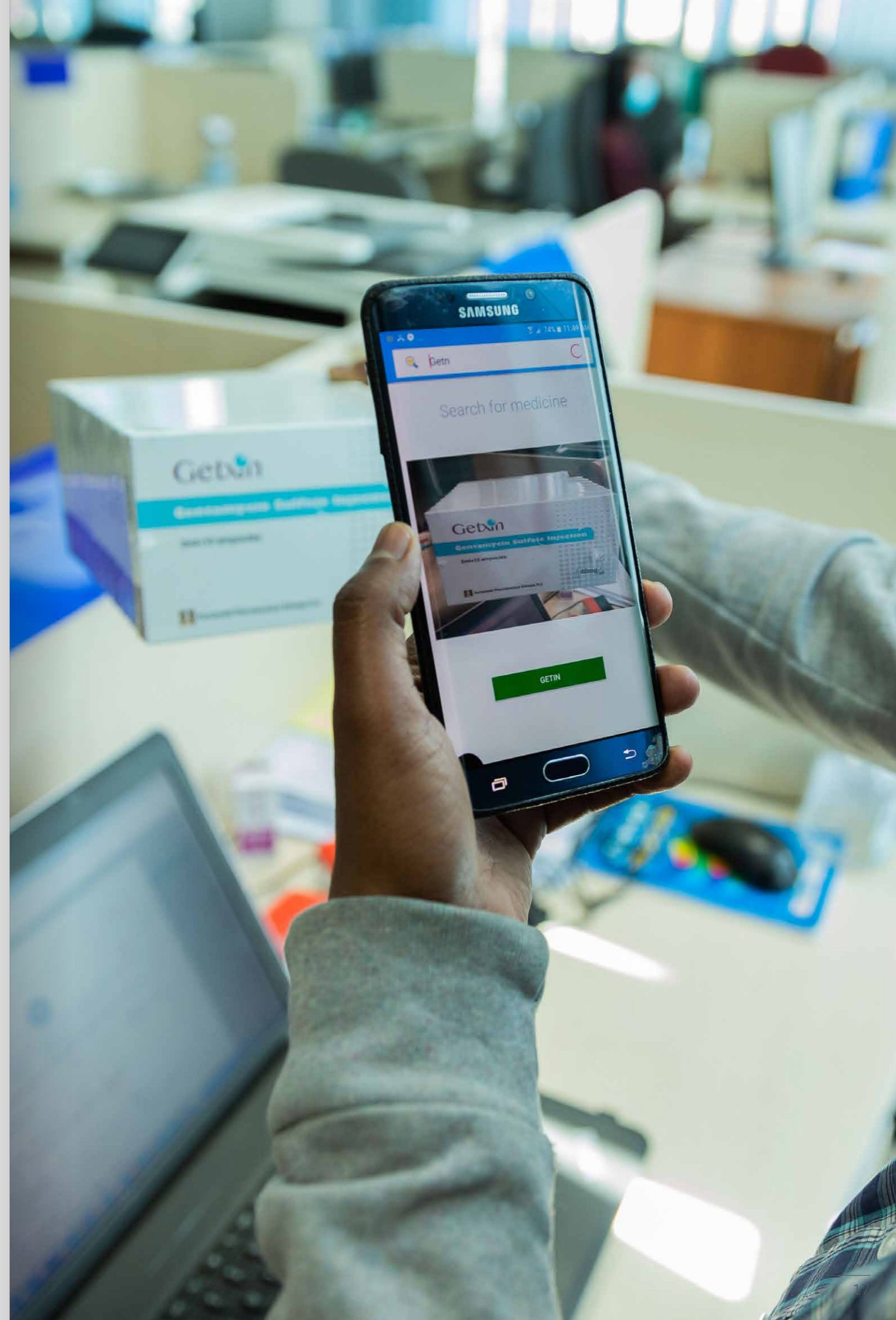
About the authors

Heran Gerba
Director General, Ethiopian Food and Drug Authority (EFDA)

Heran Gerba is director general of the Ethiopian Food and Drug Authority (EFDA). She has over 18 years of experience working in various managerial and technical positions in EFDA, including physicochemical and pharmaceutical microbiology analysis, head of a physicochemical division, team coordinator for the pharmaceutical microbiology section, good manufacturing practice inspector, and senior medicine dossier assessor. Heran earned a master's degree in pharmaceutical analysis and quality assurance and a bachelor's in pharmacy from the Addis Ababa University School of Pharmacy.

Yeshialem Bekele
Track and Trace Project Coordinator, Ethiopian Food and Drug Authority

Yeshialem Bekele has been the coordinator of the traceability unit at the Ethiopian Food and Drug Authority (EFDA) since 2018. She has 25 years of experience working in various managerial and technical positions in the health sector at federal level, and in regional health bureaus and hospitals.

Kidanemariam G/Michael
Lead for Pharmaceutical Track and Trace Project, Ethiopian Food and Drug Authority

Kidanemariam G/Michael has 14 years of healthcare experience and has held various management and leadership positions within EFDA. He is currently the track and trace project manager and the pharmaceutical regulation advisor to EFDA. Mr Kidanemariam is responsible for implementing a pharmaceutical traceability system in Ethiopia and for digitisation and strengthening of the pharmaceutical regulation systems.

About the organisation

The Ethiopian Food and Drug Authority (EFDA) is a government organisation managed by the Ministry of Health. The EFDA, at present, is the national regulatory authority in the country mandated by Food and Medicine Administration Proclamation No. 1112/2019 to ensure the safety, quality, and/or effectiveness of food and medical products. Its headquarters are in Addis Ababa and it also has seven branch offices and 15 ports of entry (POE) across the country.

www.efda.gov.et

Healthcare Providers

Healthcare institutions around the world are working to provide the best possible care for their patients, often under pressure to save time and money. GS1 standards are helping them do all this.

The Netherlands

Sharing best practice on the implementation and use of GS1 standards in hospitals

Challenge

GS1 standards are increasingly being implemented in hospitals across the globe. By scanning barcodes assigned to products, places and people, it becomes possible to precisely track healthcare processes. However, hospitals – and even different departments within those hospitals – often approach the implementation of standards in different ways. What this can mean is that those involved in these projects inadvertently 'reinvent the wheel'; failing to take lessons from previous implementations. This then reduces the efficiency with which standards are implemented and the speed at which benefits are realised.

Approach

GS1, in partnership with IT services and consulting firm PinkRoccade, has developed the Hospital Implementation Dashboard (HID). The dashboard brings together information on how hospitals have implemented and are using GS1 standards. It is being used to support knowledge sharing between hospitals, meaning teams can learn from one another on how to reap the benefits of such standards.

Introduction

In recent years, global healthcare regulations on pharmaceuticals and medical devices – which includes implants – have become increasingly aligned to global standards for product identification. Regulatory agencies and jurisdictions in countries including Australia, Canada, the United States, the United Arab Emirates and in nations across Europe acknowledge the necessity of global barcoding standards in healthcare for procurement and traceability reasons. In addition, there is growing evidence for the efficacy of barcode solutions in improving overall patient safety.

Teams at hospitals often work in isolation in implementing these standards, even though other organisations may have already successfully carried out a similar project and have lessons to share.

To avoid this, GS1 member organisations in a number of countries are advancing the Hospital Implementation Dashboard (HID). The dashboard was initially developed last year, in association with IT services and consulting firm PinkRoccade. Teams at GS1 Denmark, GS1 UK, GS1 Japan, GS1 Netherlands have already started to populate the dashboard with data from a variety of hospitals.

Sharing knowledge

"What we're trying to show is what use cases there are for scanning, whether patient scanning, medical device scanning, pharmaceutical scanning, asset scanning, you name it," explains Hans Lunenborg, sector manager healthcare at GS1 Netherlands. "My main aim is to show how other hospitals can help you in implementing; to learn from each other, network."
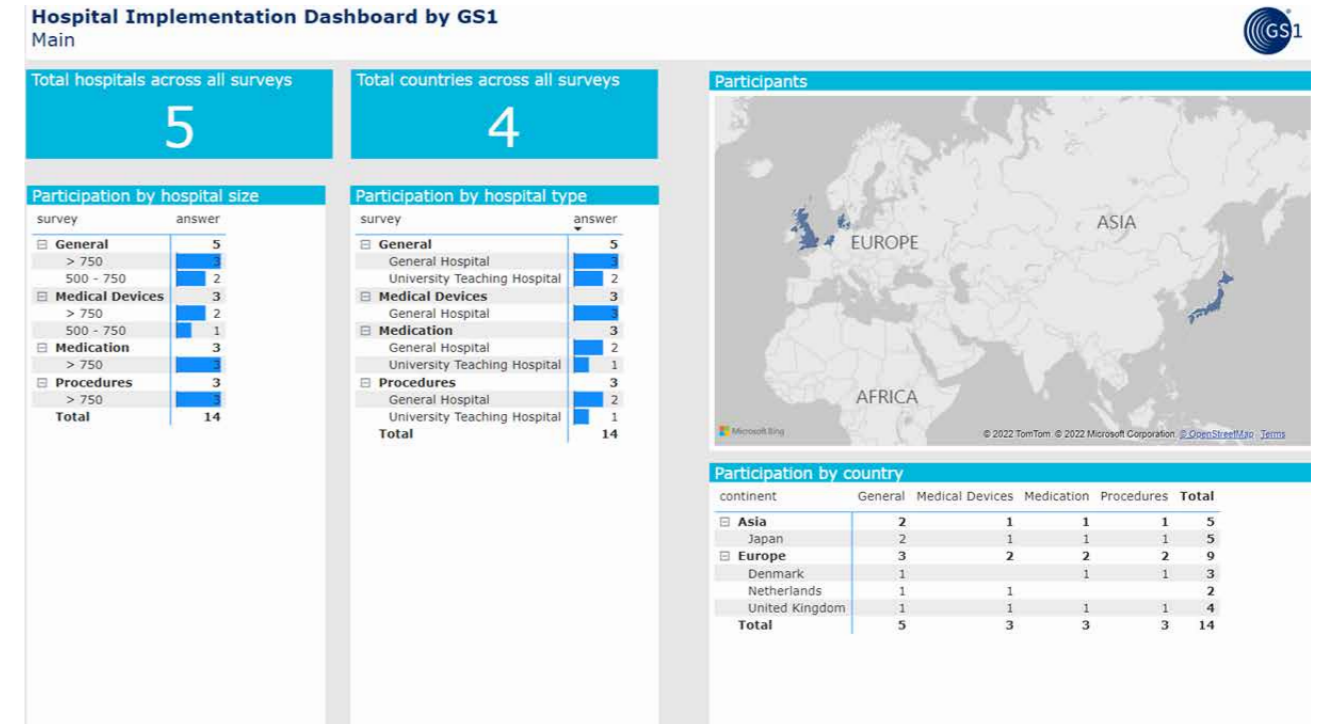
Teams at the GS1 member organisations help hospital staff to complete the relevant data, to help reduce administration burden. This means the data on the dashboard is comparable between organisations. It also provides an opportunity for GS1 to forge closer connections with hospital staff, and to lend assistance and advice on implementation generally.

With the insights the tool provides, hospitals should be able to deploy standards more broadly and more efficiently, thus enabling improvements in patient safety and increasing operational efficiency. The dashboard helps give a sense of the variety of settings in which hospitals can valuably roll out the use of GS1 standards.

Protecting the data

For now, the data on HID is only visible to staff within GS1 member organisations. This is in large part due to data protection and privacy requirements. In the Netherlands, for instance, those at one hospital would not be allowed to view data from another.

Over the longer term, the plan is to explore how to share data more widely while maintaining appropriate privacy. At present, GS1 staff use the dashboard to build their knowledge of how standards are being used and share this general information with hospitals as appropriate.

Next steps

The pilot of the dashboard in Denmark, the Netherlands, the United Kingdom and Japan has shown it can offer valuable insights into how to increase the use of barcodes in healthcare settings.

In the Netherlands specifically, there is a goal to ensure data from at least 10 hospitals has been collected and added to the dashboard by the end of 2022. Those from the team at GS1 Netherlands are going on a tour of hospitals to discuss the dashboard with healthcare workers involved in scanning processes.

In the longer term, it will also be possible to include data from other institutions on the HID – that might include, for example, laboratories and extramural institutions. Scanning barcodes is becoming increasingly important following the May 2022 passage of the European In Vitro Diagnostic Regulation (IVDR) legislation. By using the tool, it's possible to create a roadmap of
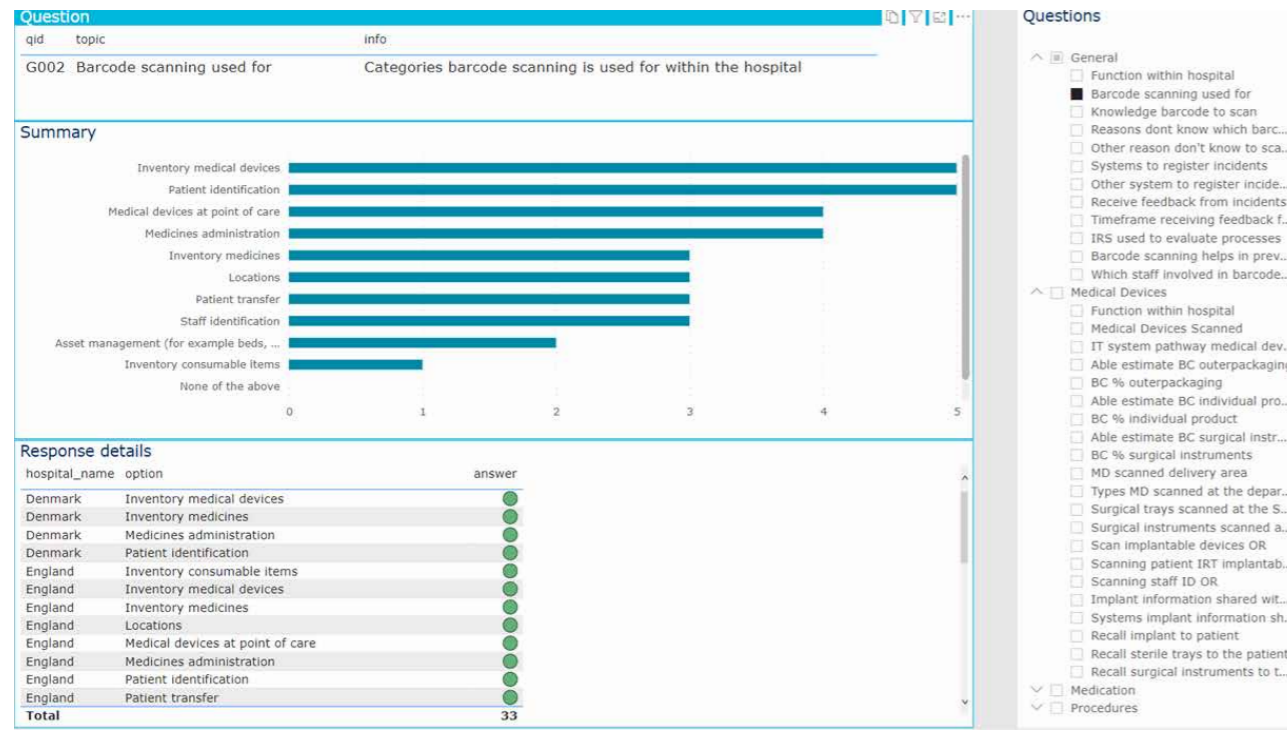
what still needs to be done in the field of, among other things, diagnostic material.

In the meantime, GS1 member organisations are keen to collect data from more and more hospitals. "I want to have this dashboard on a local level, the regional level and then on the global level," says Mr Lunenborg.

"Ultimately, we want to use the insights the HID tool provides to help hospitals, both nationally and internationally, to learn from each other's best practices."He encourages any hospital interested in sharing data to contact their local GS1 member organisation.

Conclusion

Understanding the current use of GS1 standards in healthcare – who is doing what, how, and where – should assist all those involved in the sector. It will mean lessons are shared, including on how to most effectively implement such standards.

The HID tool should help hospital teams learn from each other. In a world in which the amount of data is growing rapidly, GS1 standards can help by providing a common language to identify, record and share supply chain data. This way, important information is accessible, accurate and easy to understand. By helping hospital teams understand how best to implement standards, the HID supports the faster use of barcode scanning to improve efficiency and patient safety.

About the author

Remi Quak
Consultant, PinkRoccade Healthcare

Remi Quak works as an IT consultant in the field of quality registrations in healthcare. In this role he is responsible for the insight and management of various indicators. Within the Hospital Implementation Dashboard project, Remi is mainly involved as a link between the end users and the developers of the dashboard. His ambition is to support and improve healthcare by using the data that is already available.

Local coordination

Hans Lunenborg
Industry Manager Healthcare, GS1 Netherlands

Hans Lunenborg is industry manager healthcare at GS1 Netherlands. He and his team support providers in implementing GS1 standards in the operating room, pharmacy and other departments. They also help suppliers to comply with legislation and to exchange data easily. Hans operates in the GS1 Healthcare Leadership Team to spread his knowledge and take healthcare a step further.

About the organisation

PinkRoccade Healthcare is a provider of software solutions in the Netherlands. The business unit, Hospitals BI, ensures that hospitals have the necessary data management at their disposal. Hospitals BI has an extensive data warehouse as well as ample knowledge of quality and patient safety. Its solutions include:

• Performance monitor: Current total overview of the quality indicators in a hospital
• Datadash: Anonymise data to support the GDPR legislation
• Geniq: Complete data warehouse for the most critical flows in the hospital

www.pinkroccade-healthcare.nl

United States

## Leveraging standards for inventory visibility

Challenge

Geisinger Health, like many large-scale healthcare institutions, used manual processes to store and replenish medical supplies. These processes can be prone to error.

Solution

Geisinger made an investment in technology that uses the latest identification standards for medical devices to eliminate manual processes, beginning in areas that use life-saving implants, such as cardiac catheterisation labs.

Geisinger teamed with Owens & Minor to implement QSight®, a cloud-based inventory management system, to leverage the data in barcodes affixed to medical devices for the US Food and Drug Administration (FDA) unique device identification (UDI) rule. Geisinger can easily capture and store a product's Global Trade Item Number® (GTIN®) – the most widely used UDI standard – and other critical data with a simple scan.

Elimintate manual processes

Identification standards for medical device

Investment in the latest identification technology

Cloud-based inventory system
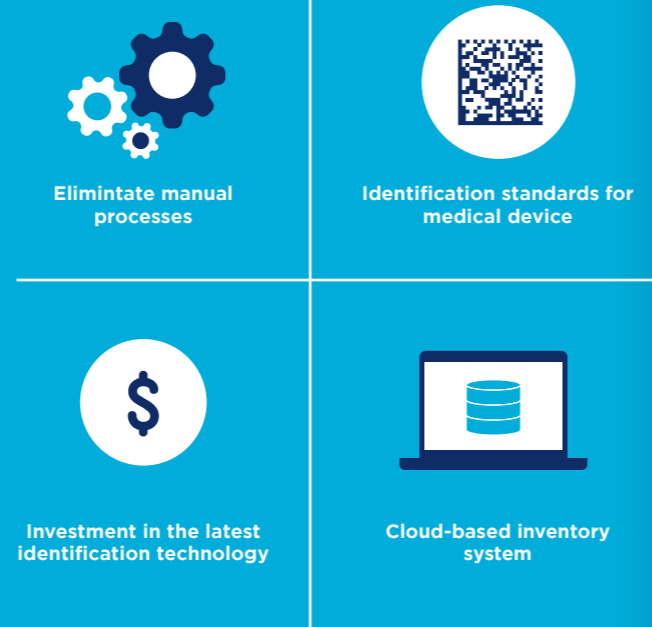
Benefits

- **Accuracy, efficiency, productivity.** Multiple clinical professionals within the healthcare system are no longer tasked with manual record-keeping rife with error. A simple barcode scan places a product into inventory. Subsequent scans track its lifecycle throughout the healthcare system, recording where and whether it is used, disposed of, returned, or recalled.

- **Profitability.** Inventory management eliminates waste, guaranteeing supplies are not over-ordered and that products are used prior to expiration. It also delivers fiscal benefits by enabling automated centralised purchasing on behalf of large institutions like Geisinger.

- **Patient safety.** Inventory management assures patients that any tissue or implant used in their treatment is readily available. It allows clinicians to interface with both the electronic medical record (EMR) and an individual's electronic health record (EHR) with detailed record-keeping for more accurate documentation.

- **Future-proofed planning & implementation.** Through its inventory management initiative, Geisinger has established a baseline for system-wide data quality that will enable future operations and initiatives, including accurate and efficient recall management and advanced analytics related to cost and patient outcomes.

Geisinger Health has been a leader in healthcare innovation, seeking solutions to modern healthcare challenges and adopting technologies in service of its patients, caregivers, students, and community. This commitment to innovation is one of the reasons Geisinger Health can boast more than a century of service to its Pennsylvania communities, and why research and consulting firm Gartner consistently ranks Geisinger in the Healthcare Supply Chain Top 25.

What truly sets Geisinger apart is exceptional due diligence in leveraging every possible capability from the supply chain. At Geisinger,

any new technology implemented to meet a challenge is scrutinised for features that can introduce efficiencies to other departments, other practices, other facilities.

"Technology right out of the box might have more capability than you initially need, but you need to create a roadmap for enabling other features that will increase the performance of the business," says Kevin Capatch, director of process engineering at Geisinger Health.

A case in point is Geisinger's comprehensive data and inventory management programme that uses increasingly critical supply chain data to drive patient safety within its areas of care. Geisinger leverages the same codes required by the US Food and Drug Administration (FDA) regulations for unique device identification (UDI) and automatic identification and data capture (AIDC) encoded on medical devices to identify products in inventory.

Pencil and paper to keyboard

"Over a decade ago, I watched as a well-intentioned cardiac catheterisation technician managed his inventory storage area using paper and pencil, then keyed his shopping list into an enterprise resource planning (ERP) system template to reorder," says Mr Capatch.

Manual processes like these were rife with potential for error and were occurring in every procedural area of the Geisinger system. Moreover, hospital technicians might be tempted to over-order or unintentionally pass over products close to expiration, costing the institution valuable resources or – worse yet – leaving staff facing an out-of-stock on a critical device needed by a patient.

And with no system to manage the dates, expirations were inevitable. "The combination of capturing information with a barcode scan and having a system that can use and act on that captured information has allowed Geisinger to turn the tide on managing expirations in our procedural areas."

