

## Introduction

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

In our last article, we talked about selecting global solutions, the risk of an overstretched supply chain, the need to fully understand your supply chain, and undertaking a thorough impact assessment across the organisation. In this article, covering tips 7 to 12, we talk about our other learning points.

## A reminder – what is serialisation?

Serialisation 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.

## Learning 7: Develop and leverage standard solutions where possible

For larger organisations, where there will be a number of sites, packaging lines and possibly distribution operations to enable for serialisation, developing standard solutions has proved very useful in enabling roll-out in a timely and resource-efficient way. Serialisation systems are complex and, therefore, not trivial to design and implement. The various solutions also need to interface effectively with each other. Selecting and developing standard solutions, therefore, provides an opportunity to design and prove capabilities once and significantly reduce the overall timeline, cost and risk of subsequent implementations.

In complex organisations, it is unlikely that it will be practical to develop single solutions for capabilities such as the packing lines. However, it should be possible to achieve significant simplification by adopting this approach and selecting a small number of standard solutions and or methodologies.

**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 second paper of two, we provide the second 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.**

A knock-on impact of this approach is that there needs to be time built into the project plans to enable this approach to be successful. The initial implementations need to be given the time and resources to develop well thought through and comprehensive solutions. Furthermore, ideally these solutions need to be implemented and optimised before rolling out subsequent solutions so that learning can be built into these later implementations. Unfortunately, given the long lead times of developing and implementing initial solutions, time is rapidly running out for companies wanting to fully benefit from this approach.

## Learning 8: Do not underestimate the amount of resources required to deliver serialisation

Given the broad reaching impacts of serialisation across an organisation, a great deal of time and effort is required to deliver effective solutions. It is all too easy for projects to focus on aspects, such as line solutions and the enterprise information technology (IT), and miss some of the other impacted areas.

As with all projects, deliverables cannot be achieved to acceptable time, cost and quality without sufficient resources with the right skills and knowledge being applied to the problem at the right time. Many of us have a tendency to underestimate the amount of resources required to achieve any given set of tasks. This can often be compounded by the new nature of serialisation; meaning, that organisations have little or no analogous experience to be able to adequately assess the resources needed. Therefore, in order to ensure the correct level of available resources throughout the project, we would recommend starting conservatively in defining the resource levels required and tracking the achievement of resourcing plans and resource utilisation.

### **Learning 9: Put a capable, dynamic and motivated leader on the problem**

Serialisation is clearly a complex and evolving topic that touches many parts of an organisation. With the challenges facing the leadership that is charged with implementing such capabilities, they need to have a broad range of skills, the drive and motivation to anticipate risks and issues, as well as ensure they are effectively managed proactively.

Serialisation is a complex technical problem involving engineering systems at the line and distribution operation levels, as well as enterprise IT systems at the site and global levels. It should also be remembered that many of the solutions lack maturity, therefore, there will be many practical issues to deal with during implementation. Consequently, the leadership of a program needs to have the technical strength and breadth to succeed in managing this technical challenge.

Furthermore, serialisation touches many parts of any organisation, often crossing the traditional organisational lines of supply chain, commercial, and research and development. More often than not, company boundaries also need to be negotiated as contract manufacturing, third party logistics providers and commercialisation partners need to come together to provide effective end-to-end solutions. Therefore, the leadership of a program often needs to have the cross-functional and cross-organisational skills and experience to effectively navigate this complex change management environment as well as the technical skills and knowledge described above.

### **Learning 10: Ensure you understand the evolution of serialisation legislation and instruct the organisation accordingly**

Serialisation legislation can be somewhat vague, incomplete and sometimes contradictory, with individual pieces of legislation often evolving over a long period of time. Interpreting the legislation as it evolves and predicting its impacts can present significant challenges. We have found that there are several key pieces of expertise required to successfully interpret evolving requirements. Local regulatory and legal representatives will be required to obtain the legislation, manage dialogue with the regulatory agencies, and interpret its application to a company's products and the consequences of non-compliance.

Serialisation expertise is clearly a necessity, both in the technical aspects of the topic, but also in the ways that serialisation legislation typically evolves. Local and central management also need to be involved to ensure that the requirements are interpreted appropriately in the context of the local environment and company situation. Also, an important and practical point to remember is that the

legislation will, more likely than not, need accurate translation into English.

When considering the timelines allowed in the legislation, history has shown that timelines are often vague and subject to change. However, when implementation dates are finally set, they often do not allow enough time for robust implementation. Therefore, waiting until the legislation is clear can result in missing deadlines.

Given the uncertainties in requirements and timing, organisations need to ensure there is a clear way of communicating their considered view of the legislative requirements at any particular moment to the various project teams who are responsible for designing and implementing solutions. Failing to do this will potentially result in individual functions or groups creating their own interpretations of legislation and timelines, which at minimum is wasteful of resources, but at worst results in capabilities being implemented which do not meet the eventual requirements of the legislation.

