Key learnings from serialisation projects – Part 1

by Andrew Love and Stephen McIndoe

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. This next series explains, 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 infor¬mation 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

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.

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.

Learning 3: The supply base is overstretched

For many years, there has been a great deal of uncertainty in the implementation timing of certain legislation requirements, and legislators have often delayed deadlines. This has had a knock-on effect on the solution providers. Understandably, they have been reluctant to commit to expanding their businesses until they were confident that the customers would require the capacity.

To date, this has often meant that, particularly in the enterprise solution space, actual capacity and development activity has been limited. Indeed, whenever legislative deadlines have approached in the past, it has been clear that the vendors quickly became capacity constrained, with availability of key staff being highly restricted and noticeably extending delivery lead time.

With implementation dates in the US and EU looming, vendors are reporting significant expansion to meet the anticipated demand. Whilst this is very good news in terms of the capacity it will create, there are two related issues that will likely spin out of this. Firstly, it is very challenging to rapidly expand any business without impacting the quality of products and or service. Secondly, the expansion is being carried out to meet an anticipated significant increase in demand and, therefore, this new capacity is unlikely to do anything more than meet this additional demand.

Therefore, we recommend ensuring that any serialisation plan be built using conservative lead time estimates and that capability implementation be phased. Also, consider avoiding plans that call for significant capability implementation in the 2017/18 time period. We predict this period will be highly challenged, much like dealing with the Y2K issue in 1999.

Learning 4: Ensure a robust cross-organisation impact assessment is carried out and maintained

To successfully implement serialisation solutions, pieces of capability need to be implemented across many functions and geographies in an organisation. More often than not, pharmaceutical companies also need to ensure that capabilities are implemented in many third-party supply chain partners as well. Impacts on such aspects as products, countries, supply chain nodes, supply chain partners, supply chain processes, and information technology systems all need to be considered.

Given the long lead-times and complex interdependencies between the different elements of the serialisation capabilities, we have found it essential to ensure that an early and comprehensive impact assessment is carried out and then acted upon.

Furthermore, serialisation requirements and typical pharmaceutical companies are constantly evolving. Therefore, there needs to be a mechanism in place to ensure that any impact assessment is reviewed regularly to ensure changes are adequately addressed in a timely manner. It is our experience that relying on established business processes, such as change control, do not provide a timely or robust mechanism to achieve this objective.

Learning 5: Ensure the true complexities of your supply chain are understood early

To implement effective solutions to address serialisation, it is important to understand the true complexities of the product/supply chain mix. Many day-to-day realities of a modern pharmaceutical supply chain can present significant issues to serialisation implementation activities if not understood early.

Situations such as local re-labelling and kitting activities; sale of product packs into one market which are designed and manufactured for another; locally driven cross-market supply; and multi-market presentations can all present significant challenges.

Also look for situations where your organisation is acting as

a contract manufacturer for another company. In this type of situation, you will be faced with integrating your solutions into the serialisation model of your customer. This is an area where standards and solutions are not well developed in many instances.

Furthermore, the high cost of implementing serialisation capabilities means that it is sometimes appropriate to change the supply chain to reduce cost. This type of change often requires significant time to achieve and, in the case of such things as regulatory approvals, is not always within the control of the pharmaceutical company.

Learning 6: Choose solutions that will be globally capable

With the drive to implement initial solutions quickly, it is often tempting to "keep things simple" by selecting and implementing solutions that are only capable of meeting the immediate or limited requirements.

Clearly, tactical solutions of limited scope and or capability have their place. If nothing else, they may be the only practical way to meet short-term legislative deadlines in some cases.

We have experienced several instances where initially selected tactical solutions become the company standard by default over time, despite the fact that these solutions were not originally selected for a broader capability and or geographical scope. This often creates significant issues to subsequent implementations which could have been avoided.

We, therefore, recommend resisting the temptation to rush into implementing short-term tactical solutions wherever possible. Where this is necessary, some mechanism should be put in place to review their suitability in the face of expanding requirements and allow switches to more appropriate solutions if necessary in a timely manner.

Conclusion

In this article, we have talked about the need for corporate sponsorship for a corporate-wide issue, to select solutions that are globally capable whilst recognising that the supply base is already overstretched and some solutions are immature. The increased complexity of global solutions will potentially place greater strain on your chosen suppliers. We also discussed the need to understand the true complexities of your supply chain and the need to undertake robust impact assessments across the organisation. Without fully understanding your operation and the impacts upon it from serialisation, you risk implementing suboptimal or even incomplete solutions. In the next article, we will look at the further Learning points 7 to 12.

We hope you find this information useful. We are always searching for ways to improve our work, so of you have any feedback, please do not hesitate to contact us at enquiries@be4ward.com.

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.