"You must enforce [standards] in all disciplines; internally in your technology, in your business processes; externally with your vendor community and your solution providers."

Kevin Capatch
Director of Process Engineering, Geisinger

After this encounter, Geisinger opted to introduce technology that would eliminate manual processes governing inventory and eliminate the three "nevers" in healthcare supply chains: never run out of a critical product, never waste inventory due to product expiration, and never fruitlessly search for recalled items.

Geisinger teamed up with Owens & Minor, a global healthcare solutions company, to use its QSight® inventory management platform.

"QSight gives us product visibility from the moment a product comes into Geisinger, until it is either used with a patient, expired, disposed of, returned, or recalled," Mr Capatch says. "It brings inventory control, it brings functionality for recalls, it brings expiration management, it brings lot and serialisation control – the inherent benefits we set out to acquire by instituting an inventory management program."

A standard of supply chain care

Data standards development had been underway for a few years when Geisinger and O&M began working together. In fact, data standards development continues to this day throughout healthcare and adjacent industries. As Mr Capatch points out: "You must enforce [standards] in all disciplines: internally in your technology, in your business processes; externally with your vendor community and your solution providers."

GS1 standards – including Global Trade Item Numbers (GTINs) and Global Location Numbers (GLNs) – are the preferred and prevalent standards used by the healthcare community, pharmaceutical firms, medical device manufacturers and distributors, and are accredited by the FDA to support UDI implementation for all classes of medical devices. Some 87 percent of all UDI submissions utilise GS1 standards, which work in conjunction with standards unique to healthcare[1]. But many entities in the healthcare ecosystem have yet to adopt GTINs and GLNs, which adds a level of complexity to any inventory management effort.

"We are proponents of GS1 standards. If a vendor is on the fence, or deciding about upgrading business systems, we strongly encourage them to move to GS1 standards. Theirs are more global. It's a lot easier to interpret [GS1] application identifiers. This was an integral part in choosing our solution," says Mr Capatch.

Quality of data care

Data quality is imperative for optimal performance: it allows for seamless digital communications among systems, allows UDI data supplied by manufacturers to be used with confidence, and it powers inventory management.

"The importance of data quality is incalculable. Without clean data and a 'single version of truth' for all products coming into your system, you are hamstrung in what you can accomplish," Mr Capatch says. "That is why we benefitted from teaming up with a solution partner that made an investment in managing the item master data using standard identifiers where available, and we did not have to duplicate their efforts, just leverage them."

"When working with a new client, the first thing we do is data cleansing," says Vicky Lyle, vice president of industry associations at Owens & Minor. "We go into a [customer] department, scan each instance of every single product in that department to make sure the product exists in the global item master. In the instance where a product is not in the database, we utilise the GTIN to source the data from the GUDID [Global Unique Device Identification Database] or directly from the manufacturer's site."

Affiliates within the Geisinger system use QSight's highly enriched item master database. A scan of GS1 barcodes on any given facility's stockroom shelf will yield a product match of up to 95 percent. Once a product is added in the global item master, it is available for any customer that scans GS1 barcodes.
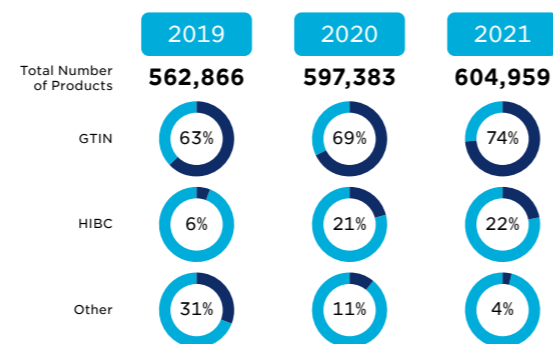
In the age of Big Data, hospitals are faced with collecting and interacting with massive amounts of data for thousands of products, most of which carry enriched attributes that go beyond manufacturers' production information. A standards-based inventory management system provides a secure repository and communications nucleus, bringing value to healthcare facilities like Geisinger needing to leverage the data in several vital ways, including patient safety.

Distribution of device identifiers in QSight®

Currently, QSight has over 600,000 stock keeping units (SKUs) in its cloud-enabled database, which is available to all customers, with 74 percent of SKUs tied to a GS1 Global Trade Item Number® (GTIN®). QSight allows for flexibility so that these alternate identifiers can be "tied" to the GS1 GTIN, when necessary, and supports the industry transition from proprietary identifiers to the standards-based UDI. QSight enhances its databases constantly when additional products are scanned by customers. And because it is cloud-based, the collective information is available to all customers as the scanning takes place, consistently recognising a product via the GTIN encoded as the unique device identifier. That the constant evolution of QSight data is shared among all users benefits everyone.

Distribution of Device Identifiers in QSight®

	2019	2020	2021
Total Number of Products	562,866	597,383	604,959
GTIN	63%	69%	74%
HIBC	6%	21%	22%
Other	31%	11%	4%

[1] Health Industry Bar Code (HIBC) standard is used to produce uniform data transfer for patient safety and unique device identification (UDI). An ISBT code is an international standard for the transfer of information associated with blood transfusion, cellular therapy and tissue transplantation.

> "When the standard is present, a match happens almost effortlessly. You don't have people looking at descriptions because part numbers don't matter"
>
> **Kevin Capatch**
> Director of Process Engineering, Geisinger

"That's where we're starting to see some gains in using systems that are built on GS1 standards," Mr Capatch says. "We can use standards to figure out what items we all have in common."

The expansiveness of GS1 standards provides a means of capturing specialised attributes that are crucial in tissue and bone implant procedures. A hip replacement appliance must include the side of the human body into which it is intended for use, for instance; tissue grafts may require information taken from a visual inspection or preparation of the biological material. The need for greater specificity to populate medical practice records as well as individual medical histories is satisfied using standards-based inventory management.

From dock to doc

The enterprise resource planning (ERP) system that purchases products is primarily quantity-based. ERP confirms receipt of a carton of 12 stents, for example, but does not note the 12 individual serial numbers or differing expiration dates. By making the connection via QSight between the quantity received and the enriched data connected to those products, visibility and inventory integrity is achieved.

For example, in the cath area, the receiving dock creates a delivery ticket using ERP data; QSight matches the ERP data to the requesting specialty inventory analysts in the cardiac catheterisation lab expecting delivery of the stents. Each stent is scanned individually – each with its own serial number along with its lot number and expiration date. From that moment on, Geisinger has visibility into each stent until it is used on a patient, is expired, or is returned to inventory because it was ordered in a case but a larger stent was needed during the medical procedure.

A scan of the barcode will have captured everything about that stent and Geisinger's inventory will reflect every step in the lifecycle of that product. ERP uses the incoming shipment's GTINs to match the source to the order placed. The cath lab personnel capture critical attrib-

utes – size, expiration data, lot/batch number – in addition to the unique identifier to link back to the manufacturer in the event of a recall. And nurses who scan the individual stent's barcode in the procedure room allow the metadata to automatically populate the electronic medical record (EMR) and an individual's electronic health record (EHR).

Although the industry continues to advance in standards adoption, exceptions still arise, so support of master data management by allowing for the recognition of products that are new to Geisinger is crucial. Product procurement can bypass ERP systems entirely, for instance. Stents from a new supplier might be ordered directly by the specialty department needing them (ie. the cath lab). When the stents arrive at the point-of-care, the lab technicians scan the GS1 barcodes for supporting data for the devices, effectively introducing them into the master data system and placing them in the inventory management system.

Not only will the stents automatically be recognised at every subsequent juncture when scanned within the hospital, the data is automatically available within QSight. Its cloud-based model of data distribution then makes the data available to all customers simultaneously, consistently linking the same unique identifier or GTIN encoded in the barcode to the product.

"When a barcode scan matches, almost everything else happens effortlessly," Mr Capatch says. "You don't have people looking at descriptions, and other identifies on the packaging, you know the product is in your catalogue, and can become trackable in inventory."

The proof is in the inputting

Data quality is imperative for optimal Geisinger has successfully integrated inventory management fully into all non-OR procedural areas – including the catheterisation (cath labs), electrophysiology, and interventional radiology labs.

"The cath lab was first, but we didn't have to do a lot of convincing after the first implementation: 'That's so much better than my paper-and-pencil grocery list inventory system!' and 'I don't have to worry about expirations anymore because the system tells me you're 90 days out on this item' were common reactions from other departmental areas within Geisinger," says Mr Capatch. "Departments lined up. It was virtually self-marketing for the next installation."

While the three initial practice areas are using QSight for all product tracking, inventory management, and data governance, Geisinger is now concentrating on bringing the operating rooms managing tissue and implants into full utilisation.

"ORs are a little bit more challenging. You're getting into a world where the identifier may have been on the packaging of the non-sterile item, and that identifier gets removed when it's put into the sterilising case. So we are figuring out how we're going to capture data on things like non-sterile implants," Mr Capatch says.

He adds: "Without end-to-end inventory management, a nurse in the OR might have to employ multiple tools to scan multiple implants, which is not just bothersome, it's potentially dangerous. And without standards, none of the automatic identification of products is possible."

> "Without end-to-end inventory management, a nurse in the OR might have to employ multiple tools to scan multiple implants, which is not just bothersome, it's potentially dangerous.
>
> And without standards, none of the automatic identification of products is possible ."

Kevin Capatch
Director of Process Engineering, Geisinger

> "We are proponents of GS1 standards. If a vendor is on the fence, or deciding about upgrading business systems, we strongly encourage them to move to GS1 standards. Theirs are a more global and it's a lot easier to interpret [GS1] application identifiers."

Kevin Capatch
Director of Process Engineering, Geisinger

Conclusion

Enabled by standards-based master data and the advanced data analytics available in QSight, Geisinger can drill-up to gain supply chain insights or drill-down to the case level to get the information the healthcare system needs, aggregated in the way it chooses.

Geisinger's extensive inventory management efforts provide the underpinning for a system-wide recall process. The system's assimilation of GS1 standards facilitates visibility – not just into individual products in inventory but into the network's entire operations by supplying reliable parallel comparisons. This is the kind of analytics needed to improve performance, which in the case of healthcare, can have profound consequences such as improved patient safety, expense management, and reimbursements. Standards open the door even wider: multiple hospitals can team up to conduct lifesaving research into health outcomes when apples-to-apples analyses are achieved through standards. These forward-thinking initiatives on Geisinger's roadmap will all be enabled by leveraging data made available by scanning the barcodes on medical devices.

About the authors

Kevin Capatch
Director of Process Engineering, Geisinger

As a director at Geisinger, Kevin uses Lean-Thinking to focus on magnifying the value and eliminating the waste in the core value streams. Kevin's evangelistic leadership style and manufacturing-based operational expertise, combined with his information systems background, has allowed him to stimulate new thinking and promotion of process redesign in Geisinger's supply chain information and care support delivery systems. He is a foundational leader with the Healthcare Transformation Group (HTG), the Community Advisory Board (CAB) for GS1 US Healthcare, and now serving on the Board of the newly formed Partnership for DSCSA Governance (PDG). He is active on multiple GS1, AHRMM, ASCx12, and C4SCS workgroups. He has completed AHRMM's Healthcare Supply Chain Leadership Institute and completed his master's degree in project management.

Vicky Lyle
Vice President, Industry Associations, Owens & Minor

Vicky Lyle is the vice president of industry associations at Owens & Minor, where she leads the company's involvement with industry and trade organisations worldwide. She currently serves on the executive board for Professional Women in Healthcare as the chair for the 2021 and 2022 term. She also serves on the board of Healthcare Supplier Diversity Alliance and serves on the Council of Supplier Diversity for Health Industry Distributors Association. Vicky has been with Owens & Minor for 35 years, contributing business and technical expertise across all facets of the supply chain.

Prior to her current role, she served as operating vice president service line strategy, a role in which she was responsible for the development of the inventory solutions platform along with service line operations, implementation and support.

In her time with the company, she has led several strategic cross-functional projects, including business acquisitions, distribution centre strategy, and the creation of Owens & Minor's Third Party Logistics (3PL) service offering.

Vicky holds a BA in business administration from Averett University, where she graduated Magna Cum Laude.

About the organisations

Geisinger Health is a healthcare system located in central Pennsylvania serving one million people. Founded more than 100 years ago by Abigail Geisinger, the system now includes 10 hospital campuses, a health plan with more than half a million members, a research institute and the Geisinger Commonwealth School of Medicine. With nearly 24,000 employees and more than 1,600 physicians on staff, Geisinger boosts its hometown economies in Pennsylvania by billions of dollars annually.

www.geisinger.org

Owens & Minor, Inc. (NYSE: OMI) is a Fortune 500 global healthcare solutions company integrating product manufacturing and delivery, home health supply, and perioperative services to support care through the hospital and into the home. Owens & Minor drives visibility, control and efficiency for patients, providers and healthcare professionals across the supply chain with proprietary technology and solutions, an extensive product portfolio, an Americas-based manufacturing footprint for personal protective equipment (PPE) and surgical products, as well as a robust portfolio of products and services for patients managing chronic and acute conditions in the home setting. Operating continuously since 1882 from its headquarters in Richmond, Virginia, Owens & Minor is a 140-year-old company powered by more than 20,000 global teammates.

www.owens-minor.com

China

Improving medical device management through the use of GS1 standards

Challenge

Managing medical devices, particularly high value ones, is a core part not only of modern hospital management but of ensuring the quality and safety of services. At China's The First Affiliated Hospital of Zhengzhou University, in common with all large hospital facilities, it could be a challenging process. There was a desire to ensure staff were using devices as safely and appropriately as possible; to ensure accurate billing; and to guarantee the traceability of medical devices.

Approach

The hospital implemented new processes for the delivery, acceptance, warehousing and billing of medical devices. These processes were supported by GS1 standards and linked to the operation effective system (OES, used for the management of medical devices) and the hospital information system (HIS, used for billing).

30 minute
reduction in billing time

97%
increase in accuracy of registered information on the use of medical devices

Medical device traceability for both the hospital and governmental supervision department

Improved risk management

Sterile medical devices are sent to the operating room

Introduction

Today, Chinese hospitals must meet new regulations on the supervision and administration of medical devices and on the use of unique device identification for such products. These regulations include strict requirements on traceability.

Traditionally, the management of medical devices in major hospitals has been very challenging. Firstly, submitting, reviewing and summarising the required information about medical devices in clinical departments is inefficient and error-prone. Secondly, many different medical devices are used and products cannot be tracked across the full pathway. Thirdly, the lack of full traceability of medical devices leads to quality risks. Fourthly, information is siloed with little sharing and coordination between departments. Fifthly, there is a lack of information sharing between suppliers and hospitals. Sixthly, it is difficult to oversee the credentials of medical devices and suppliers.

To sum up, the biggest difficulty is the traceability of high-value consumables and the lack of full closed-loop management of medical devices. Most

of these issues can be addressed by implementing and using unique device identification (UDI).

To overcome the drawbacks of traditional management of medical devices, reduce the cost of consumables and form an effective internal control system, The First Affiliated Hospital of Zhengzhou University has established a complete closed-loop system for the management of medical consumables, which works alongside processes in the hospital information system (HIS). It has also implemented full tracking of medical devices, verification of suppliers and devices, information sharing between hospital departments and with suppliers, and all through an entirely online process.

In July 2019, China's National Medical Products Administration (NMPA) and the National Health Commission launched a pilot programme for unique device identification (UDI). The First Affiliated Hospital of Zhengzhou University was one of the pilot sites and so began to introduce a new way of managing medical devices, based on GS1 standards. In 2022, the hospital was selected as a national UDI demonstration unit.
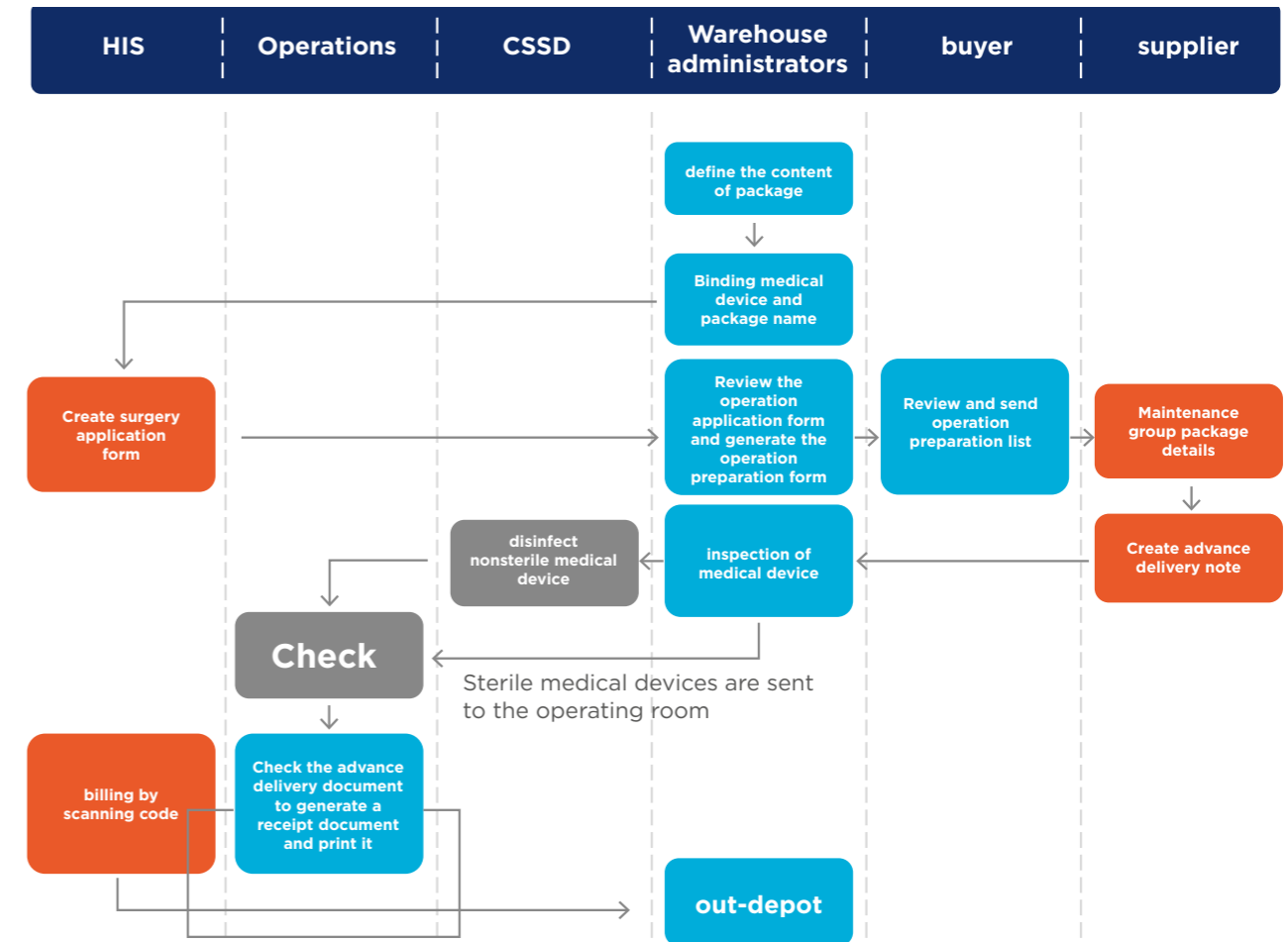
Overall process of consumable management

National regulations require medical institutions to inspect devices on purchase, which mainly involves checking whether the expiry dates and product information are consistent with the information initially supplied.

When the device is then used, clinical staff need to record additional information. In the past, manual registration was mainly used to record the production and use information of medical devices, such as manual registration, computer manual input, etc. There are various risks in manual operation, such as recording the wrong product information, billing errors and low work efficiency.

At The First Affiliated Hospital of Zhengzhou University, these processes are now automated. An updated operation effective system (OES, used for the management of medical devices) can automatically capture the product information and production information of medical devices by processing data from GS1 barcodes. The system searches the UDI database, and generates the corresponding delivery note according to the hospital order. It means all the recorded product information comes from the automatic analysis

of a GS1 barcode when the hospital purchases medical devices. When the user department records the use information, it only needs to link the user's information to the product information. This ensures accuracy and greatly reduces the time needed to record use information.

Closed-loop procurement management

Procurement is now a full closed-loop management process, from department order, warehouse checking, supplier delivery, acceptance, to final settlement. The process is similar to selecting products from an online shop, except that the clinical department can only select the medical devices they need from the bidding directory. The purchase plan is pushed to the corresponding warehouse administrator. Following approval, the warehouse administrator pushes it to the medical equipment department. The leader of the medical equipment department generates the corresponding delivery note and pushes it to the supplier after approval. If the administrator finds any errors, or if the quantity requested exceeds the department's average consumption for that item leaving the administrator with queries, he or she can reject the purchase plan.

The supplier can receive the order simultaneously via mobile phone and computer. The order contains the address of the hospital and department, as well as the corresponding name and quantity of medical devices. The supplier generates a delivery note according to the purchase order from the hospital. This is a very important step in the efficient management of medical devices. Suppliers need to fill in a lot of information when generating delivery notes, including production date, expiration date, registration certificate number. If hospitals in turn record this information manually, bit by bit, errors are likely.

The implementation of the UDI solves this problem. The hospital obtains information on devices via scanning the GS1 barcode, which automatically generates batch number, expiration date and other important information. The data is very accurate, which greatly improves efficiency.

The hospital no longer needs the supplier to manually maintain static information on medical devices but can directly scan the code to extract the information and record it in the database.

Warehouse management

The warehouse of the high value medical devices of the operating room will write off and issue medical devices according to the result of code scanning and billing to achieve zero inventory. The entry of medical devices into the secondary warehouse is a virtual warehousing. Only after code scanning and billing are completed, the only associated GS1 code products will be considered as products to be settled by the hospital.

A demonstration of the process is shown in Figure 1.