### **Learning 11: Involve local country teams and management early**

In many cases, particularly in track and trace serialisation models, local country teams will have to work with the local supply chain and local suppliers to ensure that robust local elements of the overall serialisation solution are implemented. This is in addition to the local responsibilities with respect to interpreting the legislation that we have described elsewhere.

A few things need to be considered for this to be successful. Firstly, local country management is typically sales and marketing focused which often means that supply chain and technology issues are not high on their agenda. Secondly, the lead-times required to deliver complex serialisation solutions are often far longer than typical local project timelines in sales and marketing organisations. Thirdly, local IT and engineering resources are either non-existent, or very thinly spread across many issues.

Local teams are often most appropriate to deliver local solutions. However, it is often neither efficient nor effective for such teams to operate in isolation of central or other resources who have established experience of designing and implementing serialisation solutions. This is particularly important where the implementation of standard solutions is required and will always be the case when interfacing local solutions with central capabilities. We recommend that central teams and their governance consider carefully how to ensure this happens effectively.

As difficult as the technical challenges are to overcome, the cultural and geographical challenges of distance can often be greater. Good change management practice is essential to

ensure that effective relationships are formed, collaborative design activity is carried out, and implementation is managed in a coordinated way. We have found that there is no effective substitute for some degree of face-to-face activity throughout a project, with its implications on travel budgets and resource time. Furthermore, constant focus needs to be given to establishing effective day-to-day ways of working between remote teams. Simple issues, such as establishing effective video/teleconference facilities, can often be surprisingly challenging.

Another aspect which needs to be considered is that of culture. Central teams need to understand the local culture, particularly with respect to local decision making, day-to-day working styles, and risk and issue management. Once understood, mechanisms need to be put in place to ensure a culturally effective management and governance approach is established. Therefore, we would recommend engaging with local country management and resources early to ensure that robust and timely local plans are in place, supported by the right level of competent resources and ways of working.

### Learning 12: Get an end-to-end solution working early

The end-to-end serialisation solution in any organisation is complex and holds a myriad of opportunities for individual solution elements to not work as planned, interfaces to fail, and other things to go wrong. In our experience, organisations benefit a great deal from learning first-hand how to deal with these practical complexities and put the appropriate support capabilities in place to deal with them through the implementation of early end-to-end solutions.

It is also the case that certain aspects of serialisation present significantly more difficult challenges, complexity and knock-on impact than others. An obvious example of this is implementing track-and-trace capability and the requirement to aggregate product to shippers and shipments that it drives.

Whilst an organisation may not have the legislative drive to implement complex capabilities early, there are likely to be many learning benefits in implementing such a complex end-to-end solution early. This can test and prove solutions as well as creating lessons learnt from these early and complex implementations at a time of lower business risk. Buy-in by senior management to such an approach is essential, as investment decisions will need to be supported earlier than they otherwise would.

### And finally, do not forget the non-legislative benefits of serialisation

Our experience suggests that serialisation programs often set out from one of two places. On the one hand, there is the first

group of programs that are very pragmatic and strive to deliver solutions which are focused on meeting hard legislative requirements and nothing more. On the other hand, there is the second group that strives to deliver a broader capability and benefit to the organisation at the outset. For example, capabilities that can be leveraged to enhance product security, improve customer relationships, and provide product movement information and supply chain visibility. Often, senior management is rightly concerned in getting the maximum return for the organisation's significant investment in this area.

Regardless of the starting point, many programs quickly iterate towards the first category as the practical reality of the size of the legislative task alone hits home. Whilst it is often appropriate for a program to focus in the shorter term on delivering to the hard legislative deadlines, it is unfortunate if this is also done by limiting scope and capability designed into solutions to merely meet these short-term needs. If this is allowed to happen, then reaping the broader future benefits from the solutions may prove to be significantly more difficult than it otherwise might have been. Therefore, we would recommend putting mechanisms in place to monitor the ability of solutions to properly support the broader solution requirements, even when these are not immediate priorities.

### Summary

From all of the above, there are some key learnings that should be borne in mind when defining your serialisation strategy.

- Recognise the significant supply risk and manage it accordingly, establishing senior cross-functional governance early.
- Mobilise your regulatory, legal and technical teams to establish effective access to, and interpretation of, the emerging legislative and technical standards.
- Actively interpret the evolving requirements and standards for the organisation using tools such as the 'Target Response'.
- Establish a programme of activity to build organisational and extended supply chain capability.
- Be realistic about the emerging nature of these capabilities and build in adequate time and resource to effectively test and iterate solutions.
- Design serialisation activities to closely couple related actions to minimise the possibility for errors due to abnormal events.
- Design both the normal processes and the regularly

occurring non-standard events to avoid product supply quickly grinding to a halt.

- Ensure cross-functional teams are established to carefully design the interfaces between departmental and organisational boundaries.
- Ensure adequate time is allowed for packaging design changes to be made to accommodate serialisation features required.
- Be cautious about suppliers who have little practical experience in this area.

### Conclusion

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, however, we hope in these series of tips we have covered the key areas to consider. We believe using these ideas when devising your serialisation strategy will reduce your risk and ensure a successful implementation.

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