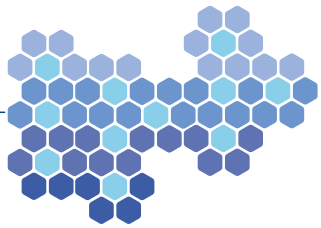

Serialisation Data: Help or Hindrance?

By Ramesh Chougule at Infosys

A growing need for serialisation is spreading around the globe. A reduction in counterfeiting is clearly desirable, but the implementation of successful solutions is not as easy as it might sound

Serialisation is now a mandate. It started with specific states in the US and was quickly followed by various countries in Europe, and now even emerging economies, such as China and India, have set up timelines to make pharmaceutical products serialised in their supply chains. The intention is to reduce counterfeiting by tracking products in supply chains and improving compliance fulfilment, but there is also an opportunity for pharmaceutical companies to improve inventory visibility and patient safety. However, the serialisation agenda is not without its challenges. In order to be successful, it needs to be supported by a technological backbone, a clean implementation roadmap, a robust process and security framework, and sufficient data analytics technology.

When it comes to serialisation, possibly the greatest challenge, and asset, for pharmaceutical companies is data. Regulations require that data is captured at various stages of the supply chain, transmitted to regulatory agencies and stored for various periods of time for future use. During the operational execution, multiple implementations indicate that the database size doubles every 18 months. Integrating this serialisation data with existing petabytes of enterprise resource planning (ERP) data is creating a phenomenon known as big data, where pharmaceutical companies are not only having to cope with huge volumes of data but also multiple types, including structured and unstructured.

Keywords

Serialisation

Enterprise resource planning (ERP)

Big data

Serialisation not only offers technological and security challenges; it also creates significant problems in process design and data integration. To meet industry regulations and obtain the business benefits on offer from serialisation, the captured data in global supply chain operations need to make sense in relation to the existing transactional data elements in both ERP and in the data warehouse. Taking advantage of big data will help to build this relationship and to make the optimum use of captured serialised data a boon to business.

Overview of Serialisation Regulations

Product traceability is a hot topic in the pharmaceutical industry at the moment due to the widespread adoption of serialisation regulations by governing bodies across the globe, such as California's e-Pedigree law or the serialised 2D barcode mandated by the EU. While in essence all of them track the product at various parts of supply chain, such as receiving the product from the previous entity or dispatching it to the next entity in the process, which then needs to be submitted to the governmental agencies, each regulation is specific to its own region. For example, California e-Pedigree law requires creation of a pedigree document at each stage of the supply chain. As of now, the law mandates pharmaceutical companies to complete the implementation for at least 50 per cent of their products by 2015, and 100 per cent by 2016.

Aside from the US, the Chinese authorities have also mandated the traceability and submission of the information to their Ministry of Health by March 2011, and Turkey has the requirement to complete Phase 1 by March 2010 and Phase 2 by January 2012. Lastly, from a European perspective, the EU wants pharmaceutical companies to comply with the European Federation of Pharmaceutical Industries and Associations (EFPIA)

Figure 1: Serialisation requirements in various countries

model and be able to provide traceability information at the point of sale by 2017. Figure 1 depicts the details of serialisation requirements by various countries.

Data Collection and the Role of Big Data

Data collection is pivotal to the tracking process, with information collected about the product at multiple stages of the supply chain and in various logical units, such as sales unit, case, bundle and pallet. To compound this, there are usually multiple partners in the supply chain, from different organisations with varying applications and interfacing solutions, and with data in numerous formats. Understanding and managing this big data is one of the main issues facing pharmaceutical companies when it comes to serialisation.

To use this data for business decisions, pharmaceutical organisations need to integrate serialised data with ERP data. However, because it all comes from different sources, the first step is to turn it all into a single format. Ensuring that this can be done quickly is a competitive driver for reducing the cost of a traceability report, but with data doubling every 18 months, bringing forth homogeneity and producing such useful decision-supporting information elements is key.