By binding the hospital billing code to the static code of GS1 (DI part of the UDI) of medical devices, billing can also be completed by scanning the GS1 barcode. This not only ensures the accuracy of billing, but also saves time. In the past, it was necessary to enter the billing code manually. When more consumables were used in surgery, it took a lot of time. Now, scanning the code reduces the time needed for billing by three quarters. In addition, the accuracy of billing has improved by nearly 90%.
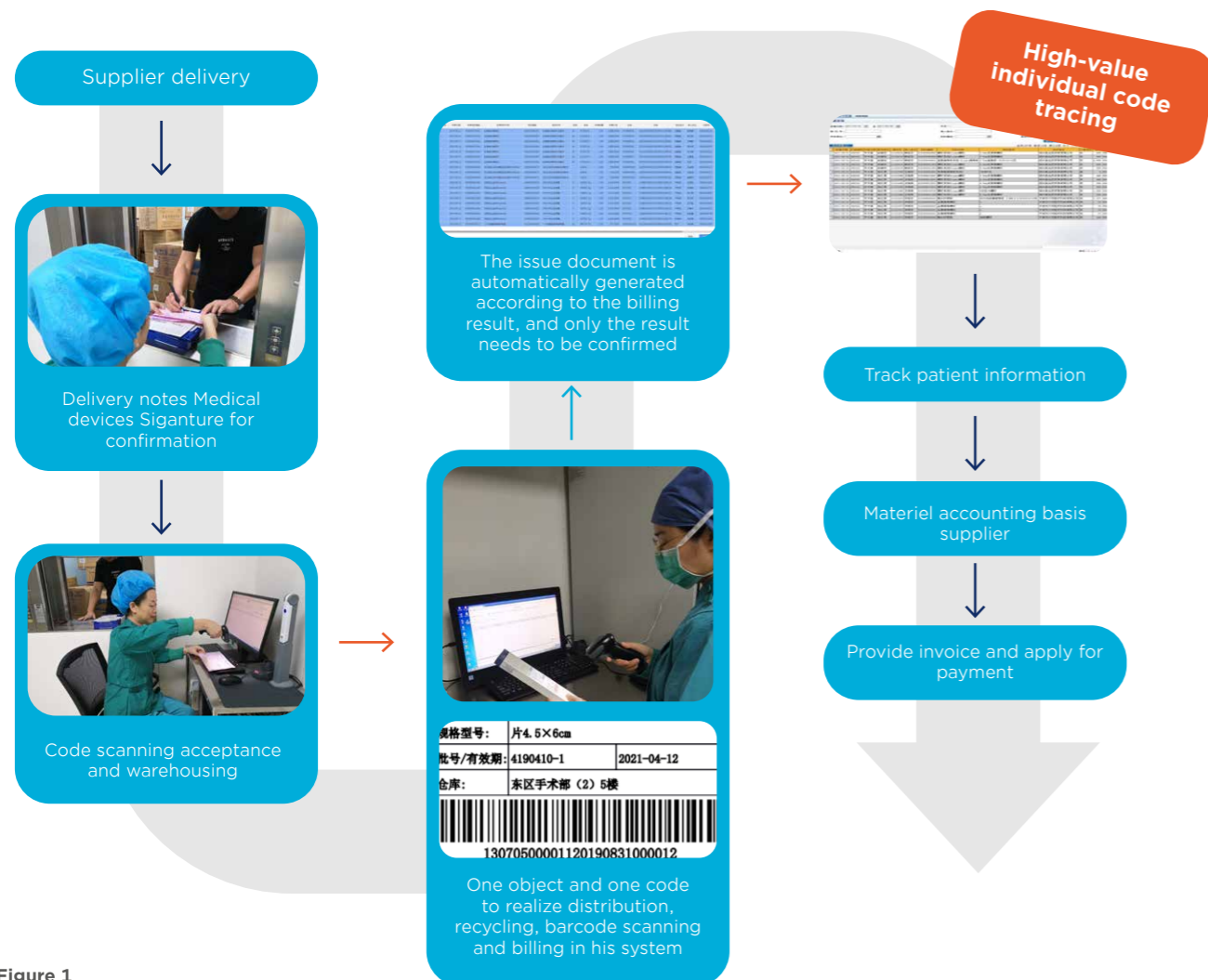
Next steps

At present, The First Affiliated Hospital of Zhengzhou University only manages class III (high value) medical devices in this way. It is hoped that government departments, medical institutions and medical device manufacturers can jointly promote the implementation of UDI, so that more medical devices can be assigned with GS1 barcodes that can be scanned.

There are plans to develop the hospital's OES to draw more information from the GS1 barcode: for instance, it could automatically store and analyse the quantity of a product, and it can scan multiple products for billing at one time by using a Serial Shipping Container Code (SSCC).

Conclusion

The application of unique identification of medical devices has improved the management of high-value medical devices at The First Affiliated Hospital of Zhengzhou University. Staff efficiency has increased, medical errors fallen, and the hospital now better meets laws and regulations in this area. It is hoped that GS1 standards can increasingly be used on medical devices, more effective information can be identified, and more departments such as food and drug administration department, customs and taxation can cooperate to create a larger data platform and promote the safe and rational use of medical devices for the patient.

About the author

Simeng Wang
Engineer, The First Affiliated Hospital of Zhengzhou University

Simeng is an engineer in the medical equipment department of The First Affiliated Hospital of Zhengzhou University, the largest hospital in China. She graduated from Macquarie University and holds a double master's degree. Simeng has four years' experience in managing medical devices, including writing the hospital's procedures in this area, and in promoting the implement of the UDI on medical devices. She is a member of several groups in the academic community on medical equipment and has been invited to speak on the topic at many meetings.

Local coordination

Xue Wang (Shirley Wang)
Engineer, Promotion Department, GS1 China

Xue Wang joined GS1 China in 2012 and has been responsible for UDI promotion since 2019. She has worked with colleagues from 47 branches to establish UDI pilots and to develop UDI guides. She took the lead in organising more than 30 national and regional UDI training sessions, covering 200,000 participants in total. Xue holds a bachelor of logistics management from Air Force Command College.

About the organisation

The First Affiliated Hospital of Zhengzhou University (hospital) was initially established in September 1928, and its predecessor was The Affiliated Hospital of Henan University Medical College. In 1958, it moved from Kaifeng to Zhengzhou and changed its name to The First Affiliated Hospital of Henan Medical College. It was renamed as the First Affiliated Hospital of Henan Medical University in 1985. In 2000, under the support of the central government, the former Zhengzhou University, Zhengzhou Technology University and Henan Medical University merged. The hospital was then named as the First Affiliated Hospital of Zhengzhou University, and also known as the First Clinical College of Zhengzhou University. In 2012, it was established as the hospital co-sponsored by the province and the Ministry of Health. In 2017, clinical medicine was selected in the national list of world-class universities and first-class disciplines. The hospital is currently the largest Level-3/Grade-A hospital in China, integrating treatment, teaching, research, prevention, healthcare and recuperation.

www.zdyfy.com/ywb

Figure 1

▶ **Watch more**

▶ **Watch more**

Denmark

Creating IT architecture for supply chain automation in hospitals

Challenge

Zealand University hospital is going to be the main specialist hospital in the Region Zealand. The hospital will be completed in 2025. With hundreds of surgeries performed daily, including many specialist treatments, and thousands of outpatient visits each day, hospital supply chains will play an important role in its efficient operation. If medical devices and pharmaceutical products are not at the right place at the right time, treatment of patients will be at risk.

Solution

The aim is to have a hospital with an automated logistic infrastructure that is agile and can be adapted to future patient needs. A well-driven supply chain must get the right goods to the right destination at the right time. This requires the skills and involvement of many different departments, including procurement, production and logistical planning. To achieve this, the hospital is implementing a transport management system that is able to receive transport requests and send transport orders to the physical transport systems through the use of GS1 standards.

Electronic identification supports workflows and strengthens security

Hospital has a high degree of automation of workflows

35 autonomous mobile robots and more than 3,000 trollies form part of the automatic flow

More than 1,200 shipments handled for the hospital each day

Introduction

When complete, Zealand University Hospital will be the main specialist hospital in Denmark's Zealand region. The new hospital is three times the size of the existing one. The aim is to have a hospital with an automated logistical infrastructure that is agile and can be adapted to future patient needs. Using GS1 standards as part of the IT architecture is an important part of achieving this.

Regional business functions for supplying, linen, medicine, uniforms, and daily goods etc. are placed outside the hospital. Most of the goods are packed in trollies before they are transported to their final destinations – for example, wards and depots. Several IT-systems have been installed to enable automated transport without human intervention. Specifically, the hospital has installed an automated goods terminal and autonomous mobile robots (AMRs). The logistical trollies have a double function as both means of transportation as well as local storage.

Background

In 2026, Zealand University Hospital will be located in Køge. Køge is the first location to accommodate an automatic supply chain in the region. The hospital building in Køge is government funded. The current budget is 4.0 billion Danish Krone.

The University Hospital will have a special role, as it will:

- Be an emergency hospital for about a third of the region's population.
- House almost all specialised treatment in the region.
- Handle research and teaching tasks at a high level.

It is the region's vision to take advantage of technological opportunities including:

- A high degree of automation of workflows.
- A coherent patient pathway supported by logistics.
- Electronic identification to support workflows and strengthen security.

Facts about Region Zealand

837,225 inhabitants in **7,274 km²**, **17 municipalities** (April 1, 2020).

General areas: The health area, The social and special education area, Regional Development

The Danish healthcare system is universal and based on the principles of free and equal access to healthcare for all citizens. The healthcare system offers high-quality services, the majority of which are financed by general taxes. The state holds the overall regulatory and supervisory functions in health and elderly care. The five regions are primarily responsible for the hospitals, the general practitioners (GPs) and for psychiatric care. The 98 municipalities are responsible for a number of primary healthcare services as well as for elderly care.

In 2007, Denmark implemented a public sector structural reform that included an administrative and political reorganisation of the health sector. This provided an opportunity for a large-scale modernisation of the Danish hospital infrastructure to ensure access to state-of-the-art health services and improve quality across the entire health system. A cornerstone in this modernisation is the Super Hospital Programme.

IT-systems make the daily work at the hospital possible

With hundreds of surgeries performed each day, including many specialised treatments, and thousands of daily outpatient visits, hospital supply chains will play an important role in the efficiency of the hospital. If medical devices and pharmaceutical products are not in the right place at the right time, many treatment of patients will be at risk. To have an efficient, well-driven and transparent supply chain at the University Hospital in Køge, IT-systems supports automation and business functions.

The number of shipments throughout the regional supply chains has been estimated, and the likely activity in each area of the hospital. This information has then been used to plan for physical transport systems such as autonomous mobile robots. As the new University Hospital will be ready step-by-step – it will progress gradually up to 2025 – the patient activities will also scale-up stepwise. Likewise, the use of the new automation systems will scale-up as needed.

The final output is estimated as visible in the table below – data box:

| Data box description	
Estimations based on benchmark from other regional hospitals in Denmark	
Goods categories to be handled in the hospital – manually and automatic	20 +
Number of shipments per day to be handled in the hospital	1200 +
Number of trolley variations to be handled in the hospital – manually and automatic	20 +
Total number of trollies to be part of the automatic flow	3000 +
Number of autonomous mobile robots in 2026	35
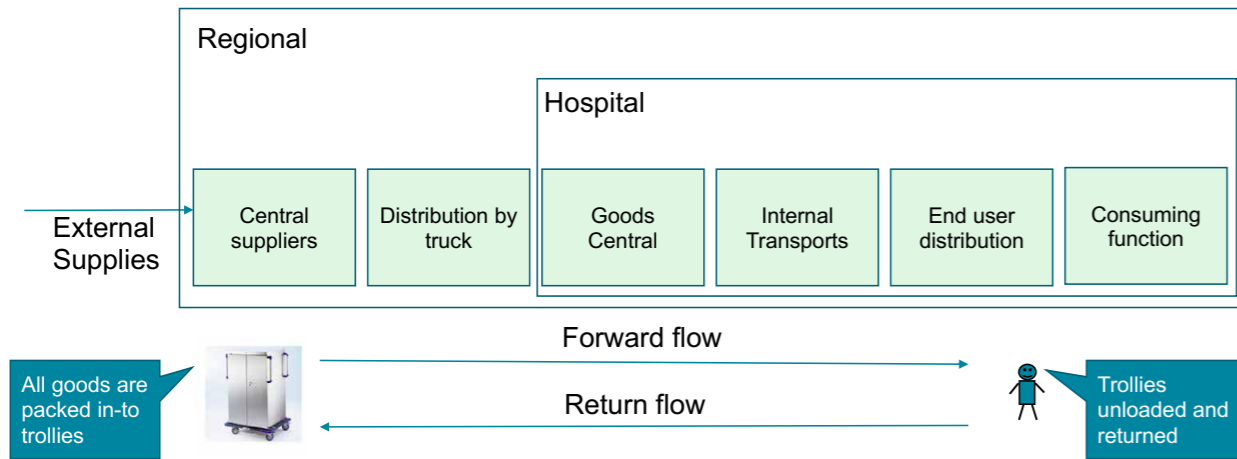
Figure 1: Future Regional supply chain, goods must be pack into trollies transported though all links and returned to the central supplier. Hospital refers to the physical location that hosts the business functions goods central, internal transport, end use distribution and consuming functions. Central suppliers are placed outside the hospitals. Trollies are transported from these central suppliers by truck to the goods terminal.

The future regional supply chain

Central regional suppliers such as warehouse and laundry acquire, produce and distribute goods to the hospital. These functions are responsible for the right goods being available in the right quantities and right places. Shortage of goods will be reported to these central suppliers.

The hospital is striving towards a push supply chain by using third party and fourth party logistics strategies – opposite to the existing pull-method. The major game changer is the movement of the decoupling point in the existing regional supply chain: the monitoring and ordering of goods is moved from the hospital ward staff to the logistics experts and the central suppliers. The other game changer is the major support for a higher level of controlled IT and information sharing infrastructure at a regional level.

However, there is no one best-fit supply chain strategy. A suitable supply chain strategy will be adopted based on needs and product type. Over time, the entire physical flow will find its best way of preventively building and re-building an overall regional supply chain based on capacity management – whether lean, agile or leagile.

Figure 1 above is a conceptual illustration of the automated supply chain.

The key points in the flow are:

1. Trollies are packed with goods and their destination registered.

2. The shipment's Serial Shipping Container Code (SSCC) is linked to the trollies' identification (Global Returnable Asset Identifier - GRAI), for both forward and return flow.

3. A goods category is assigned to the shipped trollies to manage the distinction between medicine, linen etc

4. Shipment, trollies, goods category, destination (consuming function) and sender (central supplier) is registered and printed on paper and attached to the trollies. This dispatch advice is used by the service personnel either when manually distributing the trollies after arrival or in case of errors where the information is not accessible through IT systems.

5. The actual content, the goods, is registered by the sender in the sender's system. This packing list can also be printed and added inside the trollies for the convenience of the receiver.

Business functions, automation and IT-systems

On one hand, each business function must be able to manage and perform their tasks; on the other hand, the supply chain must be efficient, well driven and transparent. To achieve this, each business function has an IT-system for local control that receives instructions from an overall IT-system that controls the shipments. The local IT-system manages the physical transport. The overall IT-system manages the logistics, a so-called transport management system. This deals with the planning, execution and optimisation of

the movement of the trollies. It covers incoming, outgoing and internal flows. It is making sure the shipment is compliant and proper documentation is available.

Figure 2 outlines business functions in the regional supply chain, the level of automation and IT-systems necessary to achieve automation. As mentioned above, the figure distinguishes between the logistic IT-system , also known as the transport management system, responsible for the supply chain as a whole and the physical transport IT-systems, each responsible for a part of the supply chain.

The region purchased physical transport systems for each business function and the transport

management system for the overall control of the automated supply chain. This decouples the logistics concerns and the automation concerns. This has two advantages, firstly, the transport management system can support the business steps as defined in the Core Business Vocabulary (CBV). This specifies the structure of vocabularies and specific values for the vocabulary elements to be utilised in conjunction with GS1 Electronic Product Code Information Services (EPCIS) for data sharing. Secondly, well defined interfaces between the transport management system and the physical transport IT-systems eases the replacement of existing systems and the introduction of new ones.

Figure 2: The figure outlines business functions, type of automation and IT-systems necessarily to achieve automation.

IT-systems and their interaction

The transport management system must be able to receive transport requests and send transport orders to the physical transport systems. To do this, it must receive adequate information when relevant events happen – the physical transport systems must send alerts when trollies arrive at the hospital, arrive at the destination, and when trollies are picked up from the stations. The GS1 EPCIS standard already supports most of these events through the CBV. This standard enables the physical transport systems to share information about the physical movement and status of the trollies as they progress thoughout the supply chain. So far, only transport request and transport order are added in the vocabulary customised to the automated supply chain.

Figure 3 show the initial implementation (first transition) of the IT architecture. The user registers the transport in the transport management system via a web interface, which then creates a commissioning and returns an identification of the transport for the user to enter in their warehouse management system (or equivalent). Alternatively, the two systems can be directly integrated, sending transport requests without the web interface. Currently, the fleet management system for trucks is not included, but can be included if beneficial at a later stage. In addition, the distribution from the trollies arrival station to the consumer is currently provided by service personnel but could potentially be replaced by dedicated robots at a later stage, freeing up staff for other tasks.
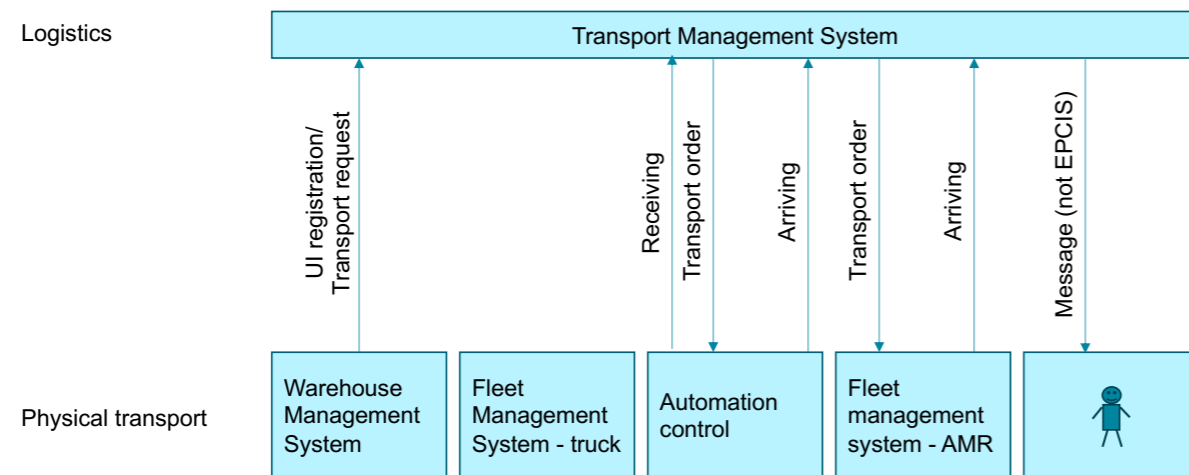
Figure 3: Use of GS1 EPCIS events in the IT architecture currently implemented. The figure is a simplified for illustration, it does not show all events and flows.

Challenges

It is helpful to specify sequence diagrams for all types of flows – in-bound, out-bound and internal – to ensure a strong and well understood interaction between the software systems. These diagrams show both of the IT systems, robots, stations and certain user interfaces. The diagrams are currently finalised in cooperation with the IT-system suppliers, who have acknowledged them as a good tool for precise specification.

For optimal planning across all types of flow, capacity management has to be implemented in the transport management system. This will require balancing planned transports with non-planned. The planned transports are registered before trollies are inserted into stations, whereas the non-planned are not. This is not a trivial problem. It requires planning, forecasting and prioritisation to be built into the transport management system.

	Data category	Description	Standards	
Categories of Data in the 'Share' Layer of GS1 standards. Table 2-2 in EPCIS implementation guide v 1.2	Master Data	Data, **shared by one trading partner to many trading partners**, that provides descriptive attributes of real-world entities identified by GS1 Identification Keys, including trade items, parties, and physical locations	GDSN	
	Transaction Data	Trade transactions triggering or **confirming the execution of a function within a business process** as defined by an explicit business agreement (e.g., a supply contract) or an implicit one (e.g., customs processing), from the start of the business process (e.g., ordering the product) to the end of it (e.g., final settlement), also making use of GS1 Identification Keys	GS1 eCOM XML	
	Visibility Data	Details about physical or digital **activity in the supply chain** of products and other assets, identified by keys, detailing where these objects are in time, and why; not just within one organisation's four walls, but across organisations.	EPCIS	Logistics control
Added by author	Automation	**Automation** and control of physical handling off goods and their transport.	PACKML, MQTT, OPC-UA	Physical transport

Figure 4: Automation is usually realised using standards that are real-time such that the state of moving parts is known near-immediately. In logistics, however, the events of interest are from minutes or even days apart.

Standardisation

Supply chain automation requires both standards from the logistics domain and the automation domain.

The use of GS1 standards plays a central role in the IT architecture. Modifications to the GS1 CBV standard are implemented to achieve this.

The GS1 standards are able to create the merge between the business processes and the execution systems (eg. AMRs) – thereby GS1 standards can cover and support the whole stack for supply chain concerns but for the automation part a different set of standards are used. In figure 4 some examples of such standards are shown in the bottom row.

Conclusion

Controlled management of the supply chain supported by automation gives better opportunities to streamline, increasing productivity and efficiency. At University Hospital Zealand, an IT infrastructure has been built through which the logistics IT-system and the physical transport IT-system are separate but closely communicate. GS1 standards have supported this since they provide a business terminology (CBV) and predefined syntax (EPCIS) for IT system vendors to follow.

About the author

Lars Østrup Leiding
Enterprise Architect, Region Zealand

Lars has 17 years' experience in enterprise architecture. He works within interoperability, change management and standardisation. Lars is engaged in strategic initiatives for the region, creating a modern health sector and developing agile solutions for its hospitals. He holds an MSc in physics and computer science and is TOGAF (The Open Group Architecture Framework) certified. Lars would like to express thanks of gratitude for the inspiring corporation with colleges that made this article possible. Especially thanks to Gulshan Akhtar Din, Troels Werner Christensen, Martin Andersen, Frank Thomas Hansen and Lisa Dalum for knowledge sharing and feedback.

About the organisation

Region Zealand safeguards tasks, services and interests for a total of 821,000 citizens. The wide range of services is spread out across 22 cities in the region. Region Zealand is a politically governed institution, and it performs two main tasks: regional development and an operational enterprise in the area of healthcare and social affairs. Every year around one million outpatient treatments are completed and 190,000 patients are treated in the region's hospitals. The Regional Council consists of 41 directly elected members, who are elected for a four-year period. Region Zealand's vision is to create the best framework for sustainable growth and quality of life for its citizens.

