China

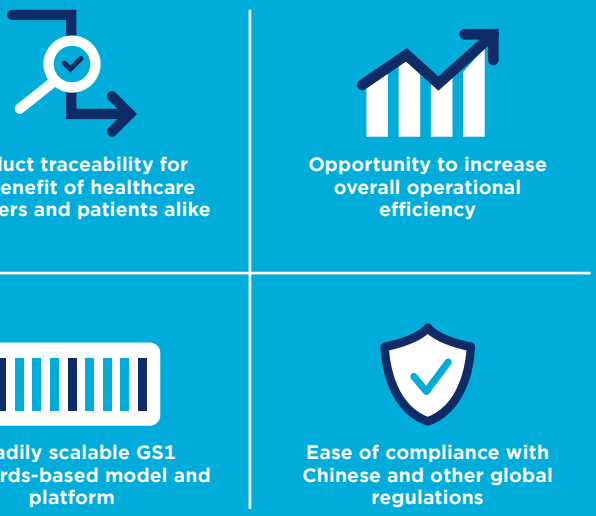
Johnson & Johnson Supply Chain: The evolution of pharmaceutical product traceability in China

Challenge

Transitioning to a GS1 standards-based solution, while desirable, requires changing systems and processes and impacts the entire supply chain. Could a transition occur effectively and efficiently?

Approach

Johnson & Johnson Supply Chain (JJSC) embraces the concept of standardisation and has invested in standard operating procedures, common platforms and GS1 standards. A portfolio of products was selected to be converted from the original track and trace technology used for China to a global standardised approach using GS1 standards.



In the 2000s, prior to its global recognition of GS1 standards, the China regulatory agency published its initial pharmaceutical track and trace regulation and a local technology company implemented a proprietary solution to meet the requirements. In 2019, China revised its regulations, allowing for the use of GS1 standards. However, most of the pharmaceutical industry had already complied and implemented the original proprietary solution.

China's path to GS1

The use of serialisation to track and trace pharmaceutical products to improve visibility throughout the supply chain is not a new concept. It has been long recognised that its potential benefits are multi-layered: improved patient safety, enhanced inventory transparency and increased operational efficiency.

At its core, serialisation and traceability are considered effective tools to combat the counterfeiting and diversion of products. Pharmaceuticals are potentially one of the largest markets for counterfeit goods globally, estimated to be worth $200 billion per year[1].

The China Food and Drug Administration (CFDA), an early adopter of product identification and traceability, began to establish regulations for pharmaceuticals in 2007[2]. In the absence of global alignment to GS1 standards, local standards and solutions were designed.

By 2013, other countries enacting serialisation and traceability regulations started aligning to GS1 standards as they provide a framework to implement consistent product identification and traceability by using a common language to uniquely identify, accurately capture and automatically share vital information about products, locations, assets and more.

[1] World Health Organization. (2020). Growing threat from counterfeit medicines. Retrieved from https://www.who.int/bulletin/volumes/88/4/10-020410/en/
[2] Rodgers, Dirk. (19 June 2019). China: NMPA Drug Traceability Guidance. Retrieved from https://www.rxtrace.com/2019/06/china-nmpa-drug-traceability-guidance.html/

The result was manufacturers implementing two different technologies and supply chain processes to manage both the Chinese traceability requirements and the requirements set forth by other countries using GS1 standards. This scenario also imposed complexities for Chinese manufacturers exporting to other countries.

Overall, with the focus mainly on manufacturing compliance and less on the additional benefits of product traceability, supply chain stakeholders (distributors, hospitals and healthcare professionals) were less inclined to adapt to a drug traceability system.

In 2019, the Chinese National Medical Products Administration (NMPA), formerly the CFDA, revised its pharmaceutical track and trace regulation, allowing the usage of GS1 standards – a notable achievement. The next step was to find manufacturers in the pharmaceutical industry willing to move from China's proprietary solution to GS1's global solution since it would require a significant change to IT systems and processes throughout the entire supply chain.

Johnson & Johnson Supply Chain begins transition in China

Embracing the concept of global standardisation, JJSC welcomed the opportunity to transition to GS1 standards in China, starting with a select portfolio of products.