In addition, to tackle big data challenges pharmaceutical companies need to consider a solution that can connect the serialised data with the sales unit, its location, the time of the event, and so on with the transactional data such as the sales order, dispatch documents, manufacturing orders, and the recipes utilised for manufacturing the sales units. By combining the different data sets as the process goes along, pharmaceutical companies will find it easier and more efficient to collate the traceability reports.

Technology Challenge

However, it is not just the data itself that is posing a challenge. Pharmaceutical companies are also struggling to effectively integrate existing ERP solutions with serialisation needs. In the serialisation process, the product needs to be tracked at the sales unit, bundle, case and pallet levels during its movement through the supply chain. Track and trace solution architecture has four important components: packaging line solutions; distribution/warehouse processes solutions; interfacing with the ERP backbone; and interfacing with applications of external entities, such as the Ministry of Health. Most pharmaceutical organisations have already

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established the ERP backbone for the defined business processes. The packaging line solutions, however, involve deeper integration with manufacturing execution systems. ERP applications, such as SAP and Oracle, do not yet provide the packaging line solutions. The challenge lies in integrating the serialised data created by these solutions and organising it in a meaningful way that ERP systems can integrate with.

Security and Disaster Risks

There are also security issues associated with track and trace solutions. Barcode and radio-frequency identification (RFID) technologies, for example, carry a particular risk because their technology could be replicated. There are also concerns regarding unauthorised access to sensitive data. Such risks could be mitigated, however, by applying strict security governance and deploying multiple layers of authorisations. The security and access frameworks have matured in the last few years and security breaches have been reduced. In addition to these security concerns, the distributed data captured in the supply chain also poses the risk of an equal or higher number of disasters or failure risks. This issue needs thorough disaster recovery planning, considering multiple locations of data captures in the supply chain.

Process Architecture

Another complex task in the implementation process is creating the architecture for serialisation. As depicted in Figure 1, the traceability requirement varies from country to country. In such cases, the defined process needs to meet the requirements of multiple authorities and feed the necessary information into multiple governing bodies. Clearly, defining the traceability points in the supply chain, creating the right serialisation code structure and establishing process governance are all important tasks. Business process teams from various parts of the supply chain across the world need to spend coordinated efforts to define the process blueprint for this implementation. Typically, serialisation implementation programmes run for a substantial time because the compliance timelines are changing and the maturity of requirements are continuously evolving. Establishing the process that will meet currently defined requirements and will also be flexible enough to accommodate the new standards and business changes is a very a challenging task. It consumes extensive business resource bandwidth, not to mention the significant technological efforts involved.

Cost Perspectives

Lastly, the implementation cost of serialisation is relatively high because of the levels of diversity that come from different data formats, distributed locations of operations, diverse technologies to be integrated, and different sets of teams which must work together to implement it successfully. The infrastructure cost is relatively higher with multipoint solutions (primary hardware as well as disaster recovery), the cost of tags and barcodes, and the price of software applications. In the current context of changing regulatory requirements, organisations need to plan the phases and milestones of implementation programmes carefully so that any rework costs in the implementation cycle are kept to a minimum.

However, despite all these challenges, meeting serialisation regulations is a future that all pharmaceutical companies must face, if they are not doing so already. Additionally, apart from allowing them to remain compliant, there are business benefits to be had, derived from the product traceability. For example, organisations can use the process of getting ready for serialisation to improve their inventory visibility in the global supply chain, reduce the cost of returns and replacements, respond to any adverse events faster and at a lower administration cost, and improve their own sales intelligence, to name just a few. Serialisation will also help companies to manage the supply of short shelf-life products more effectively and reduce the loss due to the expiry of items. The ability to track items will create the ability to cross-supply, retrieve and ship much faster than before, which will add equally to top line and bottom line.

Today, pharmaceutical companies pay huge fees to distribution companies to obtain meaningful sales data at the right time to make their sales strategies work. However, in a fully serialised supply chain, this data is available immediately from within the organisation, helping the business to improve sales and reduce any inefficiencies.

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