United Kingdom

Harnessing GS1 standards to reduce unwarranted clinical variation

Challenge

Manchester University NHS Foundation Trust's (MFT) is one of the largest healthcare providers in the UK, with 10 separate sites. Obtaining full visibility of supplies across the organisation has traditionally been very difficult, leading to inefficiencies.

Approach

Challenged to become more efficient and reduce procurement costs and product waste, MFT decided to implement an inventory management system (IMS) to improve stock control across the organisation.

The IMS can hold Global Trade Item Numbers (GTINs), enabling tracking and tracing of supplies throughout the organisation.

Via the IMS, the materials management department can track all inventory from purchase through to usage. This has improved stock control for expired products or recalls, so reducing wastage, and also improved patient safety.

Nearly 3,000 individual implants captured in just one year amounting to almost £1M

Product recalls processed in minutes instead of days or weeks

One day a week saved for every senior radiology nurse – time back to patient care

Reduced unwarranted clinical and cost variation between surgical procedures

Introduction

Product traceability is a fundamental part of any safe and effective healthcare system. From supply chain through to the patient pathway, the benefits lie in the ability to accurately trace products from the point of manufacture to the point of care or use. This is an important patient safety requirement, but also helps to drive efficiencies and reduce waste.

Manchester University NHS Foundation Trust (MFT) is the largest acute NHS trust in the UK, delivering care to more than 750,000 local people. As the single biggest provider of specialised services in the north west of England, and with 10 different hospital sites making up the trust, achieving full visibility of inventory can prove challenging.

At eight of these sites, responsibility for supply and demand falls to the materials management department. The team was challenged to be more efficient and reduce procurement costs across the sites under its remit. Traditional routes had been explored, such as sourcing cheaper products and finding smaller product quantities to reduce wastage, but the trust needed to find alternative ways to maximise efficiency.

The drivers for change

Maintaining consistent supply levels largely relied on regular stocktakes often conducted by theatre staff, or notifications from teams if a product could not be located or had run out of stock. This was particularly challenging for high-priced items where the risk of overordering had significant cost implications.

Without real-time inventory data available, it was difficult to accurately forecast product usage. The lack of stock visibility sometimes resulted in products being wasted because they had expired. In addition, it was hard to trace product use and link an item to the patient at the point of use. This added to the complexity of product recalls.

It was also hard to be confident in the exact costs attributed to a particular procedure for a particular patient (so-called patient level costings) and it was even harder to compare those costs for different consultants across the trust's multiple sites.

So in 2014, when the Department of Health and Social Care published the NHS eProcurement Strategy for England, MFT took the opportunity to optimise its procurement infrastructure and implement a new system to improve stock control across its hospital sites.

Centred on enhancing transparency, driving efficiencies, and reducing waste throughout the supply chain, the government strategy promoted the adoption of GS1 and PEPPOL standards to automate the NHS's purchase to pay activities. GS1 Global Trade Item Numbers (GTINs) were required to uniquely identify products and PEPPOL standards to place orders using electronic data interchange (EDI) directly with suppliers via the PEPPOL network.

A blueprint for trust-wide IMS rollout

MFT needed a new inventory management system (IMS) – one that would be capable of holding GTINs and associated information for products supplied to and used by the trust. After reviewing several options, the trust secured Genesis Automation's full inventory system to operate across all relevant sites.

The Genesis system tracks medical devices and inventory from purchase through to usage and offers patient safety benefits with functionality that alerts users to out of date stock or product recalls. It also has significant reporting capability. This makes it possible to use the system to monitor data and establish trends, understand the costs for every procedure performed within theatres, and to explore the costs of unused or discarded products.

To capture inventory usage and patient-level information costings in real time, the trust needed to capture product data – via the GTIN – directly at the point of care/use so it could be fed into the IMS. To do so, MFT chose to introduce barcode scanning technologies as part of the rollout. Items needed for a procedure are scanned at the point of use to update the live inventory. Product information such as expiry date, lot/batch number, and serial number is held in the system along with stock levels and minimum stock thresholds.

To be sure this process works, the materials management team aims to ensure all products supplied into the trust have a GTIN, making a conscious effort to avoid any items without a valid GTIN.

As well as scanning products before use, the patient ID is captured (via the wristband using the GS1 Global Service Relation Number, GSRN), the staff and surgeon ID, and the time. This means staff can build a full picture of all procedure details for traceability and for analysis.

Initially, the system was implemented as a three-month trial at Royal Manchester Children's Hospital. This was later extended to 12 months to gather data to test the reports to determine patient-level costings. The initial focus was on a couple of specialties which commonly use high value items because this made it possible to best assess the benefits of the new setup. Eventually the project expanded into 16 theatres, expanding to every speciality over a 12- to 18-month period.

Cultural change

The system implementation was one part of the shift to traceability, but it also required a cultural change for the clinical teams. Staff needed to consistently adopt real-time scanning in theatres. The idea was initially met with some resistance as staff were concerned about the time it would take to scan each item at the point of use. However, the product availability data, the reports, and time saving benefits provided the incentive to adopt this new working practice.

Real time inventory data meant staff in the materials management department could better understand what products were being used on a regular basis. Minimum stock thresholds were set up in the Genesis systems to enable automatically ordering once levels were low. This removed the need for manual stock takes by theatre staff.

Subcommittees with lead surgeons were set up to determine what data would be most valuable to which members of staff – for some it was financial benefits; for others, it was patient safety focused. This was then used to generate reports with the information that staff wanted, not what the team thought might be needed.

The benefits and results

1. Product availability, forecasting, and waste reduction

At a cost of almost £1M in inventory, MFT captured nearly 3,000 individual implants through scanning. As well as being able to see what is being used where, it is possible to highlight any areas where there may be potential cases of over-consumption of products.

Automated stock replenishment has reduced the risk of items not being reordered in sufficient time – lowering the risk of them being out of stock when needed for a procedure. This decreases the number of cancelled surgeries and prevents delays to patient care.

The materials management team also monitors expiry dates on a six-month rolling basis and prompts clinical staff to use certain stock before expiration. This has helped the trust to reduce the volume of product waste.

2. Patient safety and product recalls

All locations of inventory held in the IMS have GS1 Global Location Identifiers (GLNs) assigned to them. With lot/serial numbers and expiry dates also stored, product recalls are now processed in a matter of minutes instead of several days or weeks.

Genesis syncs all the item usage into the electronic patient record (EPR) every minute, so the information is available to clinicians in near real-time. If a product recall is issued, a search can be performed in the IMS to identify the product, stock levels, and the location of the stock, so items can be quickly removed from circulation. If already implanted into a patient, it can be recognised in the EPR so the patient can be identified and notified within minutes. Any potential risk of harm can be prevented for others.

3. Unwarranted clinical variation

Tracking product usage has enabled the materials management team to benchmark procedure costs across each of the relevant trust sites. MFT has now standardised kits for most procedures. This means there is less variation in the items used, so eliminating any cost differences. Standardising equipment has also made it easier to share stock between theatres in the even t of shortages.

4. Releasing staff capacity

Staff no longer need to conduct manual stocktakes to ensure consistent supply levels. Instead, Genesis' reporting function allows for reports to be generated at the touch of a button. Interfaces have been set up between

Figure 1

Genesis and various internal and external trust systems – GHX, the trust's cataloguing systems which ensure product process are always up to date, and NHS Supply Chain, to share accurate procedure cost information.

Instead of manually sourcing the relevant information to send via email each week, the procedure reports with product usage and costings can be generated with ease. In MFT's radiology departments, senior nurses would previously spend every Friday producing these reports which can now be done within minutes. This has saved a day's worth of time each week for every senior radiology nurse which can instead be spent on direct patient care.

Figure 2

Embedding traceability throughout the trust

By scanning GTINs in theatres, staff at MFT now have greater insight into product usage, enabling the reduction of waste and releasing clinical time. The trust is also better equipped to monitor supply and demand, to reduce unwarranted clinical variation, and crucially to trace products through to point of use/care, creating an even safer environment for patient care.

The intention is to continue rolling out the IMS and patient-level costing to areas that do not yet have it. Beyond this the project will centre on asset management – tracking medical equipment throughout the trust. The pilot of this will start with high-cost equipment with a view to tracking other key moveable assets such as beds and trolleys. As part of this, staff are seeking to map all remaining locations in the trust using GLNs, so making it possible to accurately track equipment to any location in the organisation.

"We will use it [this data] to drive standardisation in thoracic surgery as well as to measure the financial impact of introducing new procedures when we link in with data such as length of stay and complications for example.

I can't tell you how long I have been waiting for this level of quality data!"

Mr Felice Granato
Consultant thoracic surgeon and trust specialty training lead

About the authors

Mark Stevens
Head of Purchase to Pay, Manchester University NHS Foundation Trust

Mark Stevens has worked for Manchester University NHS Foundation Trust for more than 25 years in a number of procurement roles. He currently manages a team that provides a modern and fully integrated purchase-to-pay service including an accounts payable function. With over 100 staff, it is one of the largest and most developed such teams in the country. Mark became a member of the Chartered Institute of Procurement and Supply in 2005 and is currently undertaking a master's degree in leadership. He has spoken at numerous conferences, including the GS1 UK Healthcare Conference, on the importance of developing supply chain management in the NHS.

Jacob Parry
Scan4Safety Senior Development Manager – Procurement and e-Commerce, Manchester University NHS Foundation Trust

Jacob Parry has more than five years of experience working for Manchester University NHS Foundation Trust and currently occupies the role of Scan4Safety senior development manager. In this role, he manages a team that is responsible for the maintenance and upkeep of the trust's inventory management system, as well as the roll out of Scan4Safety initiatives to various departments within the trust. He is studying towards a professional diploma in procurement and supply and has a passion for using technology and data to drive better patient care.

About the organisation

Manchester University NHS Foundation Trust (MFT) is one of the largest acute trusts in the UK, employing more than 28,000 staff. It is the main provider of hospital care to approximately 750,000 people in Manchester and Trafford and is the single biggest provider of specialised services in the north west of England. MFT was formed on 1 October 2017 and since then has been responsible for running a family of 10 hospitals across six separate sites, providing a wide range of services from comprehensive local general hospital care through to highly specialised regional and national services. From 1 April 2020 a 10th hospital – North Manchester General Hospital – joined the wider family of MFT hospitals, creating a single hospital service for Manchester. MFT is the lead provider for a significant number of specialised services including breast care, vascular, cardiac, respiratory, urology, cancer, paediatrics, women's services, ophthalmology, and genomic medicine.

www.mft.nhs.uk

Healthcare suppliers

Responsible for the medicines and medical devices needed at all levels of patient care, manufacturers need to make sure they are doing this as safely and accurately as possible. Using GS1 standards helps to ensure they know where products have come from, where they're going, and that they are safe for use.
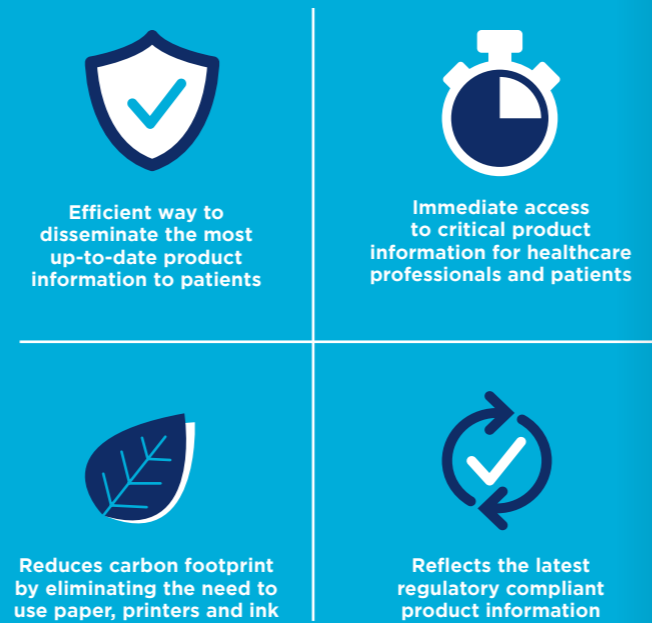
Singapore

Using an GS1 Digital Link-based app to give patients up-to-date information about their medications

Challenge

There is an increasing societal expectation of, and demand for, quick and easy digital access to information. Healthcare is no exception. Yet in many instances the primary source of sharing information with patients about medicines is a paper patient information leaflet which can quickly become out of date and which is often discarded with the medicine packaging.

Approach

Johnson & Johnson Supply Chain has developed a solution which enables patients to quickly receive information about their medicine, digitally. It's based on the GS1 Digital Link standard, integrating a network of systems to provide accurate and up-to-date information.

Efficient way to disseminate the most up-to-date product information to patients

Immediate access to critical product information for healthcare professionals and patients

Reduces carbon footprint by eliminating the need to use paper, printers and ink

Reflects the latest regulatory compliant product information

Developing a digital solution

The healthcare industry is on a digital journey. Expectations are high and the desire for rapid access to information and on-demand healthcare intensifies daily. There are numerous milestones being achieved along the way with solutions that have the power to affect every aspect of business, from manufacturing, distribution and operations to the customer experience and patient care.

In 2020, Johnson & Johnson Supply Chain started developing a digital solution that would advance the way patients and healthcare professionals access key product information. This solution needed to be standards-based and enable interoperability throughout the industry digital ecosystem.

Using GS1's Digital Link standard as the foundation, Johnson & Johnson Supply Chain developed a GS1 standards-conformant resolver to link GS1 barcodes and product URLs. They

function as connectors, providing the end user with the information they need in an electronic format.

The fundamental aim of GS1 Digital Link is to enable anyone to find answers to their questions about the thing in front of them. Traditionally, there have been large but discrete databases covering as many items as possible and then an item identifier is used to look up the relevant information. GS1 Digital Link works differently – it starts with the item, through a barcode, and points the person scanning it to one or more places with information about the product in question. Getting specific, up-to-date information is as simple as scanning a barcode.

The digital solution is designed to work with the existing GS1 barcode and Global Trade Item number (GTIN) on the product or pack without the need to add an additional barcode just to access the electronic leaflet.

"As the first healthcare company to build a GS1 Digital Link standard-based solution that is integrated with the GS1 resolver, we are excited by the numerous innovative electronic benefits we will be able to build and deliver to patients and health care professionals"

Shekhar Nambi
Director of digital identification & traceability, Johnson & Johnson Supply Chain.

A phone with an application pointed at the barcode decodes the embedded information and passes information to the GS1 Resolver. The GS1 Resolver redirects queries for the products to their resolver which shares the appropriate information with the end user.

Barcodes can be read using Scan Matrix, an easy-to-use mobile application. Once downloaded, the user can scan the barcode located on the package with a smartphone or by entering the GTIN directly on the mobile application. The user is linked to a secure online system and is taken directly to important, updated, regulated electronic product information. The combination of the Scan Matrix application and the GS1 Resolver is a digital solution that any manufacturer can leverage.

Piloting the digital solution in Singapore

In 2021, the Health Sciences Authority of Therapeutic Products Branch for Singapore published its finalised guidance on the labelling of therapeutic products. Under this guidance, pharmaceutical companies were allowed to replace physical paper package inserts with electronic patient information leaflets for products sold in Singapore.

Physical packaging inserts and patient information leaflets, while necessary to communicate important information about a product, have their limitations. They are labour intensive, difficult to read and search, and may not reflect the most up-to-date product information.

Based on Singapore's finalised guidance, the Janssen Pharmaceutical Companies of Johnson & Johnson seized the opportunity to pilot a digital solution with IMBRUVICA® 140mg tablets. This was the first Janssen prescription-only medicine to include electronic package inserts accessible by scanning the 2D GS1 DataMatrix barcode on the product box.

This launch marked a new milestone for Singapore and Janssen, as it is the first country to launch elabelling via the GS1 DataMatrix. "With this digital advancement and a foundation in place, we are able to facilitate the timely dissemination of accurate approved product information which meets new elabelling regulatory requirements, effectively and efficiently," says Shekhar Nambi. "Over the next few years, we have a localised plan to transition all Janssen prescription products in Singapore to the ePI format."
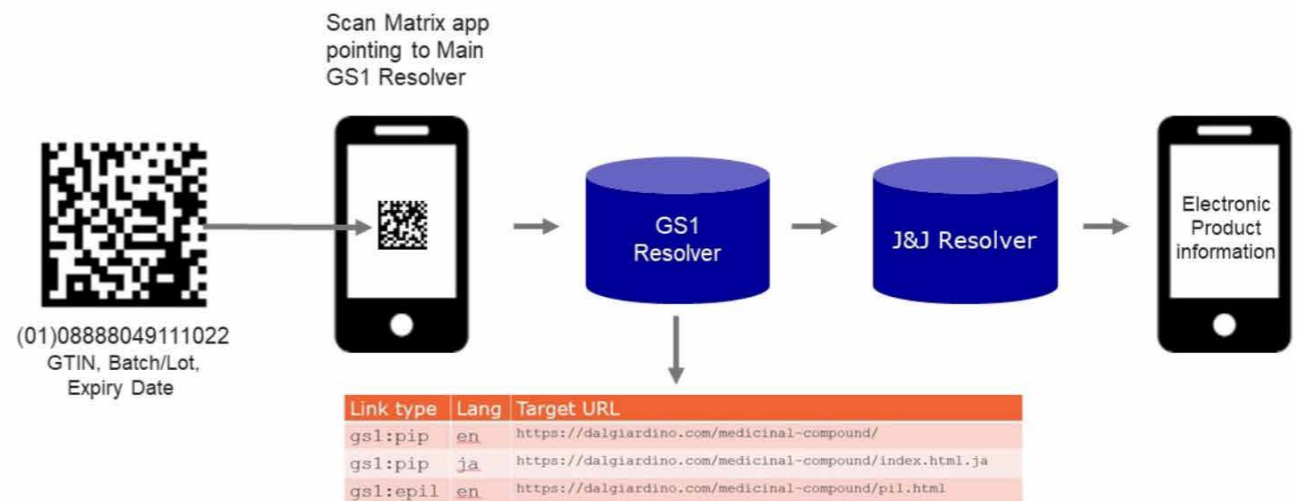
Conclusion

The adoption of a digital solution has numerous benefits and helps to abate the challenges that often occur with paper packaging inserts and patient information leaflets. It has the potential to expand operational efficiencies, improve the customer experience, benefit the environment, enhance patient care, and advance patient safety.

It's an efficient way to disseminate the most up-to-date product information to healthcare professionals – clinical use, efficacy, and safety of a product – and help them make informed decisions when treating patients. As health authority information and regulatory procedures change, companies can react swiftly and deliver eleaflets and elabelling that reflect the latest and most accurate information.

The digital solution is environmentally friendly and reduces the cost of operations by reducing use of paper, printers and ink. The patient experience improves as they can quickly gain access to the information they need. In the future end users can receive digital information in a variety of formats (document, video, audio) in multiple languages and in a format which is better structured, friendly to navigate and easy to search for specific information.

Johnson & Johnson Supply Chain's digital solution creates new opportunities for innovation and drives the company and industry towards sustainability and end-to-end digitisation, ultimately improving the customer experience and patient safety.

About the author

Shekhar Nambi
Director Johnson & Johnson Supply Chain

As a Director for Johnson & Johnson Supply Chain, Shekhar Nambi leads Digital Identification & Traceability platforms in the Asia Pacific region. He focuses his efforts on delivering digital product information and evolving technologies (Digital Link, eLabeling) and is also responsible for serialisation and traceability and unique device identification deployments. Shekhar's 24 years of experience span multiple industries including healthcare, media and entertainment and telecommunications. He has a degree in computer science and engineering.

About the organisation

At **Johnson & Johnson**, we believe good health is the foundation of vibrant lives, thriving communities and forward progress. That's why for more than 135 years, we have aimed to keep people well at every age and every stage of life. Today, as the world's largest and most broadly-based healthcare company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities, and put a healthy mind, body and environment within reach of everyone, everywhere. We are blending our heart, science and ingenuity to profoundly change the trajectory of health for humanity.

www.jnj.com

Jordan

Implementing GS1 standards to fulfill future national traceability program requirements

Challenge

The absence of a common healthcare electronic database system which enables information to be shared across supply chains, and of a national traceability programme, means efficiency and safety is sometimes affected in the Jordanian healthcare sector.

Approach

Since 2013, the Jordan Food and Drug Administration (JFDA) has been working to develop guidance on traceability and information sharing aligned to the global framework and the use of GS1 standards. By distributing this to all those involved in the local pharmaceutical supply chain, the hope is to increase compliance with established best practice and ultimately create a national traceability programme.

Patient safety and supply chain efficiency

Adoption of global best practice for regulation of the pharma industry

Fighting fraud

Increasing the efficiency of pharma registration technique

Introduction

GS1 Jordan provides services to more than 3,000 Jordanian companies. Healthcare is one of the most important sectors served, incorporating pharmaceutical companies and factories; drug stores; and organisations manufacturing medical equipment, devices and supplies.

The Jordan Food and Drug Administration (JFDA) is working with local healthcare stakeholders on the definition and on the implementation of a traceability programme.

At the local level, the programme aims to protect society by tracking medicines from manufacture to consumer, increasing the ability to recall faulty products and ensuring safety.

TQ Pharma is a relatively new pharmaceutical company, with a primary plant in Jordan. It has 65 products in its portfolio covering most therapeutic groups.

Forging relationships

As part of the development of the national tracking programme, GS1 Jordan has worked with partners to encourage the adoption of the GS1 two-dimensional barcode DataMatrix in the pharmaceutical sector. Instructions on this were agreed by a working group including the Jordan Food and Drug Authority, the Food and Drug General Authority, GS1 Jordan and many other bodies such as the Pharmacists Syndicate, the Federation of Pharmaceutical Manufacturers and Warehouses in Jordan, the General Supplies Department, and representatives of factories and companies in the pharmaceutical sector.

One of the companies working to meet the guidance is TQ Pharma. By this firm and others in Jordan using GS1 barcodes, it is hoped that all those in the supply chain will easily be able to review information on drugs – including patients.

TQ now uses GS1 standards for identifying and barcoding pharmaceutical products and continues to work to comply with legislative requirements. It uses GS1 identification keys to identify products and locations by GTIN and GLN. It also uses GS1 DataMatrix barcodes to capture data connected to all of its produced pharmaceutical products. All its production lines are equipped with 2D barcode printers.

