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Patient Safety and the Challenge of Serialisation at UCB

Abstract

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

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

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



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The concept of serialisation

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

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

To date, two traceability models are emerging:

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

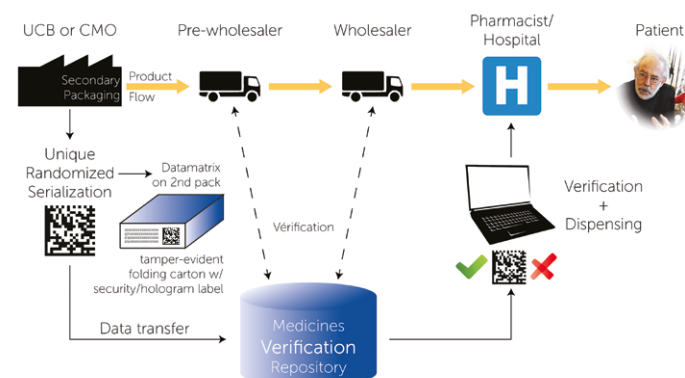
At UCB, the decision was taken to implement item level serialisation with the required information to be printed in human readable format and encoded either in a linear bar code or a two dimensional (2D) bar code, such as the GS1 DataMatrix, depending on the legislation.

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

The European Stakeholder Model

Overall Goal - Improve patient safety

Reduce the risk of counterfeit products being dispensed, detect expired products automatically, perform product recalls more effectively and efficiently, deliver the right product to the right patient.





Initiating the serialisation programme

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

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

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



Structure of the programme

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

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

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

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

Using GS1 Standards

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

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

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

Key success factors

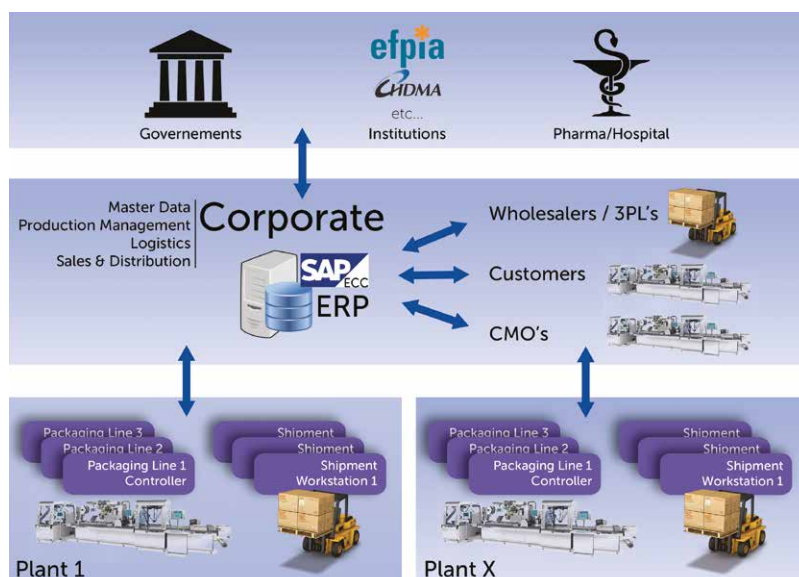
From a **regulation perspective**, the programme started at a time when very little information was available on the requirements and key assumptions had to be made on points such as information to print, bar code format and contents, aggregation, and randomization. At the same time, UCB wanted to design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





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

It had to consider a scalable architecture to adapt to various sizes of plants and, at the same time, be able to comply with evolving regulations.



UCB's global solution design

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

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

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

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

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

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

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

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

Benefits

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



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

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

Beyond product safety, identification will also allow to track additional information assigned

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

Conclusion

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

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

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

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

About the authors

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

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About UCB

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