The project scope included:

- Serialisation of eight stock-keeping units (SKUs) using a GS1 type of "license plate" that includes a Global Trade Item Number® (GTIN®), serial number, batch number and expiry date
- Identification of an IT solution provider that could deploy a cloud solution to enable track and trace in the market
- Funding and enablement of new automated capabilities through the track and trace cloud solution so enhancements could be explored, and supply chain efficiencies realised by the companies involved. Some examples of these enhancements are: mobile device connected real-time with the track and trace platform; possibility to develop business-to-business connectivity using webservices and operational process automation; leaner and more optimised end-user interface; exploration of relevant online content via mobile phone scanning by end customers and healthcare professionals (electronic leaflets, educational content and product information)
- Integration between JJSC and the solution provider platform, automating the electronic files exchange, supporting basic supply chain track and trace operations. One of the examples of files to be shared across platforms is the Advanced Shipping Notice (ASN) containing all serial numbers and hierarchies (carton > shipper case > pallets) communicated by the JJSC enterprise platform to the solution provider platform when products get shipped from global sites to the Chinese market
- Purchasing of warehouse mobile devices (PDAs) to be used by downstream distributors to scan the GS1 products in this first phase of the project

Solution provider selected

At the end of 2019, following an assessment of several solution providers, an agreement was formalised with a multinational technology company based in China. "One of the biggest advantages to having this technology company manage the track and trace process in China is that they have a multi-purpose mobile application that could be a useful tool for end customers and healthcare professionals scanning products and retrieving value-added online content," says Leandro Oliveira, Digital Identification & Traceability Asia Pacific Lead at Johnson & Johnson Supply Chain.

Distributors identified

"In 2018 and 2019, we conducted surveys with Tier 1 distributors. Results indicated a clear willingness to explore more innovative and effective approaches to handle product traceability. Distributors' interest in GS1 and global standards was gradually increasing. This is one of the factors that led us to make the change in China," adds Lindsay Tao, Corporate Director, Global Policy, Worldwide Government Affairs & Policy.

All distributors that would eventually handle the initial eight SKUs were identified. Focal points representing each distributor were engaged and trained, and a strong communication strategy was enabled.

Project deployment

Project deployment kicked-off in January 2020 with a core team comprised of members from both a cross-functional team led by JJSC and the technology company. Requirements were defined, aligned and implemented, and recurrent project meetings occurred throughout 2020.

In addition to internal business and IT functions, other external organisations were involved, including the Partnership for Safe Medicines, GS1 China, China Pharmaceutical Industry Association and the China Pharmaceutical Commerce Association—all willing to promote the use of global standards.

By the end of 2020, the technical implementation was finished, initial batches following GS1 standards were being commercialised, the entire supply chain handling these products was trained and the equipment was in place to start exploring the GS1 benefits.

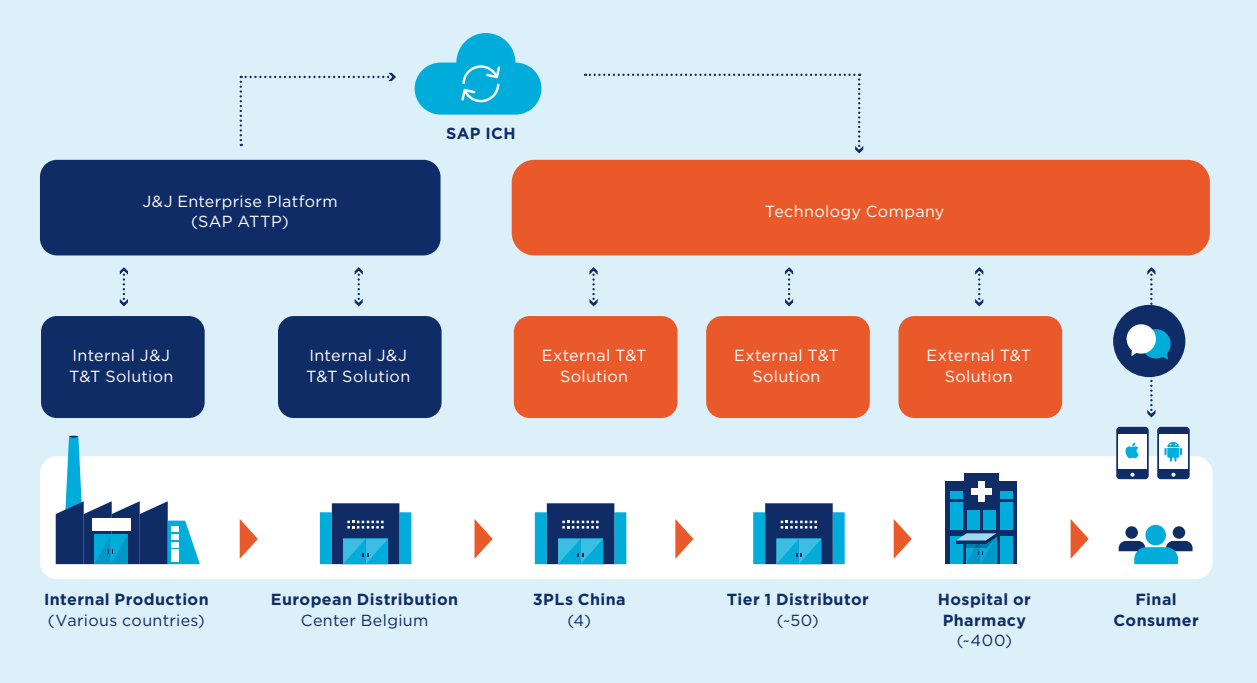


Figure 1: JJSC supply chain in China

Next steps

Moving to the next phase, JJSC is planning to expand the scope of products operating under the new business model and platform for China. The advantage to the new model and platform is that it is readily scalable, and no new infrastructure needs to be built.