It took around 18-24 months to introduce full compliance with standards across a packing line. There were a few separate challenges:

• Ensuring cross-site coordination for serial generation for similar product line.

• Integrating with enterprise systems.

• Optimising of existing technologies/machineries.

• Dealing with the impact of the coronavirus pandemic, including employee absences due to sickness or childcare; clients not paying their bills; reduced logistics services; reduced certification services; reduced investment.

Forging relationships

The impact of mandating the use of the GS1 DataMatrix barcode across the Jordanian pharmaceutical sector has been assessed to better understand how a national pharmaceutical traceability programme might be implemented. This has included:

• Meetings and workshops with the sector and representatives of pharmaceutical companies, factories and drug stores

• Surveys circulated through e-mail, text messages and direct communication with customers and workers in pharmaceutical companies and factories

• Direct training

The aim is to:

• Develop the national programme to track all registered human medicines manufactured inside the Hashemite Kingdom of Jordan or imported from abroad.

• Require pharmacies and hospitals to have access to computers, the internet, and an approved two-dimensional barcode reader. Link the pharmacy or hospital with the legislative and regulatory authorities supervising the tracking programme at the national level.

• Develop and update the systems used in the government procurement sector in line with what is being recommended to the pharmaceutical and healthcare sector

• Involve the private sector in establishing and implementing the national tracking programme

The companies in the sector have unanimously agreed that GS1 barcodes should be used on manufactured, registered and sold medicines in the local Jordanian market. It is taking some time to implement fully, but all are committed to doing so. The obstacles along the way for the industry may include:

• The local commercial market is not ready to read the barcode according to the instructions issued

• Changing work mechanisms in factories and across production lines

• Investment in purchasing equipment, printing mechanisms, databases for this type of barcode, and devices for validating barcode printing and checking its quality

• Integration with local systems

• Optimum use of the technologies and/or mechanisms invested in

• Challenges related to selling medicines to the government procurement department, which is not yet ready to receive products bearing two-dimensional barcodes. This has meant that, for now, there either have to be two barcodes on such products or dispensation to use a one-dimensional barcode.

Conclusion

Ultimately it is for JFDA to determine exactly how the traceability programme should be implemented and will work. But however it ultimately does, the programme will help develop the healthcare sector in Jordan and ensure it is safe and efficient.

About the author
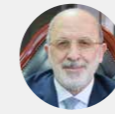
Dr Farouq Murad
General Director, TQ Pharma

Farouq Murad is a doctor specialised in paediatric surgery. His specialisation has generated a passion for establishing and managing a pharmaceutical company that selects from drug groups the necessary items in the local and foreign pharmaceutical market. He is the chairman of the board of directors, general manager and the main founding partner of TQ Pharma Industries which was launched in 2006.

Local coordination

Areej Rawashdeh
Industry Engagement Supervisor, GS1 Jordan

Areej is a consulting professional with a BSc in the engineering/industrial management field and a demonstrated history of working in the information technology and services industry. For the past four years she has been a GS1 healthcare leadership team member, representing the Middle East, Mediterranean, Africa (MEMA) region but working with colleagues across the globe. She is GS1 advisor in the fields of healthcare, traceability and other applied GS1 engagement projects. She offers technical support and consultations on traceability application in different sectors, and specialised technical support and consultations in health care sector.

Mai Ali
Registration and Customer Service Senior Supervisor/Technical Department, GS1 Jordan

Mai holds a BSc in information technology & computing and provides technical support and consulting services to help companies comply with legislative requirements on exporting to foreign markets. Mai provides technical support to the healthcare sector, running workshops for pharmacies, drug stores and medical device manufacturers. She helped prepare the study for the implementation of the traceability project with the JFDA.

Germany

Ensuring compliance with track and trace requirements across multiple regions

Challenge

Though headquartered in Zurich, Switzerland, pharmaceutical company Acino needed to ensure compliance with track and trace requirements in a range of countries around the world.

Approach

Acino selected Movilitas' full set of SAP solution services and accelerators to ensure compliance with serialisation regulations in the European Union, Middle East and the Commonwealth of Independent States (CIS). Using SAP PI/PO (Process Integration/Orchestration) as a middleware, Acino's SAP Advanced Track and Trace system was directly connected with its packaging site, contract manufacturers (CMOs) and customer systems. This connection enables the exchange of relevant serialisation data with the company's CMOs and supply chain partners. An integration with Acino's SAP ECC system was also established to exchange master and business transaction data.

**Pharma serialisation and regulatory compliance (EU FMD, CIS, Middle East) worldwide with GS1 standards**

45% faster reporting process

Successful rollout across three packaging sites located in Switzerland, Ukraine, Estonia

Implemented GS1 standard Serial Shipping Container Codes (SSCCs) for logistics and Serialised Global Trade Identification Numbers (SGTINS) for pack coding for all regions
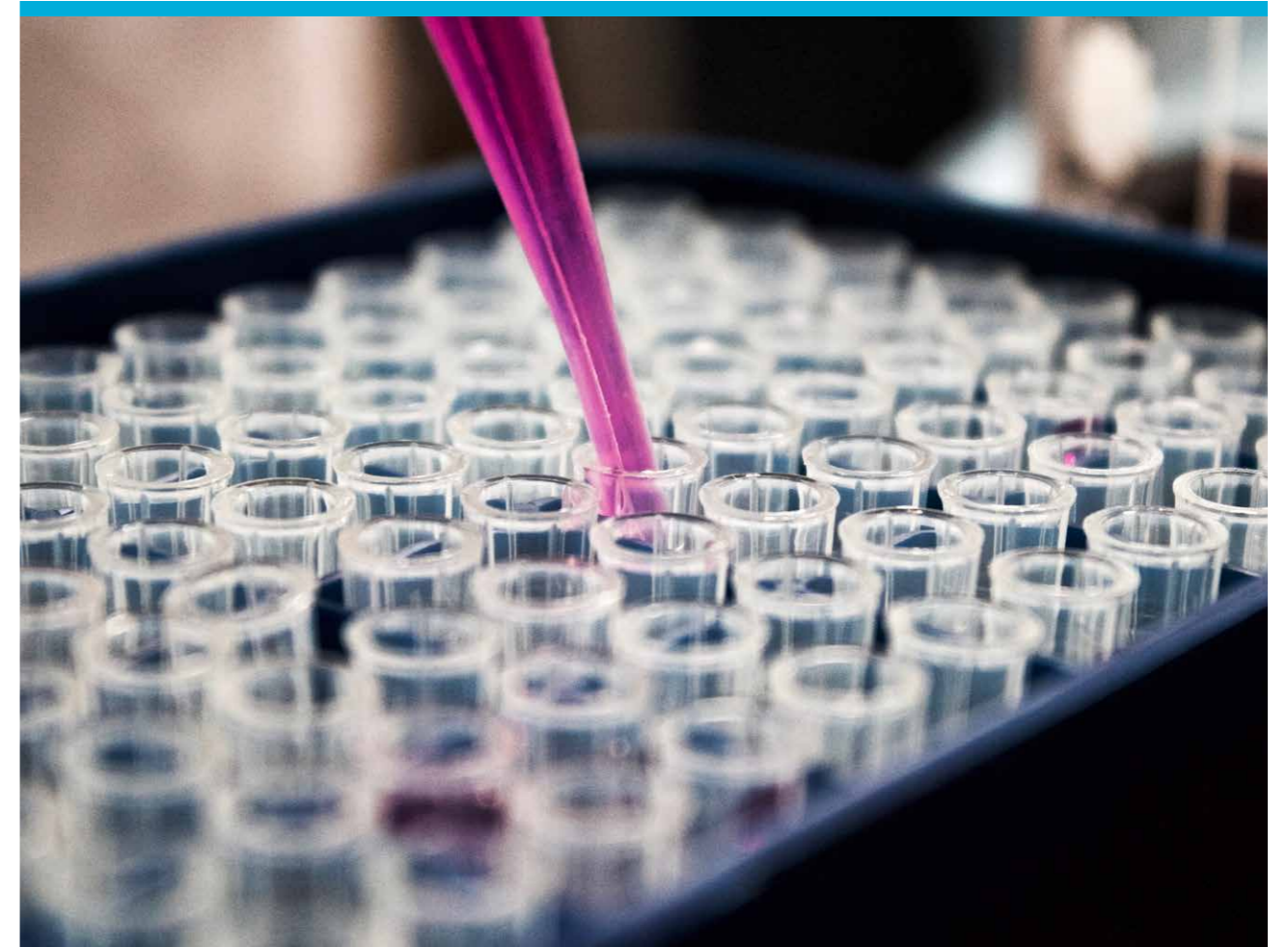
Introduction

A Swiss pharmaceutical company headquartered in Zurich, Acino develops, manufactures and delivers internationally well-proven and innovative pharmaceuticals. Focusing on emerging markets in the Middle East, Africa, the Commonwealth of Independent States (CIS) countries and Latin America, Acino is operating in some of the most dynamic nations of the world. Acino leverages its high-quality pharmaceutical manufacturing capabilities and network to supply leading companies through contract manufacturing and out-licensing.

It is necessary for Acino to understand and meet the regulatory compliance rules for each geographic area in which it manufactures or distributes products. Regulatory requirements generally range from serialisation to traceability to reporting requirements. These regulations put in place over the past few years all serve the important purpose of protecting customers and helping to reduce the rate of counterfeit products.

Understanding the need

Acino needed a solution to ensure compliance with all relevant regulations in the EU and in CIS and Middle Eastern countries. It would be necessary for any solution to integrate with external systems, enabling the exchange of serialisation data with customers and partners and ensuring Acino's contract manufacturers (CMOs) also complied with relevant regulations.

The solution also needed to enable Acino to manage internal and external serial numbers during all manufacturing processes and to efficiently handle serialised goods in their warehouses.

Selecting a solution

Acino selected Movilitas' full set of SAP solution services and accelerators. SAP Advanced Track and Trace (SAP ATTP) is the cornerstone of the solution, delivering future-proof regulatory

compliance and simplified reporting processes. Based on GS1 standards, the solution supports the company's mission to manufacture and commercialise high quality pharmaceuticals for the benefit of patients.

Implementing for success

Using SAP PI/PO (Process Integration/Orchestration) as a middleware, SAP ATTP was directly connected with Acino's packaging site, CMOs and customer systems. This connection enables the exchange of relevant serialisation data with the company's CMOs and supply chain partners. An integration with Acino's SAP ECC system was also established to exchange master and business transaction data. The company uses the GS1 standard Serial Shipping Container Codes (SSCCs) for logistics and Serialised Global Trade Identification Numbers (SGTINS) for pack coding in all regions.

The system has been integrated with Acino's warehouse and serialisation processes. A mobile solution was introduced to accelerate scanning activities and capture events at the company's warehouses.

The role of GS1 standards

GS1 standards for product identification are required to fulfil compliance with global regulations such as the European Union Falsified Medicines Directive (EU-FMD) and directives in the Middle East or CIS countries. By using standards such as SSCC and SGTIN, Acino can make sure all regions are aligned and the global supply chain is secure and resilient against counterfeits.

All systems involved in the project adhere to GS1 standards and, therefore, are interoperable. This has increased the speed of reporting by 45%, as the standards allow for an easier exchange of information.

Conclusion

Movilitas' integrator services and industry expertise with multiple country serialisation regulations enabled Acino's successful SAP implementation, delivering future-proof compliance using GS1 standards. Additionally, the company's internal manufacturing and logistics processes have been streamlined. Previously manual regulatory reporting and compliance processes have been automated. The result has been improved operational efficiency and traceability. Acino has gained greater visibility and data integrity across its extended supply chain network.

"In 2015/2016 we carried out our first successful serialisation project with Movilitas for the implementation of EU FMD. We chose Movilitas as our global strategic partner for serialisation projects and services based on their long-term industry record and profound expertise. During the project, we got to know Movilitas as a very reliable and a highly competent partner for any kind of serialisation project."

Andreas Eckerlin,
Global head SAP CC, Acino
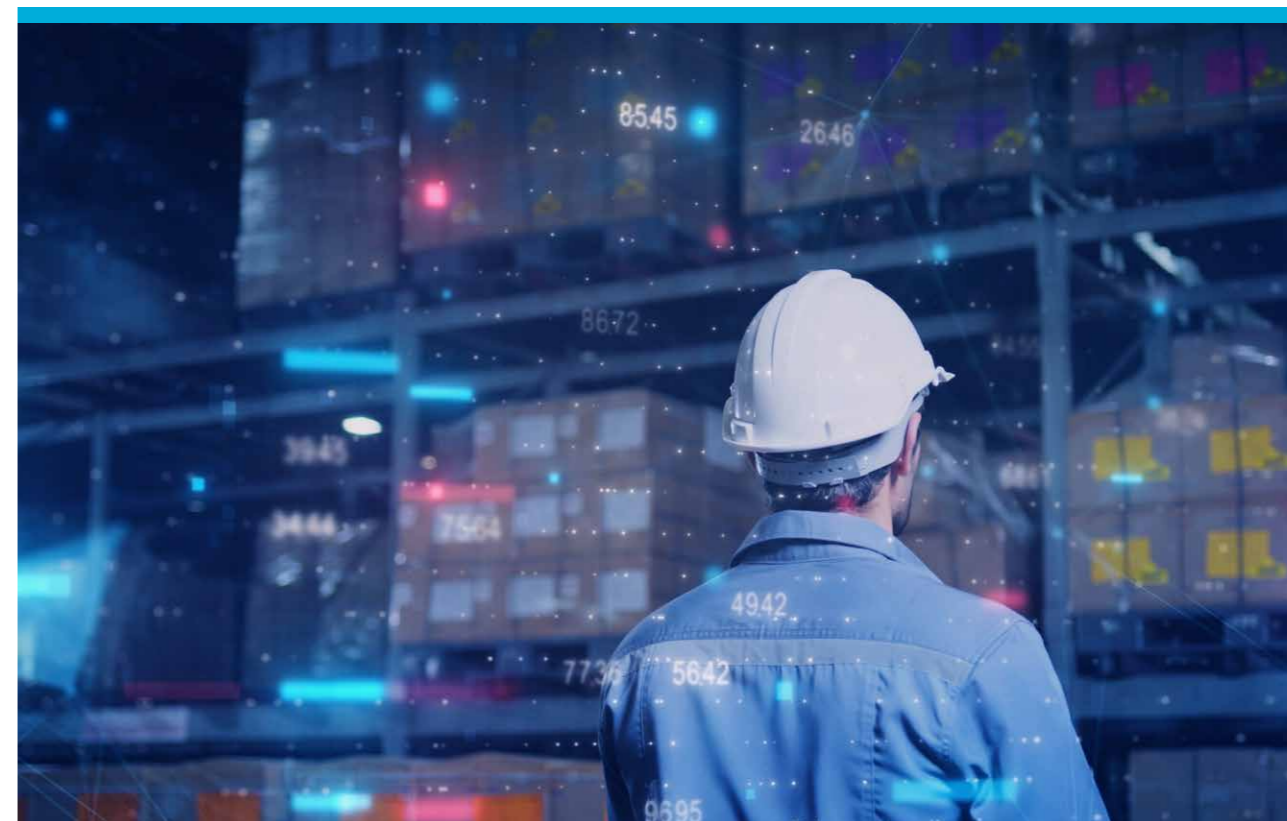
About the author

Marco Steinkamp
Sales Director EU, Movilitas

Marco Steinkamp studied logistics at the Fontys University of Applied Science in Venlo, the Netherlands. In 2005, he joined British American Tobacco (BAT). He held several roles during more than a decade with the firm and was a member of BAT's local and global supply chain organisation. For several years, Marco supported BAT's global track and trace programme as senior project manager in logistics as well as manufacturing environments. With this end-to-end supply chain track and trace experience and expertise, he joined Movilitas as the European sales director for track and trace in May 2015. After moving into the role of global sales director for track and trace in 2017, Marco became European sales director in December 2019.

About the organisation

Movilitas is a global consulting services and solutions company, part of the Engineering Group's Industries excellence Global division, that helps enterprises transform their business to meet the demands of today's dynamic economy. The firm is recognised as a long-standing trusted SAP partner and strategic advisor for digital supply chain transformation. Its industry expertise, portfolio of accelerators and extensions for SAP solutions and its applications, such as Movilitas Cloud, enable businesses to future-proof operations, maintain compliance and realise new growth opportunities.
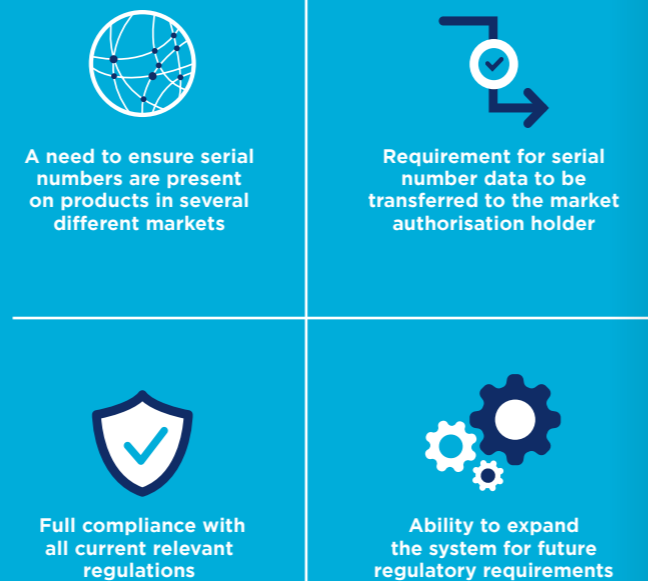
www.movilitas.com

Australia

Meeting regulatory requirements through the use of GS1 standards

Challenge

Several countries now require serial numbers to be present on pharmaceutical products, and for this data to be transferred from the manufacturer to the regulator. In 2017, the pharmaceutical company Aspen Australia was awarded a significant contract manufacturing portfolio, with many of the resulting products being exported to nations in which such requirements were in place. The company therefore needed to implement a solution to ensure compliance.

Approach

Aspen Australia implemented a multi-level serialisation solution. The implementation has successfully enabled Aspen Australia to supply a significant volume of serialised product to the numerous export markets, fully compliant with countries' regulatory requirements. The use of GS1 DataMatrix and EPCIS standards has been central to this. The system has been deliberately designed such that it can be built upon in the future to meet further regulatory requirements.

A need to ensure serial numbers are present on products in several different markets

Requirement for serial number data to be transferred to the market authorisation holder

Full compliance with all current relevant regulations

Ability to expand the system for future regulatory requirements

Introduction

The regulatory requirements related to pharmaceuticals have been constantly evolving over the past decade, with an increased focus on the detection of falsified medicines and the traceability of prescription medicines. To ensure the integrity of the pharmaceutical supply chain, improve the safety of medicines and combat counterfeits, the European Union (EU) developed the Falsified Medicines Directive (FMD). This outlines the requirements for printing unique identifiers (serial numbers) on pharmaceutical products and the transfer of the associated data from the manufacturer to the regulator. Several other overseas markets have implemented similar guidelines, intending to provide a system that can verify the authenticity of pharmaceutical products at the point of sale.

In 2017, Aspen Australia was awarded a significant contract manufacturing portfolio. This was to be implemented over the ensuing five-year period, with the commercialisation of products

staged between 2018 and 2021. Of this new contract manufacturing volume, a large portion would be exported to Middle Eastern markets (including UAE, Bahrain, Jordan, Oman, Lebanon, Kuwait, Qatar and Saudi Arabia). When added to Aspen's existing contract export volumes (which included products for South Korea and the UK) it was forecast that the Aspen facility in Dandenong (a suburb of Melbourne) would need to supply more than 11 million sales units per annum into markets that had regulatory requirements for serialised products. The common thread for all target markets was the use of a GS1 compliant DataMatrix barcode for the encoding of machine-readable unique identifiers onto pharmaceutical packs.

To meet the anti-counterfeiting requirements of the FMD and equivalent requirements issued by Middle Eastern and South Korean market regulators, in late 2018 the Aspen Dandenong site embarked on the journey towards implementing a serialisation system, to enable the contract

manufacture of products sold into these markets. The upfront challenges Aspen faced were:

- Commencing the serialisation project with a very low local knowledge base.
- Sourcing of equipment and solutions that did not exist in Australia and/or had not been implemented in Australia.
- Timing of solution implementation, to tie in with the target commercialisation dates of large-scale manufactured export volume and various in-market mandatory serialisation deadlines.
- Performing sufficient due diligence around the solutions to be implemented, knowing that such systems would become embedded in how Aspen operates and hence would be difficult to change further down the track.
- Implementing solutions that could be expanded to incorporate future packaging requirements, regulatory requirements and scope of serialisation (such as aggregation/track and trace).

Developing understanding and specifications

Before attempting to specify and source a serialisation solution for the Aspen Dandenong site, members of the project implementation team needed to perform some initial research

to gain an understanding, even at a very high conceptual level, of how a serialisation system typically works.

This included reaching out to Aspen's internal global network and to the contract customers for which the company would produce and sell serialised products. As much information as possible was gathered about the software and equipment solutions they had implemented, system hierarchy and workflow drawings, system specification documents and operating procedures.

This research was supplemented by information received from both serialisation system solution providers and market regulators. The regulatory documents released by the EU to support the FMD (Commission Delegated Regulation (EU) 2016/161) are well-written, easily accessible documents that describe how unique identifiers shall be printed onto packs. They also provide a theoretical overview of the serial number lifecycle, and of the flow and management of associated data from manufacturer to regulator through to point of sale. This, as intended, enables the verification of the authenticity of pharmaceutical products.

