Key learnings from serialisation projects – Part 1

by Andrew Love and Stephen McIndoe

Pharmaceutical product serialisation is being introduced across the world to prevent fraud and improve patient safety. Achieving this across your company supply chain has the potential to be a costly and complex undertaking. In this first paper of two, we provide a series of six tips as we cover the key areas to consider, and we believe using these learning points when devising your serialisation strategy will reduce your risk and ensure a successful implementation.

Today's feature presents the first part of this paper, including the first two key learnings. Next week we will publish another four learnings.

Introduction

In the previous articles in this series on serialisation, we have explained the issues associated with counterfeit pharmaceutical products, the various aspects of serialisation, and the how you would go about developing your serialisation strategy.

While helping clients implement serialisation programs and projects over the last 10 years, the Be4ward team has recorded many lessons learnt and continues to do so. These next articles explain, in a series of learning points, some of the key things that we wish we had known before embarking on our early projects.

We hope that this information will help you make a success of your serialisation activities and avoid some of the mistakes that were made in the past.

A reminder – what is serialisation?

Serialisation, or serialization as it is spelled in some regions, is a tool that can be used to improve product security, help ensure patient safety and prevent fraud. Because of the benefits, much legislation is either in place, or being developed across the world that mandates serialisation. Failure to comply with these legislative requirements will mean that pharmaceutical companies will not be able to sell products in the affected markets.

Generally, serialisation requires that every product pack is uniquely identified with some form of machine-readable code and registered in an external database, together with information about the product contained in the pack. Depending on the particular serialisation model, it may also be necessary to update the external database with product movement and change of ownership information, a significantly more complex requirement. Implementing serialisation across the supply chain is a major and very costly undertaking.

It is imperative that companies have a comprehensive strategy for tackling serialisation that will ensure that any risks to product supply are adequately mitigated.

Learning 1: Executives need to understand that serialisation will halt sales if implemented poorly

Serialisation is a cross-functional, and in many cases in a typical pharmaceutical company, cross-organisational endeavour, requiring all parties involved to play their part in a coordinated and timely manner. To achieve this in any organisation, it is typically necessary to have the appropriate level of top-level sponsorship.

For serialisation to be successful in protecting patients from fraudulent product, the serialisation information must align with the product in hand. If not, it will have to be stopped. Errors in systems will lead to legitimate product being stopped. At best, an investigation will clear the product of suspicion at a later time. At worst, legitimate product will have to be destroyed. In either case, the product is either temporarily or permanently unavailable for sale and, therefore, unavailable to patients.

Whilst we would always like to be in a situation of motivating action with incentives rather than threats, this potential unavailability of product for sale at some point in the supply chain needs to be understood by the relevant executives. It should be used to gain appropriate cross-functional and, where appropriate, cross-organisational sponsorship.

Furthermore, governance needs to be put in place across all the parties involved to ensure that decisions are made and activity is coordinated in a manner that will lead to timely implementation of the end-to-end solutions. In the lack of such governance, it is all too easy for local teams to make their own interpretations of legislation, and define solutions and timelines in isolation, resulting in an end-to-end solution that does not work.

Learning 2: The technology is still relatively immature

Understandably, in the early days of serialisation in the pharmaceutical industry, the late 2000s, the technology available and the supply base providing it were, by and large, relatively immature. In the intervening years, whilst a significant amount of serialisation legislation has been passed and millions of packs have been serialised, the supply base and technology in 2017 is still not as mature as one might hope for.

Of all the technology areas, the technology necessary at the packaging lines is probably the most mature, with a number of well-established suppliers offering robust and proven solutions. However, a word of caution in this area is that many of these organisations are relatively small businesses. Their scalability to meet the inevitable increase in demand over the next few years must be carefully considered by potential customers.

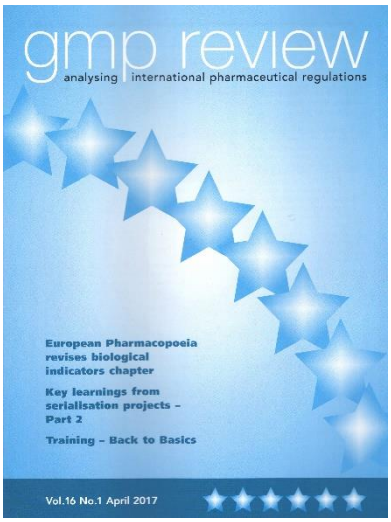
Unfortunately, serialisation solutions at the enterprise level are not yet at the same level of maturity as line solutions, even from vendors who sell both solution sets. This appears to be because of two main factors. Firstly, the reality is that in recent years, many organisations have implemented tactical serialisation solutions not requiring full strength enterprise level implementations. Secondly, to be fully mature, solutions need to cater to both the normal and abnormal business scenarios. Regrettably, there are very few countries, if any, where all these issues have been resolved. Therefore, the solutions offered by the supply base have, in general, not had the standards in place, nor the number of end-to-end supply chain implementations necessary to develop what many would consider to be mature products.

Having said that, industry and standards bodies are still working to define how serialisation will operate in many of these abnormal scenarios and/or particular situations.

Knowing this, when entering into any relationship with vendors in this area, it is best to assume that the solutions are not fully developed and that issues will crop up that, in a mature environment, you might expect to have already been resolved.

This article will be continued in next week's LOGFILE. Don't miss another four key learnings from serialisation projects.

Authors



Stephen McIndoe is a Vice President at Be4ward and works with global healthcare companies to create award-winning world class packaging labelling and artwork capabilities. He is also co-author, with his colleague Andrew Love, of the book *Developing and Sustaining Excellent Packaging Labelling and Artwork Capabilities.*

Andrew Love is also a Vice President at Be4ward. He was previously Head of Global Packaging Design at GlaxoSmithKline.

Excerpt from *GMP Review*

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