

Serialisation: The Current Conversation

Serialisation remains the hot topic across the pharmaceutical industry, and will continue to be so with the deadlines for compliance fast approaching in both the US and EU. The discussion around serialisation is a juggernaut, continuously gaining momentum with new advice, research, implementation guides and points of consideration added to the mix almost daily. The cumulative effect is the creation of a ‘serialisation echo-chamber’ brimming with information that is increasingly hard to navigate and digest. There are, however, a handful of threads that are a constant throughout the dialogue. In this article, Carlos Machado, serialisation director at SEA Vision US, talks through the advice which businesses can use to underpin their move towards an agile, future-proofed solution.

Serialisation is an Investment, Not an Expense

Serialisation still holds a stigma within the industry, particularly because of its cost. Recent research has revealed that the biggest barrier to serialisation compliance is the cost of implementation – with 54% of industry professionals citing it as their biggest concern. This hurdle is compounded by the 33% of the industry which feels that the implementation process is also a drain on internal resources¹. Whilst it cannot be denied that complete compliance will involve plenty of dedicated resource, serialisation will revolutionise ways of working and the industry for the better. The importance of seeing serialisation as an investment rather than an expense, cannot be stressed enough.

When planning and implementing a serialisation solution, additional benefits can be added along the way. Before taking to compliance strategies, businesses can look at their key performance indicators and identify any system changes that can be made alongside the serialisation up-

heaval. Companies must remember the goal; regulations exist for good reason and the long-term aim of serialisation – to establish the authenticity of each product and ultimately improve patient safety – will always outweigh any temporary burden. Serialisation will boost the industry’s reputation and protect people, meaning that a company’s brand and stakeholder value can also be protected and enriched.

Do Not Underestimate the Task at Hand

The FDA’s decision to delay the active enforcement of the Drug Supply Chain Security Act (DSCSA) to November 2018 serves to highlight another stumbling block in the way of tight timescales. This recognition of the need for more time not only brought welcome attention to the timescale issues being faced, but is further evidence of the need to acknowledge the scale of the task at hand. With some companies yet to start developing a serialisation solution, the postponement in the US came as a welcome reprieve. It is vital that the delay is not perceived as an opportunity to relax, but as a warning shot that highlights the need to start early to ensure a robust solution is in place.

Serialisation is a vastly complex process that requires comprehensive plans and a clear roadmap. Ineffective planning can lead to bottlenecks within the supply chain, faulty lines leading to low-quality service, and additional costs.



The kind of change required is fundamental to each business and impacts every department in some way. Serialisation needs to be overseen at a corporate level and should also be perceived as an opportunity to introduce standardised and modernised approaches across the organisation. This could include reviewing standard operating procedures (SOPs) and ways of working, training materials and resources, responses to faults, maintenance and support and best practice generally.

Effective planning can also help you ensure all costs are covered in advance, as many may see the need to renew or purchase new machinery, as their current equipment was not built with serialisation in mind.

Think Third Party: A Serialisation Partner

The enormity of the task at hand can be tricky for many, and as deadlines fast approach, the need to find support and outsource serialisation implementation has become more common and encouraged, particularly across smaller and mid-sized companies that do not have the in-house resources for a full-time, dedicated project team. The DSCSA delay also reinforces the need to use the additional time to find a reputable partner to guide you through the serialisation journey.

Strategic partnerships make sense due to the time-sensitive nature of the task, particularly when research shows that 36% believe they have a



knowledge gap in their existing teams when it comes to serialisation¹. Still today, many corporations have no idea what serialisation means for their operations, and think it is as simple as adding a code to their packaging.

There are key factors to consider when selecting a serialisation partner as they need to be technical experts who are well-versed in testing serialisation lines and offering scalable solutions using both proposed and incumbent resources. Scaling up means having the ability to adapt the solution in the future, allowing companies to stay on top of the latest requirements on local and global levels. These all rest alongside other vital factors such as how they communicate, manage and understand businesses, as they will guide and support them through all stages pre- and post-implementation, and even across facilities and countries.

Look and Learn

More than 40 countries across the world have serialisation guidelines, yet no two countries have the same requirements. Whilst the specifics might vary, lessons can be learned from global compliance, and between the US and EU as they work towards compliance. For example, as Turkey implemented its regulations, companies found the need to build in as much flexibility as possible into their systems to help reduce

the amount of downtime in their packaging lines. This future-proofs serialisation solutions as they can adjust to any further regulatory changes.

They also found that effective communication practices between business operations and third parties are vital to overall success, and that complacency is counterproductive when it comes to understanding international requirements.

Track, Trace and Train

A comprehensive and phased plan with regular benchmarks is a must, as evaluating progress is the only means of hitting a deadline. The project must also consider post-delivery implications which can only be managed with training and testing. Employees should be trained early and often as adjusting to new equipment, software, and ways of working is a lengthy process. Running pilot lines or test lines with newly-trained employees will allow them to practise first-hand before unveiling official production.

Summary

The number of voices contributing to the discussion around serialisation grows daily, with more advice, guidance and tips adding to the hubbub. This isn't too much of a surprise; serialisation is the biggest regulatory change to impact the pharmaceutical supply chain in many years and offers the industry

an opportunity to revolutionise its practices as we head towards compliance. Whilst the road ahead may appear daunting, there are many guides to help along the way, especially from third parties. It is important that businesses establish a realistic timeframe, recruit the best resources and get to work. The serialisation challenge is one to be met with blue-sky thinking.

REFERENCES

1. <http://www.zenithtechnologies.com/zen-blog/cost-serialization-compliance/>



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A serialisation director at SEA Vision US and is responsible for sales, operations, implementation and post-project support services in the US and Canada. As part of the serialisation initiatives, Carlos is leading the partnership between SEA Vision and Zenith Technologies, implementing its serialisation product suite, focusing on speed to deliver, engineering excellence and a superior customer experience. In his previous role as director of operations at a leading anti-counterfeiting technology provider, Carlos helped to pioneer the serialisation concept and define the future of authentication. He has a wealth of experience in assisting pharmaceutical manufacturers with track and trace technologies and has worked on more than 75 serialisation projects, from both an operations and delivery perspective.