The scope of Aspen's implementation was limited to Point of Dispense Authentication (PoDA – see Figure 1), which means that serialisation was only required at the sales unit packaging level. This is a subset of full track and trace (which involves identification and movement of
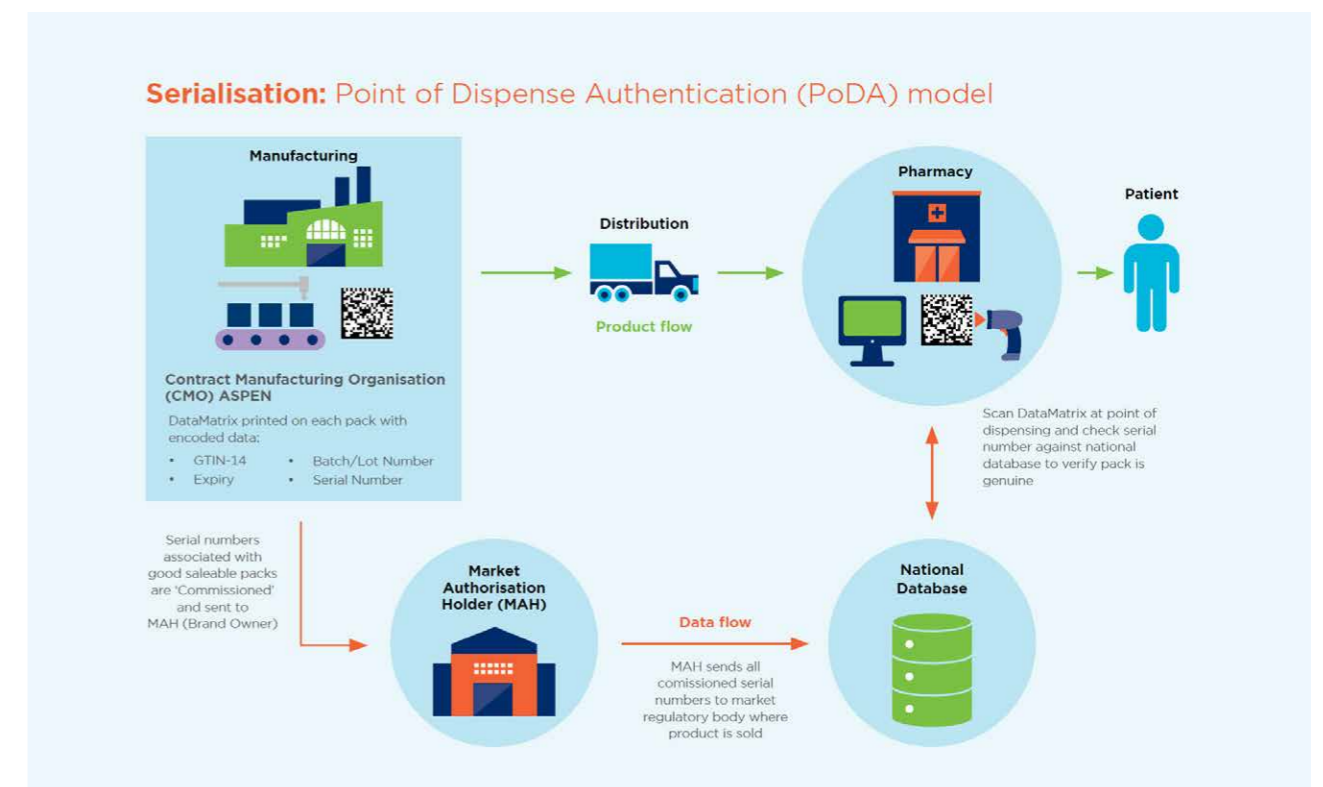

Serialisation: Point of Dispense Authentication (PoDA) model

Figure 1

The implementation

Aspen implemented a traditional serialisation model of **Level 4**, **Level 3** and **Level 2** systems (Refer to Figure 2).
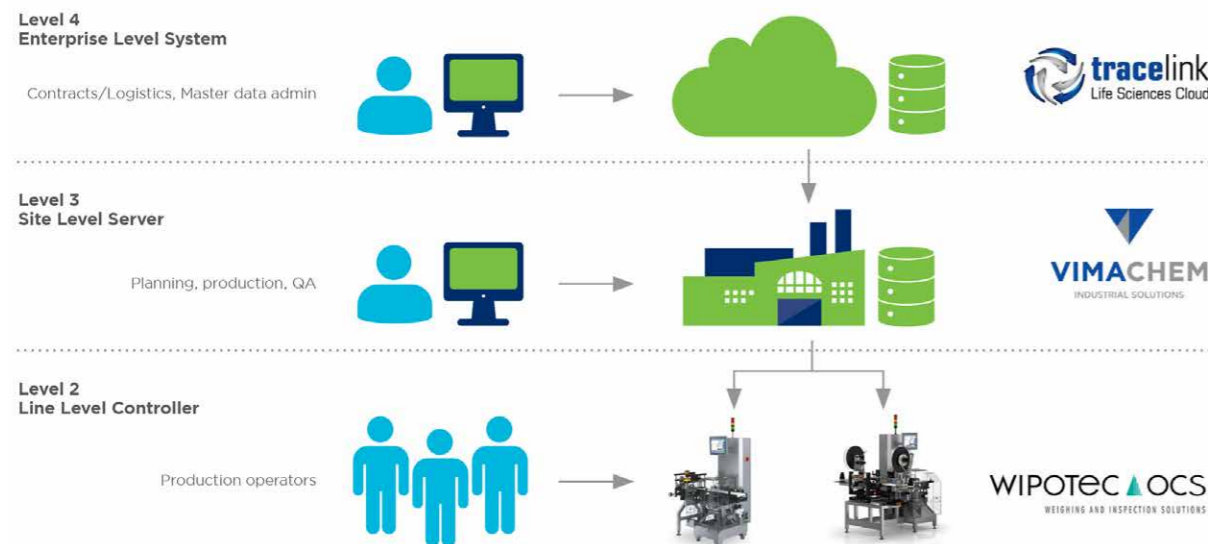
Aspen Serialisation System Infrastructure

Figure 2

data through the supply chain) and of aggregation (in which there is a requirement to serialise at all levels of packaging). Given that various markets are heading towards requiring one or both of these, it was crucial that any solution implemented by Aspen could be built upon in future to achieve such requirements.

The following selection criteria were therefore formalised for the tender process:

- **Flexibility:** The ability for system layers to integrate with alternate third-party equipment and/or software solutions in the future (ie. universal interface) instead of 'locked in' proprietary systems.

- **Scalability:** The ability to expand the system, both through the addition of more packing lines and increased functionality on existing packing lines (eg. shipper- and pallet-level aggregation).

- **Ease of use:** User interfaces that were as simple and logical as possible.

- **Balance of ubiquity and innovation:** Striking a balance between well-proven system solutions and finding opportunities to embrace new technology based on lessons from other serialisation implementations.

- **Implementation and validation support:** A resource for validation protocol generation, technical implementation, and validation execution.

- **Customer service:** Ongoing technical support post-implementation, via service level agreements or otherwise.

- **Cost** was also a key consideration of course; both the capital implementation cost as well as any continuing or volume-based fees for the likes of software subscriptions, service level agreements or commissioned serial numbers.

The solution and its implementation

Aspen implemented three distinct levels of infrastructure, which follow the traditional serialisation model and are referred to as Level 4, Level 3 and Level 2 serialisation systems (See Figure 2.)

The enterprise level system (Level 4) is the 'brains' of the serialisation system:

- Contains all company, partner and product master data.
- Manages serial number pools per product, which are either internally generated or externally replenished (depending on the customer's preference) and with quality controls to ensure uniqueness.
- Has a business to business (B2B) interface with Aspen's contract customers for transacting serialisation data.
- Is a data repository of all serial numbers transacted to meet regulatory obligations.

Aspen selected the cloud based TraceLink application as the enterprise level system. It was primarily selected for its wide and established network of B2B connections linking many pharmaceutical companies, including all of Aspen's contract customers. In addition, TraceLink's regular automated internal validation programme ensures monthly software patch updates do not impact the validated state of the application interface. This means Aspen receives a service where much of the complexity of maintaining the system is outsourced.

The implementation was led by a small project team from TraceLink. Considerable input was required from Aspen's internal and external stakeholders in understanding and agreeing on the business workflow they were trying to achieve. The team had to configure the system master data accordingly (first in a test environment, and subsequently in a production environment) and then test the connections between the Aspen site and the company's contract partners.

Site and line level systems

The site level server system (Level 3) is used for batch management at a single manufacturing facility. It is in this system that serialised orders are created, assigned to lines, monitored for status and finally quality released. This is the software layer most frequently accessed by day-to-day technical operations, meaning that the system needed to have a clean, user-friendly interface. It also needed to be able to support a range of access levels, corresponding to the types of users that interact with the system.

Aspen selected Vimachem Site Serialisation Manager (SSM), following a review of several proposals and software demonstrations from different vendors. Vimachem SSM was deemed to be best aligned with Aspen's selection criteria. It is also designed to seamlessly integrate with TraceLink and has a universal (non-proprietary) interface with the line level serialisation equipment.

The implementation was led by a small project team from Vimachem. Members of the team remotely managed the application connections at the required stages of the project, developed all specification documents, and executed a validation package across both test and production environments.

The line level controller system (Level 2) serialisation equipment is at the 'coal face' of serialisation. It receives the serial numbers from the higher-level software systems, undertakes the printing of the DataMatrix and human readable text onto packs, verifies the data and the barcode quality, performs other ancillary func-

tions (such as the application of tamper evident labels and check weighing), accepts/rejects packs, and commissions or deactivates the corresponding serial numbers.

As Aspen's initial serialisation launch was across five packaging lines, the Level 2 system implementation would take up a majority of the project budget and present the highest level of risk to timeline, functionality and future flexibility if not chosen correctly. Aspen therefore initiated a large tender to eight different vendors of serialisation equipment.

Wipotec OCS (Germany) provided the best overall fit to meet Aspen's selection criteria and was selected to supply all the Level 2 systems. The company offered a highly integrated solution with relatively simple setup and operational procedures and have a universal (non-proprietary) interface for future flexibility. The Wipotec OCS line level controllers can also be extended upon with additional systems if full aggregation is required.

The implementation of each Wipotec OCS serialisation unit included a Factory Acceptance Test (FAT) in Germany and subsequent installation, qualification and Site Acceptance Testing (SAT) on Aspen's premises by a Wipotec OCS technician, and/or by technicians from the local machine agency.


The workflow and process

- As a contract manufacturing organisation, Aspen's serialisation workflow begins with the automatic replenishment of product-specific serial number pools in the enterprise level system (TraceLink), with serial numbers externally sourced from the market authorisation holder's enterprise level system.

- When a serialised order is created in Aspen's site level server system (Vimachem SSM), the required quantity of serial numbers is request-

ed and downloaded from the TraceLink number pool. These serial numbers are removed from the available pool and move to a 'Reserved' state in TraceLink.

- When the order is due to be packed, a user in Vimachem SSM will assign the order to the corresponding line level controller system (Wipotec OCS) and the serial numbers for this order will be downloaded onto the unit.

- Each pack processed by the Wipotec OCS unit will be assigned a unique serial number from the order. The machine will print a unique GS1 DataMatrix barcode encoded with the GTIN-14, expiry date, batch/lot number and serial number and will inspect it by taking a photo of the barcode and human-readable text elements. Acceptable packs are classified as 'OK' and are allowed to continue on the production line. Packs that are not acceptable are classified as 'NOK' and will be automatically rejected and quarantined.
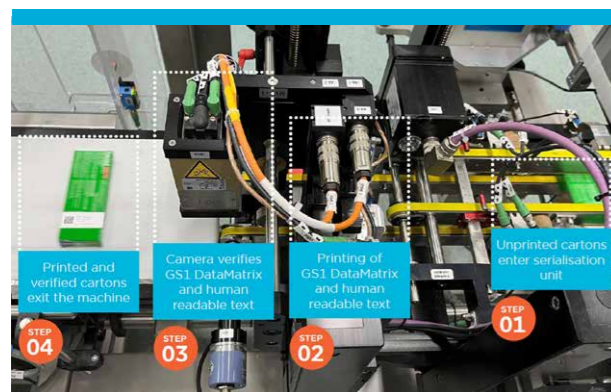
- For every pack processed, various pieces of information are linked to each corresponding serial number in the order data. This includes the OK/NOK status, expiry date, batch/lot number, date/time of processing, GS1 Data-Matrix read quality, the reason for rejection (if NOK) and pack weight (for lines with an integrated check weigher).
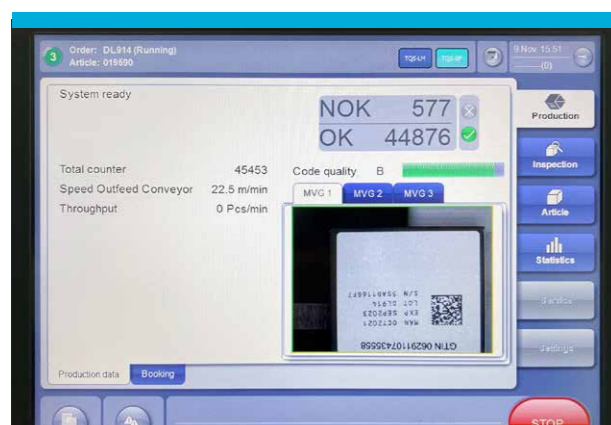
- After the order is packed, it is ended on the Wipotec OCS unit and the order data (including the disposition of all serial numbers as accepted, rejected or unused) is updated in Vimachem SSM.

- The order data remains in the site level server system pending quality release. During the final stage of quality release, a QA user will approve the commissioning of the order in Vimachem SSM to allow the transfer of the completed order data to the enterprise level system (TraceLink).

- All serial numbers in the TraceLink repository associated with the order (which up until this point have remained in a 'Reserved' status) are updated with their final disposition. The serial numbers associated with good saleable packs are commissioned and the lot-specific information (captured by the lower-level systems) is now linked to these serial numbers in the database. The serial numbers associated with rejected packs are deactivated and can no longer be used. Any residual unused serial numbers from the order are returned to the available number pool and their status is changed back to unreserved.

- Coinciding with the physical shipment of stock from Aspen's premises, a shipment transfer is performed in TraceLink. This sends the serialisation data for all commissioned packs to the market authorisation holder, together with Global Location Numbers (GLNs) describing the source and destination of the physical goods. This transaction is contained within an Electronic Product Code Information Services (EPCIS) XML file which is a GS1 standard for sharing event data and updating entries in external database systems.
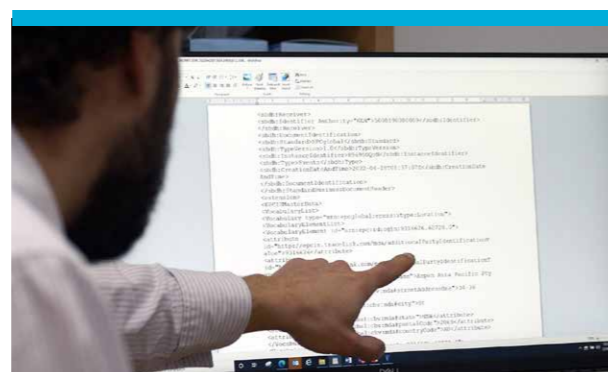
- This is the final stage of the serialisation process for Aspen as the contract manufacturing organisation. The market authorisation holder will report the commissioned serial numbers to the regulatory database of the target market in which the goods are to be sold. This provides a means of verifying the authenticity of pharmaceutical products at the point of sale.

The challenges

It took Aspen two years from conception to go live of the serialisation system (August 2018 to July 2020). The first nine months were research, pre-tender and tender phases before the final solutions were nominated. During the project, the biggest implementation challenge faced was, unsurprisingly, the validation effort involved in implementing and launching three layers of networked infrastructure, (cloud-based, Aspen server-based and factory floor-based) to meet pharmaceutical regulatory standards.

The single most valuable document to be generated during the project was therefore the project validation plan. This set out the validation strategy as a roadmap of the various implementation milestones, across the three layers of infrastructure and in both test and production environments, culminating in performance qualification exercises to rigorously test the system end-to-end.

Lessons learned

For organisations looking to start their serialisation journey, the key advice from Aspen is:

- Invest adequate resourcing into the validation process

- Allow time for stakeholder management. This is extensive and may be across several time zones, requiring strong project management and flexibility to work non-standard hours to align with overseas support

- Provide dedicated resourcing for the generation of standard operating procedures and operating manuals, as the serialisation system will introduce several new business processes across various departments

- Allow sufficient time for user training and embedding of the new workflows. This will be a very new and different way of working for many staff but Aspen's experience is that it will soon become the new normal.

"It was fortunate for Aspen that the ten different target markets adopted a standardised method for encoding the unique serial number and other critical information onto their packaging, and that method was the GS1 DataMatrix. Furthermore, the means of sharing serialisation event data between us (the Contract Manufacturing Organisation) and all our customers (the Market Authorisation Holders) is via an Electronic Product Code Information Services file (or EPCIS file for short) which is also a global GS1 standard. Hence what made this complex project more manageable and allowed us to implement a single 'catch-all' solution was the widespread adoption of GS1 standards."

Michael Hadjion,
Engineering Manager, Aspen Australia

Next steps

In addition to the five serialised packing lines implemented during the initial project, Aspen is currently in the process of adding three more serialised lines over the next 12 months. This is primarily to increase the flexibility of their solid dose blister packing operation by unlocking capacity for more packing lines to meet the growing demand for export (serialised) products from the facility.

Conclusion

Two years have passed since the commercial launch of the serialisation system (July 2020). The implementation has successfully enabled Aspen Australia to supply a significant volume of serialised product to numerous export markets, fully compliant with the countries' regulatory requirements through the use of GS1 DataMatrix and EPCIS standards.

About the author

Michael Hadjion
Engineering Manager Aspen Australia

Michael Hadjion is engineering manager at the Aspen Australia manufacturing facility located in Dandenong South, Melbourne. With 18 years of experience in the pharmaceutical industry, he initially specialised in equipment and facilities validation before heading into project engineering and maintenance roles. Joining Aspen as project manager in 2012, Michael has delivered a diverse range of projects including major capital works, contract manufacturing tender submissions, and the transfer of a large portfolio of consumer and over the counter products into the Aspen facility. Between 2018 and 2020, Michael managed Aspen Australia's serialisation system implementation.

About the organisation

Aspen Australia is a wholly owned subsidiary of Aspen Pharmacare Holdings Limited (South Africa). Commencing operations in 2001, the firm is now one of the largest pharmaceutical companies in Australia and has one of the most comprehensive portfolios of medicines in the country. This includes prescription pharmaceutical brands, generics, specialty products, over the counter (OTC), and consumer healthcare products.

Aspen Australia operates a single large-scale manufacturing facility located in South Dandenong, Melbourne. In addition to the manufacture of Aspen branded pharmaceuticals, the Dandenong site has a rapidly expanding contract manufacturing and export business.

www.aspenpharma.com.au

Pfizer

Using barcodes to support efficient clinical trials

Challenge

To run a clinical trial for a potential new medicine is to confront a challenging and very precise distribution process. Ensuring every healthcare site involved in the trial receives the right products for the right patients – including placebos, or perhaps several different doses of the active ingredient being investigated – is complicated. There is then the further issue of clinicians being certain that the right patient is being administered the right product. Getting all this correct is crucial to successfully running trials, which are in turn crucial to testing new medicines that could improve treatment options for patients. A clinical trial is a highly controlled environment, and an incorrect shipment or the wrong drug going to the wrong patient could ultimately impact the integrity of outcomes and patient safety.

Approach

To help support meeting the challenges of the distribution process, Pfizer has introduced a single GS1 standard barcode to all its clinical trial products. In the first instance, this is helping those at Pfizer's packaging and distribution centres to ensure the right products go to the right sites in the right quantities. But, in the longer term, those at the company envisage the same barcode will also be used by hospitals to help with the administration of clinical trials – and even by the patients taking part in trials, who could perhaps scan the code to access information such as dosing instructions and storage conditions.

So much information, so little space

Testing one new drug in a clinical trial actually involves testing several products. There may be a placebo as a control, enabling investigators to understand whether the active drug is making a difference or improvements. In later phase trials there may be several different doses of the active ingredient being tested, to understand what amount makes the optimal difference in comparison to an existing treatment.

All this means that there is a lot of information that needs to be included on product labels for clinical trials. "It's not like designing artwork for commercial supplies," stresses Nicola Barnes, Senior Director Global Clinical Supply at Pfizer.

"For commercial supplies, you've got six sides of a carton – all of this landscape on which you can put information. The challenge in clinical supply packaging is we usually have quite a limited label landscape. We're trying to accommodate multiple languages to give us diversity of countries to which we can provide our clinical trial material. All the country-specific regulatory requirements have to fit onto the label, as well

as the protocol information, the storage conditions, drug product information, administration instructions, expiry date, and our unique packaging reference number."

Encoding some of this information in barcodes seems like a natural solution, but until relatively recently the company was struggling to find space to accommodate sometimes multiple barcodes on clinical trials packages.

That changed when there was a decision to move to GS1 barcodes, enabling just one such code to appear on the package. When scanned, the barcode provides the protocol number, serial number, package lot or batch number, and a Global Trade Item Number (GTIN) – a unique number which identifies a product and is the 'key' to which other information is linked.

What that means is that those working in Pfizer's distribution centres can scan the barcode to make sure they are selecting the right product and right batch to the right trial site. It makes the first step in clinical trials both safer and more efficient.

Taking the time to get it right

Those at the company say the process to implement the codes has been a careful and gradual one. "There's been a lot of preparatory work around getting ready to use GS1 on our labels," explains Nicola.

That has included upgrading Pfizer's labelling software to support the use of GS1 standards, and encouraging partners to do the same.

"There was a growing awareness about GS1 among our booklet label suppliers and our vendors who do packaging and labelling for us. And to implement GSI barcodes, I needed to provide them with information on what we were trying to achieve and how we could incorporate GS1 into the label designs without distracting from the regulatory information required for clinical labels."

For staff in Pfizer, meanwhile, there was the need to find ways to manage and track the GTINs being used for clinical trials. With commercially sold products, it's possible to simply have one GTIN which identifies a particular product in a particular strength and potentially for one or multiple markets.

But with blinded clinical trials – in which patients do not know if they are receiving the actual drug or a placebo or a comparator – enormous care needs to be taken to ensure the GTIN does not identify which is the drug, the comparator or the placebo.

"That means that for every packaging configuration we create, we are allocating a unique GTIN," says Nicola. "For a blinded trial we have a unique GTIN which is the same for all of the treatments packaged in that batch, to maintain the blind."

"For open-label supplies, again, we create a unique GTIN for each open-labelled product."

"In both blinded and open product and packaging configurations, the GTIN can be reused if the same configuration is packaged again for a resupply." confirms Nicolas.

For now, these GTINs assigned are managed via a validated spreadsheet. But in the longer term, we will generate and manage GTINs within the company's enterprise resource planning (ERP) software. This should make the whole process much simpler.