"The development and deployment of a cost optimised and localised solution in China enabling GS1 standards is an important proof of concept that allows us to explore similar solutions in new and smaller markets globally," says Vivek Nadadur, Senior Director for Digital Identification & Traceability, Johnson & Johnson Supply Chain. Eventually this platform will integrate with the NMPA national platform where data can be shared with NMPA and supply chain partners, especially hospitals when needed.

Another feature being evaluated is a multi-purpose mobile application. It's an all-purpose 2D barcode scanner that could potentially become a go-to tool for product scanning and provide relevant consumer and patient value-added information, such as verification, e-IFU, patient education and online medical services.

Impacting the regulatory landscape

In addition to Johnson & Johnson, other manufacturers started to transition to GS1 global standards in 2020 and the overall regulatory landscape in China appears to be more open to the exploration of benefits and the value added with the use of global standards and best practices for product traceability. Manufacturers, third-party logistic providers, distributors, hospitals and pharmacy chains investigating GS1 and standardisation are starting to see it as an opportunity to increase overall operational efficiency. Ultimately, these efficiencies will benefit healthcare professionals and patients throughout China.

About the authors

Lindsay Tao, M.D., Corporate Director, Global Policy, Worldwide Government Affairs & Policy, Johnson & Johnson.

Lindsay Tao provides cross sector leadership in regulatory policy focusing on safety, quality and efficacy of medicinal products. Before she moved to her current position in 2009, she was the Vice President of Strategic Medical Affairs, Johnson & Johnson Medical Greater China (including China, Hong Kong, Taiwan), responsible for regulatory, quality and compliance, clinical research & medical, health policy and government affairs. Besides her role in J&J, she also represents the healthcare industry and takes different roles in regional and global organisations, e.g., GHTS SG1, UDI ad hoc working group members, WHO medical device nomenclature expert group member, AHWP Vice Chair, and APEC RHSC industry coalition alternative coordinator to promote international regulatory best practices and regulatory convergence. Ms. Tao was trained as a clinical physician and worked as an Oncologist in Shanghai Cancer Hospital, Fu Dan University before she joined J&J.

Vivek Nadadur, Sr. Director, Digital Identification & Traceability, Johnson & Johnson Supply Chain

Vivek Nadadur leads Digital Identification & Traceability and the delivery of critical enterprise capabilities in the areas of regulatory compliance, customer compliance, standards and emerging technologies. He focuses his efforts on uniting the physical product to the digital thread, driving greater supply chain transparency, integrity and effectiveness. In support of Johnson & Johnson's partnership with GS1, Mr. Nadadur is a member of the GS1 Data Excellence Board and Committee of Standards Board. Since joining Johnson & Johnson in 2013, he has been responsible for driving several strategic initiatives, including ERP portfolio strategy and supply chain systems integrated roadmap. He also led Johnson & Johnson's global deployment of the serialisation and traceability program. Mr. Nadadur holds an MBA from the University of Chicago Booth School of Business and a bachelor's degree in physics from the University of Delhi.

Leandro Oliveira, Asia Pacific Lead, Digital Identification & Traceability, Johnson & Johnson Supply Chain

Leandro Oliveira has spent most of his career in strategic supply chain functions, both in technology and business roles. He has lead global digitalisation programs for Johnson & Johnson Supply Chain, including end-to-end product traceability, UDI, RFID, cloud computing and e-Labelling. Prior to joining Johnson & Johnson Supply Chain, he worked in the energy, oil and gas industries, focusing on the deployment of technology to solve complex business problems. Mr. Oliveira has lived in three countries in different continents and is currently based out of Singapore. He has a bachelor's degree in system analysis, MBA in project management by FGV Brazil and UCI United States and holds PMP and APICS CSCP certifications.

About the organisation

Johnson & Johnson Supply Chain includes three business sector supply chains—Consumer Health, Medical Devices and Pharmaceuticals—that cover planning, sourcing, internal and external manufacturing, as well as the Supply Chain Strategy, Innovation & Deployment organisation and the Deliver organisation, which manages distribution and customer service. Additional enterprise-wide functions that are part of the Johnson & Johnson Supply Chain include Quality & Compliance, Environmental Health, Safety & Sustainability and Engineering & Property Services, and Procurement.

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