An evolving picture

That is far from the only way in which those at the company see the barcoding project developing. "We didn't just put these GS1 barcodes on our clinical trials products just because we wanted our packagers to have one barcode to process at the packaging site," says Hans Von Steiger, Group Leader in Clinical Supply Chain management. "We really did it with a much broader vision."

That vision encompasses healthcare sites making use of the barcodes as well. "We want to make sure that managing the flow of materials and then dispensing to patients is as easy as possible for these very busy caregivers," says Hans.

Scanning a barcode to automatically check the clinical trial product is the right one for a patient – and to record when and where it was administered – could be a big contribution to this. It would also make it much easier to manage a site's clinical trial inventory; ensuring they had sufficient quantities of the right products at the right times.

In time there might also be the potential to share information with patients via barcodes. "The patient could scan it and it would display a message saying: 'Now please take one of these and hit confirm when you have', or give them reminders as to when doses are due. We could then keep track of compliance in an electronic patient diary."

The simple act of moving to one barcode also helps here. "We have more space to display the other key information on the label more prominently, which helps the site and the patients read the information more readily," says Nicola. "With a single use barcode it's also easier for all those who 'touch' the product, to know which barcode to scan, as opposed to having multiple barcodes and attempting to scan the incorrect barcode."

In the future, it's possible that patients will be able to scan the codes to get detailed information. For now, though, Hans argues the most important step is for pharmaceutical companies to simply make a start with using GS1 barcodes for clinical trials. "The first step is to standardise the barcode," he says. "The second step is that our software solution providers can start building and programming software so that we can take advantage of the barcodes."

About the authors

Nicola Barnes
Senior Director Global Clinical Supply, Pfizer

Nicola Barnes is senior director global clinical supply, Pfizer. Nicola has over 25 years of experience in the industry leading clinical supply packaging and labelling operations. Nicola has developed processes and published guidance documents for Pfizer to define the requisition, design and production of IMP labels for clinical supplies. She is also a subject matter expert in clinical supply packaging design and supply strategies and has implemented new capability including the utility of 3D printing and CAD technology to advance packaging design. Nicola holds a bachelor of science degree in pharmaceutical science and a master's degree in industrial pharmaceutical science.

Hans von Steiger
Group Leader Clinical Supply Chain Management, Pfizer

Hans von Steiger started his pharmaceutical career at Procter & Gamble as a drug product formulator in the product and process development division. He moved on to Pfizer in 1996 supporting R&D solid dose manufacturing and clinical drug product outsourcing. Hans is now in Pfizer's global clinical supply chain management, responsible for a team of supply chain leads overseeing clinical supply strategy. Hans graduated from Rutgers College of Engineering with a degree in chemical engineering.

About the organisation

At **Pfizer**, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety, and value in the discovery, development, and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments, and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments, and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, Pfizer has worked to make a difference for all who rely on us.
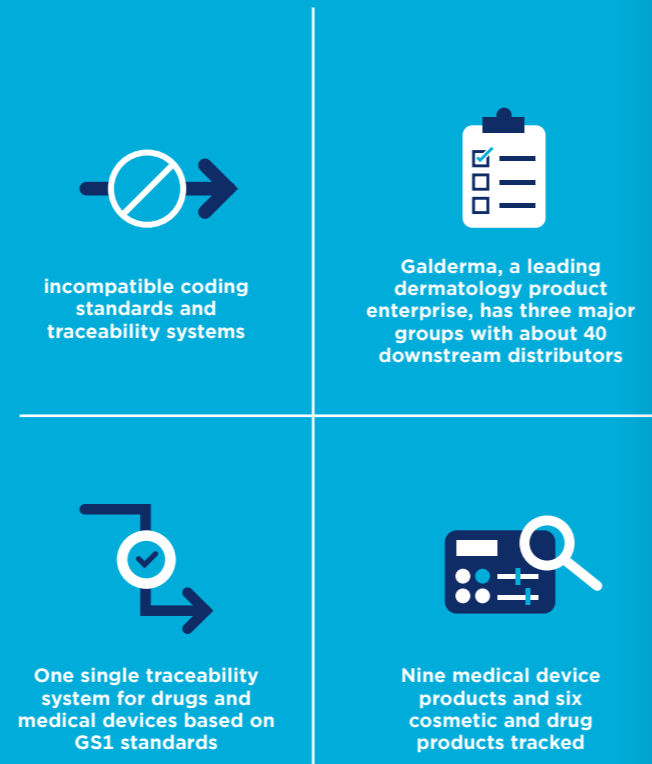
www.pfizer.com

China

Tracking drugs and medical devices on a single platform

Challenge

The supervision of medical cosmetic products is quite difficult in China, and there are problems with unlicensed and smuggled products in the market. Current traceability system standards are not unified, various coding standards coexist and each traceability system is incompatible with the others. As a leading dermatology product enterprise, Galderma has three major groups of downstream distributors using various data exchange methods. Some small distributors have no IT system at all.

Solution

Based on the research on the similarities and differences between drugs and medical devices supply chain traceability, a bespoke product traceability system (PTS) based on GS1 standards has been implemented. The main functional modules include: the master data management module of enterprises and products; encoder module, label template and barcode printing module supporting GS1 coding standard; serial number management, traceability and inquiry functions; traceability report and audit function.

incompatible coding standards and traceability systems

Galderma, a leading dermatology product enterprise, has three major groups with about 40 downstream distributors

One single traceability system for drugs and medical devices based on GS1 standards

Nine medical device products and six cosmetic and drug products tracked

Introduction

In August 2019, China's National Medical Products Administration (NMPA) officially issued The Rules for the Unique Identification System of Medical Devices, marking the official start of the legislation to implement unique device identifiers (UDIs) in China. GS1 China fully meets all requirements of the UDI issuing entity mentioned in the rule. In the subsequent two years, two announcements on effective implementation of unique identification for medical devices were issued, which clearly define the scope, schedule and work requirements for stakeholders.

Also in 2019, the NMPA tightened drug administration by introducing a "full traceability" mechanism and a drug recall system. In the new version of the Drug Administration Law, the establishment of a drug traceability system was proposed for the first time.

With a series of regulations and standards on UDI and a drug traceability information system being issued or updated, it's now possible for manufacturers to implement GS1 standards for both drugs and medical devices in China.

Driving forces of simultaneous tracking of drugs and medical devices

In the healthcare industry, manufacturers, distributors and healthcare providers all have their own needs and motivations to meet the requirements of laws and regulations and improve internal efficiency. In view of the implementation trend of global supply chain standards in China, and considering drugs and medical devices are ultimately managed together at the point

of care, the demand for the construction of a traceability system based on unified standards is gradually emerging. More and more stakeholders choose to implement GS1 standards for product identification and traceability for the following reasons.

Firstly, to comply with various regulations and policies, drug and medical device suppliers, especially multinational enterprises, should not only respond to the minimum obligations required by relevant regulations, but also provide convenience for downstream distributors to enhance supply chain traceability. Secondly, in terms of information exchange, due to the coexistence of various coding standards in the past, the traceability systems are incompatible with each other, which makes it difficult to share information. Most of the data is currently fragmented and isolated, which brings obstacles to the interaction of the traceability system along the supply chain. Thirdly, from the perspective of improving efficiency, GS1 barcodes can be read and interpreted without relying on any third-party platform to obtain the product identification and additional information. This makes the management process more convenient and cost-effective, and the whole medical supply chain will benefit.

In conclusion, GS1 standards not only meet China's requirements for drug traceability and UDI, but also provide an open, harmonised business language for all stakeholders to use globally. For downstream distributors and healthcare providers, the product traceability system (PTS) based on GS1 standards enables enterprises to respond to the relevant requirements for identification and tracking of drugs and devices at the same time under the complex supply chain structure.

The characteristics of Galderma's supply chain

Galderma fully considered the different business flows of each trading partner within its supply chain, and also took the fixed product types into account. Under the guidance of GS1 China, Galderma conducted detailed data research and distributed a questionnaire to its supply chain partners to identify the complexity and possible risk points of implementing a traceability system.

As a multinational company, Galderma (China) integrates the roles of supplier and importer, in the middle of the whole supply chain. Galderma branded products come from three types of original supplying site. The first type only produces medical devices, the second type of site produces prescription drugs, and there will be a third type of manufacturer site that supplies drugs and medical devices at the initial stage of this project (as shown in Figure 1).
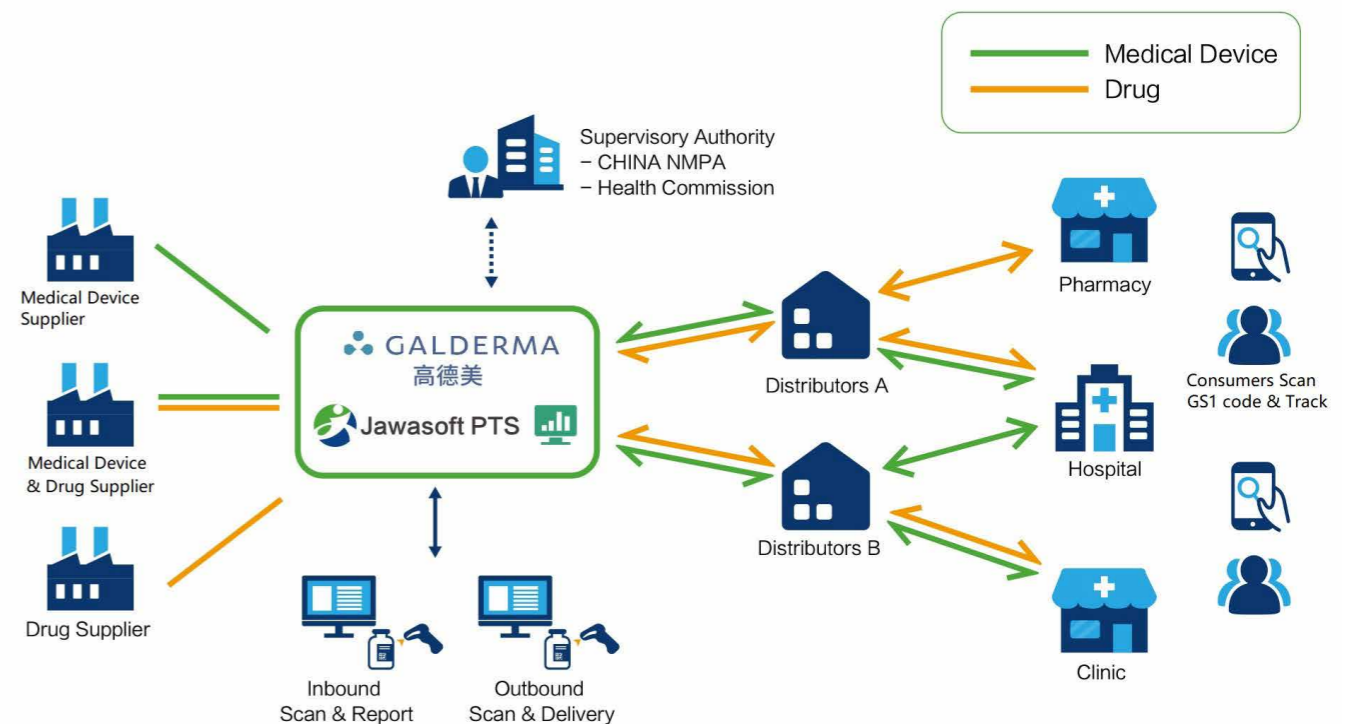

Figure 1: Galderma's drugs and medical devices supply chain

The products sold by Galderma in China include up to nine medical device products with GS1 barcodes containing GTIN, batch number and/or serial number, and six imported cosmetic and prescription drug products with GS1 DataMatrix. In downstream distribution, some distributors mainly sell medical devices, while others sell prescription drugs at the same time. As there was no unified coding system, distributors have traditionally used multiple systems to manage purchase, inventory and data of sales.

The product traceability system (PTS) based on GS1 standards will help Galderma and distributors use the same platform and unified coding system to complete the data collection and traceability of various products.

Implementing a single platform with multifunctions

Galderma reached out to one of the leading traceability solution providers in China, Jawasoft Technology. After the completion of comprehensive research on products and distribution processes, a Galderma dedicated product traceability system (PTS) based on GS1 standards was

designed and implemented. The main functional modules include: the master data management module of trading partners and products, a GS1 encoding and label template module, serial number management, traceability and inquiry functions, a report and audit function.

The original manufacturing sites for Galderma have adopted GS1 standards as the unified coding scheme. Although various sites provide different types of products, both drugs and medical devices use the GTIN as the product identification. The Application Identifier (AI) elements can be configured in the PTS's GS1 encoding and label template module.

The traceability of products is based on serial numbers and/or batch numbers. For products that are only managed to batches, the PTS will provide a batch query report to help users check the products movement. The distributors scan the GS1 barcodes upon receiving the product at the inbound warehouse and this informs the PTS that the goods have been received. Similarly, when the distributor sends product to clinics, the delivery order can be automatically created by scanning the GS1 barcode using the PTS app. Galderma's supply chain managers can query the traceability information through PTS.
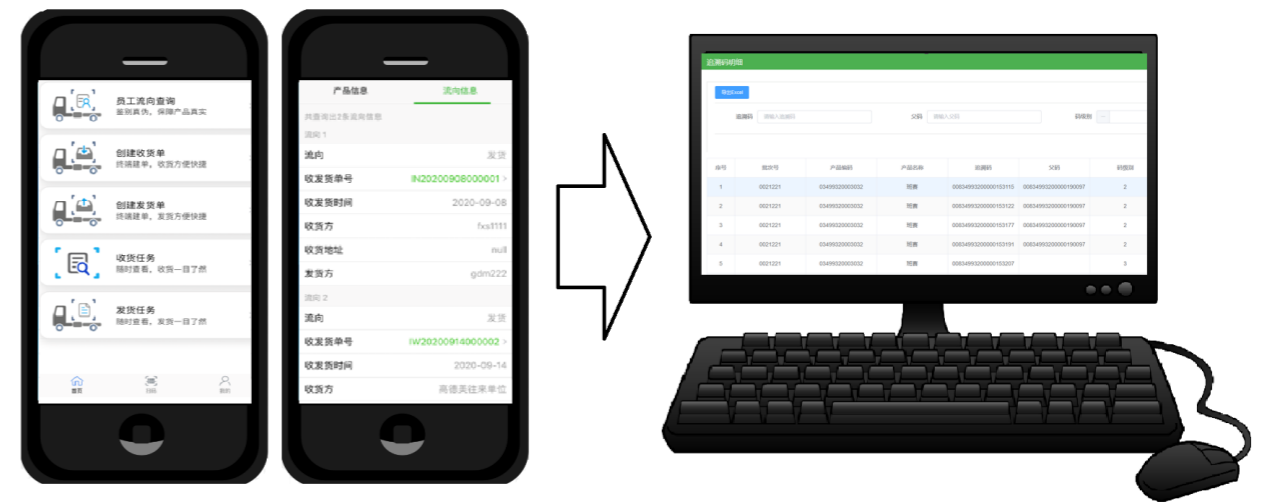

Figure 3: Distributors use mobile PTS app to stock and report

When the product reaches the clinic or consumers, users can directly scan the GS1 DataMatrix barcode using a WeChat mini-app, regardless of whether the product is a prescription drug or a medical device. A WeChat mini-app will query whether the product is genuine, and display the product name, batch, expiration date, etc. If illegal products are found, the system will alert consumers immediately.

In addition, PTS guarantees data security by authorisation management. Once a distributor is onboarded, access levels will be granted based on the supply chain structure. The main principle is that Galderma can see the data reported by its downstream distributor, but the parallel distributors' data cannot be viewed by each other. The authorisation setting is completed by the management personnel of Galderma, and the audit trail function is supported.

Figure 4: Customer scanning the UDI marking using WeChat app

GS1 Label Template in Simplified Chinese

Figure 2: GS1 encoding and label template

Successfully on-boarding downstream distributors

According to the survey data collected from the Galderma distributors before the implementation of the system, the main factors distributors were concerned about included potential extra costs, impact on current business processes and data security issues.

Thanks to the openness of GS1 barcodes and the integrated design of PTS, downstream distributors have settled into the system as stakeholders without participating in the system construction.

For distributors that currently use other systems or do not have any traceability system, there is no additional participation cost, and there is no need to carry out complex training for operators. The distributor can also continue to use the existing hardware equipment, such as basic barcode scanning equipment, a handheld PDA terminal, etc, which can transfer data with PTS without purchasing many new equipment.

From the business process perspective, compared with many systems previously used, the GS1 coding system adopted by Galderma is very convenient and fast. The downstream distribu-

tors of Galderma do not need any software or platform to analyse. It can immediately obtain the basic information, product identifier, batch number, expiry date and serial number of various products by using only one system. This not only makes the distribution process faster, but also saves a lot of system construction and operation costs for distributors and ensures that each shipment of goods is accurately and timely distributed to domestic destinations in China.

Benefit to healthcare provider and consumers

In medical cosmetic clinics, the previous manual management process has been replaced by scanning a GS1 barcode, which has improved the efficiency of stock and inventory management. The human error in the process of selecting medical products is greatly reduced in the clinic. In addition, the new process also shortens the time required for data verification and entry, enabling staff to spend more time caring for consumers.

Next steps

GS1 China plans to engage with more healthcare providers to implement GS1 standards for drugs and medical devices, and to explore what benefits GS1 standards can bring to all stakeholders. Galderma's experience shows how to solve the difficulty of managing different types of products in the healthcare supply chain.

Conclusion

GS1 China, along with global and some local stakeholders, has long been promoting the virtues of global harmonised product identification in the healthcare industry. The establishment of the simultaneous tracking of drugs and medical devices on one integrated platform based on GS1 standards proved that GS1 standards are not only compliant but also efficient in China. The project has involved a smooth transition from multiple traceability codes to the GS1 coding system for medical cosmetic company, showing a turnkey solution that can be promoted in the healthcare industry. This solution improves the overall supply chain efficiency of the industry without requiring significant additional cost.

> "To provide better services to customers, we pay great attention to the safety and quality of drugs and medical devices. The GS1 standards-based drug and device traceability system used by Galderma products can help the pharmacies and clinics quickly obtain various information on drugs and medical devices.
> That information can be related to the treatment information of each customer, providing data and system support for healthcare provider's refined management needs."

Ray Zhang
Head of supply chain, Galderma China

About the authors

Ray Zhang
Head of Supply Chain, Galderma China
Mr Zhang is head of supply chain at Galderma China. He has contributed to the development of Galderma China's supply chain management strategy and continuously improved the process to ensure efficient distribution and logistics operation. He pays great attention to the safety and quality of Galderma products, aiming to solve the distribution challenges faced by the company.

Xuejing Wang (Chris Wang)
Deputy Manager, Jawasoft
Chris Wang, MBA of Nankai University, is one of the co-founders of Jawasoft Technology. She has been in the field of pharmaceutical traceability for more than 15 years, leading the Jawasoft team to obtain nearly half of the market of the pharmaceutical industry in China. She is familiar with the traceability regulations, supply chain security and system construction in China, the United States and the European Union. She is also expert in medical device UDI requirements and in implementing UDI system for enterprises.

Local coordination

Han Du
Director of the Article Coding Innovation Application Promotion Studio, GS1 China
Han Du achieved a master's degree in information management from the University of Sydney. In 2006, he joined GS1 China, responsible for the technical research and application promotion of internet of things. He has undertaken national projects such as research on electronic product code (EPC) internet of things standard system, GS1 transport and logistics pilot on EPC and EU FP6, and started research on GS1 in mobile commerce/B2C business. Since 2019, he has served as the director of the article coding innovation application promotion studio. He has a deep understanding of GS1 standards and their application, and is fully responsible for the application and promotion of GS1 standards in healthcare, transport and logistics, and industrial internet.

About the organisations

GALDERMA
With a unique legacy in dermatology as well as decades of cutting-edge innovation, **Galderma** delivers a science-based portfolio of premium flagship brands and services that spans the full spectrum of dermatology. As the pure-play dermatology category leader, it is advancing dermatology for every skin story.

www.galderma.com

Jawasoft is an industry leading service provider of end-to-end traceability solutions. The Jawasoft team focuses on global regulatory consultation, traceability system construction, platform bridging, drug serialisation for import and export, medical device UDI, packaging line coding system and CSV service.

en.jawa-huicheng.com

Retail Pharmacies

Retail health is emerging as a means of delivering quality, convenient care to millions of consumers, as well as a model for healthcare systems to consider when providing services to new and existing patient populations. This section gives clear examples of how GS1 standards can bring value to retail health.

Portugal

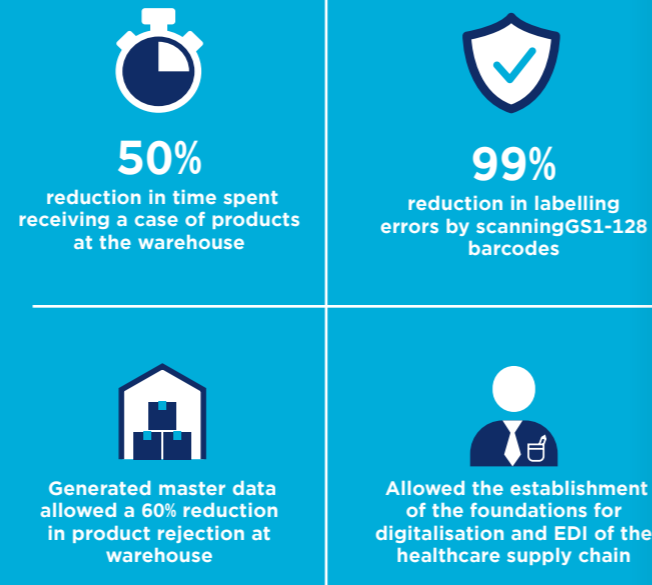## Implementing GS1 Standards to increase efficiencies at a retail pharmacy's warehouse

Challenge

The particularities of the OTC supply chain regarding product identification, unit of purchase, supplier's technological maturity and constitution of logistic units such as pallets, lead to great inefficiencies and high levels of operational errors and rejection of orders.

Approach

It is known that GS1 Standards support the decrease in operational errors and increase in efficiencies, among other proven benefits.

Using GS1 Standards, and with the help of GS1 Portugal, MC was able to standardise its case and pallet label requirements applied to orders delivered at the warehouse and align their master database.

50%
reduction in time spent receiving a case of products at the warehouse

99%
reduction in labelling errors by scanning GS1-128 barcodes

Generated master data allowed a 60% reduction in product rejection at warehouse

Allowed the establishment of the foundations for digitalisation and EDI of the healthcare supply chain

Introduction

MC is a Portuguese retailer that offers its customers an OTC **(Over The Counter)** Pharmacy service called Wells. Their warehouse operations, managed by DHL, showed severe inefficiencies and after trying to implement the same logic as MC implemented in their FMCG **(Fast Moving Consumer Goods)** retail warehouse, they understood that the healthcare sector needed a specific approach.

GS1 Portugal was asked to audit the warehouse's reception operations then present, train and implement a labelling solution on cases and

pallets based on GS1 Standards to improve efficiencies. Simultaneously GS1 Portugal was asked to work with all partners to align databases with the relevant master data, allowing the first steps in implementing EDI **(Electronic Data Interchange)**.

The project, initiated in January 2021, consisted of five different phases: preparation, gathering of evidence at the retailer's warehouse, analysis of data gathered, communication of new requirements and supporting suppliers implementing new requirements.

Phase 1 Planning and Preparation 2 weeks	**Phase 2** Gathering of Evidence at retailer's warehouse 7 weeks	**Phase 3** Analysis of Data collected 5 weeks	**Phase 4** One-to-one meetings with suppliers 8 weeks	**Phase 5** Implementation of new labels 17 weeks

January 2021 to September 2021

The status quo

At the warehouse evidence was collected from 209 different suppliers allowing GS1 Portugal to understand that the same supplier could deliver its order to the warehouse, in different logistic formats depending on the volume of the order: homogeneous pallets, heterogenous pallets or individual cases. From those that presented heterogenous pallets, only 30% used a pallet label to identify its content.

Analysing the identification used on pallets, 69% (46) of suppliers delivering pallets already used a GS1-128 logistic label and, of those, 85% used the correct Application Identifiers (AI) requested by MC.

On the other hand, case labels didn't express the same tendency. Only 18% (61) of suppliers identified their cases using GS1-128, and of those only 18% showed the necessary AIs.

The records at the warehouse showed that during the month of January 2021, 32,59% of pallets received had incidences registered relating problems with the GS1-128 pallet label and 4,68% of SKUs (Stock Keeping Units) received had invalid GTINs – GTINs not listed in the warehouse's database.

Due to these inefficiencies, an operator took in average 34.76 seconds to receive a case of products.

The solution

After analysing 209 different suppliers, GS1 Portugal presented a solution for both logistic label and case label, using GS1-128, that would allow the standardisation of information and gain of efficiencies at reception.

Different solutions were presented depending on each specific scenario:

For pallet labels

1. If a supplier delivers an order with complete cases (fixed quantity per case), then the logistic label will present the following AIs: (02) Case GTIN, (10) Lot number, (17) Expiry date, (37) Total number of cases and (00) SSCC.

2. If the supplier delivers an order with variable count of units per case, based on the purchase order, then the logistic label will present the following AIs: (02) Unit GTIN, (10) Lot number, (17) Expiry date, (37) Total number of Units and (00) SSCC - *Serial Shipping Container Code*.

For the case labels

1. If the cases are complete cases (fixed quantity per case), then the case label will present the following AIs: (01) Case GTIN, (10) Lot number and (17) Expiry date.

2. If the cases have variable quantity per case (dependant on the purchase order) and because they are not a unit of sale, then the case label will present the following AIs: (02) Unit GTIN, (10) Lot number, (17) Expiry date, (37) Count of trade items within the case.

For products identified solely with a national healthcare reimbursement code (NHRN)

1. Since legally these products don't require a GTIN code, the proposed solution was based on the assignment of a GTIN code to the unit, communication of this pairing (GTIN – NHRN) to all involved parties but didn't require the printing of the GTIN on the unit label.

   If the case is of fixed quantities the label presents the following AIs: (01) Case GTIN, (10) Lot number and (17) Expiry date.

   If the case is of variable quantities, and because the case isn't seen as a unit of sale, the label presents the following AIs: (02) Unit GTIN, (10) Lot number, (17) Expiry date and (37) Count of trade items within the case.

All solutions implied that all paring information (NHRN, unit GTIN, case GTIN and fixed quantity per case, if applicable) was shared with all involved parties beforehand to update the warehouse's master data information.

The Benefits

After extensive work with the suppliers, labels started to arrive at the warehouse correctly structured.

Of the 209 suppliers initially analyzed, 142 worked with GS1 Portugal to implement the new labels. By the end of the project, the warehouse staff registered a 136% increase in suppliers presenting a correct logistic label (from 30 suppliers to 71) and a 174% increase in suppliers presenting GS1-128 labels at case level (from 23 suppliers to 63).
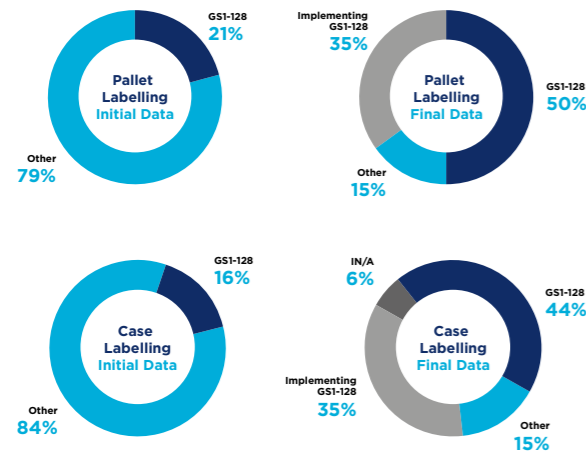
On the retailer's side, the warehouse registered improvements regarding logistic labels, product master data database and time spent receiving orders [comparison between 2021Q1 and Dec2021 + Jan2022]:

- 99.1% reduction in GS1 Logistic Label errors registered upon arrival (from 28.3% to 0.25%).

- 59.9% reduction in invalid GTIN codes [GTINs not registered within the retailer's database] (from 2.91% to 1.17%).

- 48.5% reduction in time spent receiving an order (from an average of 34.76 seconds to an average of 17.89 seconds).

GS1 Logistic Label Errors identified at Reception		
	Q1-2021	Dec.2021 + Jan.2022
Incidence (%)	28,3	0,25
Improvement (%)		99,1

Invalid GTIN codes due to Database misalignments		
	Q1-2021	Dec.2021 + Jan.2022
Incidence (%)	2,91	1,17
Improvement (%)		59,9

Average Time Receiving a Case without GS1-128 Label (s)	Average Time Receiving a Case with GS1-128 Label (s)	Reduction (%)
34,76	17,89	48,5

"This project, implemented within Wells' operations and created by the partnership between GS1 Portugal and MC – Wells, was a pioneer initiative in the healthcare sector that allowed the optimisation of not only the reception process but also the enrichment of product logistic data shared between suppliers and MC – Wells."

"The suppliers had access to GS1 training, adopting best practices in labelling of cases and pallets. The day-to-day work of the warehouse operators was simplified, guaranteeing the automated traceability of products at the point of entry of the warehouse."

Beatriz Almeida
Business Interface Technician
MC - Wells

Next steps

This project included a selected group of suppliers, chosen by MC as the most relevant suppliers at the warehouse.
GS1 Portugal and MC will continue to work together to help the remaining suppliers to implement these labelling and master data requirements.
The goal is to have 100% of suppliers compliant with MC's logistic specifications during 2023.

Conclusion

Thanks to standardised pallet and case labelling, associated with the corresponding alignment of the warehouse's product database, the reception processes became more efficient, registered by the decrease in errors caused by incorrect labels and by the time-savings gained during the execution of the verification and entry of the orders.

The project allowed GS1 Portugal to prove once again that the use of GS1 Standards brings great efficiencies at a process level.

About the author

Beatriz Almeida
Business Interface Technician

Beatriz Almeida with a master's degree in Industrial Engineering and Management from IST – Lisbon University is a partnership enthusiast and likes to learn from others daily. During her experience in Food and Pharma Retail, she reinforced her ability to empathise with suppliers and encourage their efforts.For two years now Beatriz is responsible for dealing with more than 250 pharma suppliers, being a Logistics consultant between them, the logistics service provider and MC – Wells (Pharma Retail business).

Local coordination
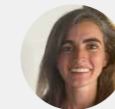
Maria Madalena Centeno
Healthcare, Processes and Standards Manager at GS1 Portugal

Madalena Centeno is an International MBA Graduate from IE Business School with a Master's degree in Veterinary Medicine. She is a Healthcare professional experienced in international and EU data quality standards and logistics. Talented project manager who leads cross-functional inter-company efforts on quality, traceability, and legislative compliance. Today, Madalena is responsible for Standards, Processes, and the Healthcare sector at GS1 Portugal engaging with the Community to help them comply with new regulations and implement GS1 Standards to improve efficiency and patient safety.

Sofia Perdigão
Healthcare Junior Manager at GS1 Portugal

Sofia Perdigão holds a MSc in Pharmaceutical Sciences from the University of Lisbon and completed three months externship at the University of Oxford in laboratory research.Before joining GS1 Portugal Sofia worked at pharmacies and pharmaceutical industries in regulatory affairs and business development areas. At GS1 Portugal, Sofia belongs to the Healthcare and Data Quality & Compliance departments, working in healthcare strategy, as well as general patient safety. She also manages several projects regarding legislative compliance and data quality standards.

About the organisation

MC is the food retail, health and wellness segment of the multinational company SONAE. MC-Wells distributes health, well-being and eye care products.

www.sonae.pt/en/

Colombia

Implementing traceability at a pharmaceutical company

Challenge

Cruz Verde offers a range of pharmaceutical services in Colombia, including wholesale distribution of medicines and other supplies to hospitals. Dosed medication delivered by the company has a lot number and expiration date, but it is coded in a non-standard way. This means that hospital staff receiving the drugs need to manually verify each medication. This takes up to eight hours and has an error rate of 1.5%.

Approach

Staff at the company have worked with teams at GS1 Colombia to design and implement a model for product identification with automatic information capture and transmission. This will make it much easier to develop good logistics practices and to ensure traceability of products, in turn increasing efficiency and safety.

Introduction

Cruz Verde, a large pharmaceutical and medical supplies company providing a range of services in Columbia, is in the process of introducing an automatic traceability system. The work involves defining an identification model and the technology for the automatic capture of information on medicines, supplies and medical devices.

The company has worked working with GS1 Colombia on the project, which consists of three different phases. The first phase focuses on characterisation; the second on the identification model; and the third on the data capture and transmission model. The idea is that, once the project is fully completed, Cruz Verde will have a traceability and identification model for medicines under the GS1 global standards.
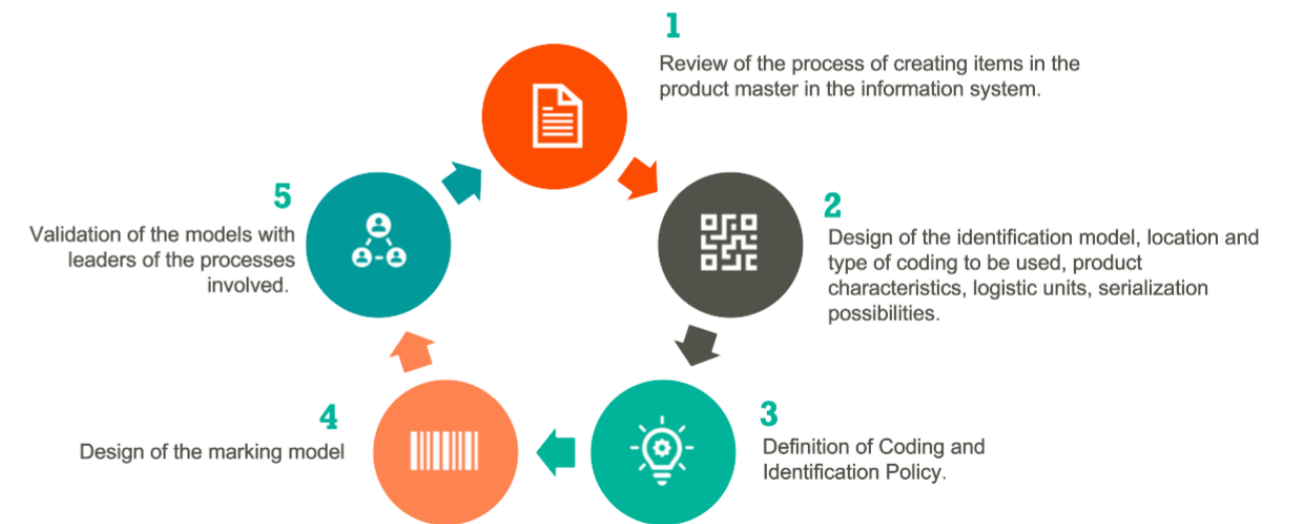
At present, the pharmacy information system in hospitals acquiring goods from Cruz Verde does not facilitate product rotation or verification. The pharmacist must do a manual verification through the packing list to enter lot and expiration date information in Excel. This is time consuming and prone to error.

When the product is dispensed, traceability information to the patient is not recorded. This means the pharmacist must perform inventory queries in Excel to understand stock levels, which takes time and resources. There are between 17% and 20% returns of pharmacy consumption.

Once the new identification model is fully in place, the process will be automatic – and much quicker and more accurate. The model will be based on GS1 DataMatrix barcodes.

Step by step

The characterisation phase of the project covers:

- Building an understanding of current logistic and commercial processes and their interaction.
- Identifying the actors involved in the supply chain.
- Identifying the information of the entities to be traced
- Performing a traceability diagnosis.

This involves information gathering about the current situation, including through interviews with relevant staff. Every step of the current process is mapped out:

- Receiving: Domestic and imported materials, returns, receiving areas, approval, quality, and unloading process.
- Warehousing: Types and special requirements of locations, capacities, infrastructure and equipment, and transfer policies within the warehouse.
- Picking: Analysis of current picking tools and processes.
- Dispatch: Product consolidation and delivery process, transfers, and documentation.
- Inventory control: Documentation and internal processes.
- Invoicing, anchorage analysis, and closing of the logistic process with invoicing.

The next step covers the development of the identification model. It involves reviewing the item creation process in the product master in the information system and:

- Designing the information structures that will support the model: labelling location, serialisation, marking, and identification level under the GS1 standard.
- Designing the marking model.
- Defining the coding and identification policy and detailing it in a document.
- Validating the proposed model with leaders involved in the current processes.
- Developing training sessions on the GS1 standard.
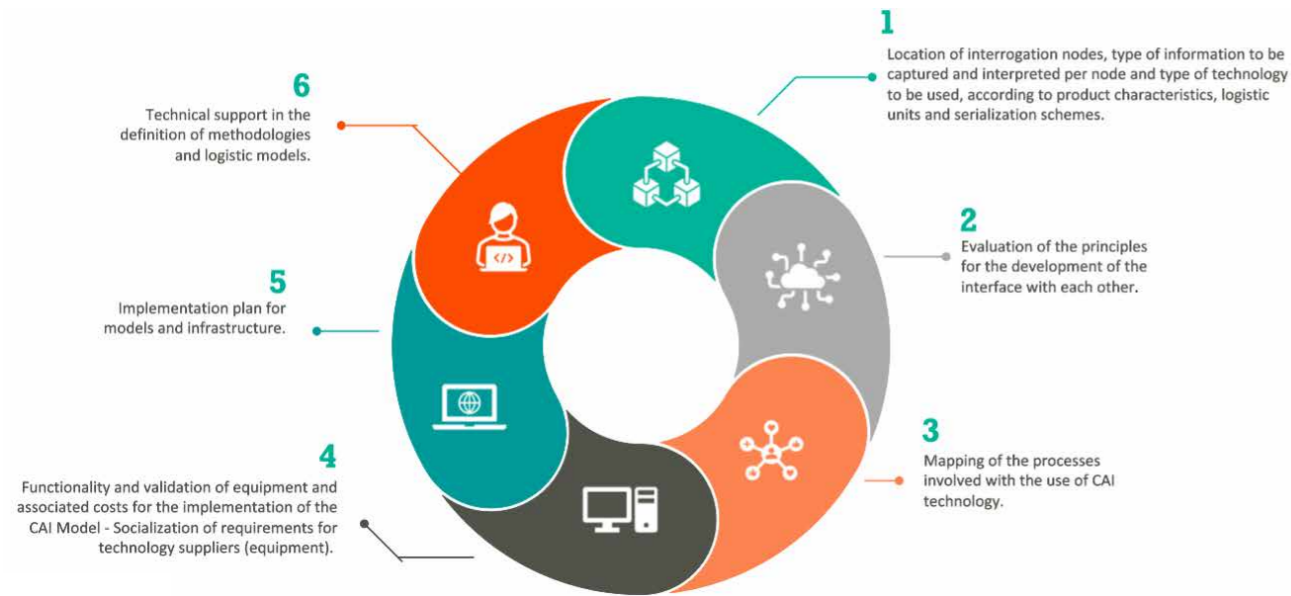
The final stage is to develop the data capture and transmission model. This includes:

- Designing the automatic information capture model with GS1's Global Traceability Standard (GTS). This is a standard that seeks to help organisations and industries in the design and implementation of traceability systems. Designing the model will involve location of point of interaction in supply chains, type of information to be captured and interpreted per point of interaction, and technology to be used, according to product characteristics, logistic units, and serialisation schemes.
- Sharing information on the automatic information capture model with all relevant stakeholders.

- Generating equipment and technology requirements for data transmission to the system.

All the processes involved with the use of automatic information capture technology are mapped, including methodologies and logistic models. Equipment and associated costs for the implementation of the model are detailed, and there is discussion about technology suppliers' requirements.

A full implementation plan for the model, and the infrastructure needed, is developed.

Next steps
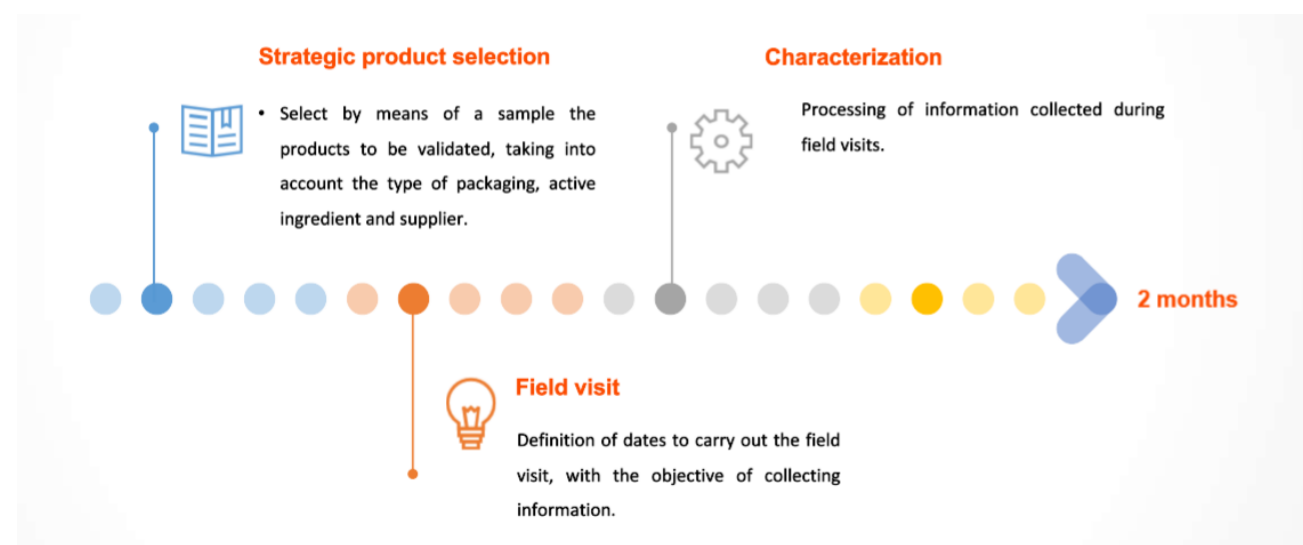
Conclusion

Implementing an automatic traceability system for the products Cruz Verde supplies to hospitals will increase the efficiency of pharmacies. It will remove manual processes which are prone to error, replacing it with automatic data capture. This will increase efficiency and safety.

Cruz Verde is already piloting the setup, testing technology to integrate the model into its information and traceability system.

About the author

Adriana Montoya Cely
Directora Nacional de Proyectos, Imagen de Alta Calidad, Cruz Verde Colombia

Local coordination

Orietta Paola Morales Barros
Hospital Value Network Leader, GS1 Colombia

Orietta Paola Morales Barros has a Master's degree in supply chain and management logistics from OBS School – Universidad de Barcelona and is nurse by profession. Orietta has 17 years of experience in the public and private health sectors, both in the clinical, administrative, and commercial areas. She works on developing initiatives for the integration of best logistics practices among the actors of the health services value network.

About the organisation

Cruz Verde has more than 35 years of experience in the pharmaceutical sector. The firm specialises in the purchase, storage, distribution, marketing, and delivery of health and wellness products and services, which, with excellence, contributes to the quality of life of customers, employees, and communities. It has provided services in Colombia since 2012 and now has a broad portfolio covering five lines of business: retail, through a chain of more than 600 pharmacies; dispensing, with the delivery of medicines to more than four million members of social security entities; wholesale distribution, with sales to more than 400 clinics and hospitals in both the public and private sectors; intra-hospital pharmacies, with the integral management of supply and dispensing inside 21 important clinics and hospitals; and Medicare, a network of 17 clinics specialising in treating complex, high-cost diseases.

www.cruzverde.com.co

NOTES

About GS1 Healthcare

GS1 Healthcare is a neutral and open community bringing together all related healthcare stakeholders to lead the successful development and implementation of global GS1 standards, enhancing patient safety, and operational and supply chain efficiencies.

The development and implementation of GS1 standards is led by the experts who use them: pharmaceutical and medical device manufacturers, wholesalers, distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, solution providers, governmental and regulatory bodies, and trade associations. Evidence available from industry implementations shows that GS1 identification, data capture and data sharing standards in healthcare deliver tangible benefits to all stakeholders. Global members of GS1 Healthcare members include more than 115 leading healthcare organisations worldwide.

Follow us on **social media**

in Linkedin.com/showcase/gs1healthcare
🐦 Twitter.com/GS1healthcare
▶️ Youtube.com/GS1healthcare

Visit our **website** and the **Reference Book digital portal**

www.gs1.org/healthcare
www.gs1.org/industries/healthcare/reference-book-portal

(01) 0 9504000 32301 1