Crunch Time: The Impact of Serialisation Requirements on Packaging Operations

A Q&A with PCI Pharma Services'
Allison Gilpin, Business Unit Manager, Global Serialisation, and **Ray Hook**, Manager, Global Serialisation Services

Abstract

The deadlines for including unique product identifiers on prescription drugs is putting a strain on multiple parts of the industry, much of which is ill-prepared to meet the target. Here, we look to the experience of a company that is ahead of the curve for lessons on how to manage and ease the transition to serialisation.

Introduction

More than three years have passed since the US federal government signed the Drug Supply Chain Security Act (DSCSA) into law. Yet, despite facing a series of upcoming deadlines, many pharmaceutical companies have held off on adapting their supply chains to the incoming requirements. Now, with the United States serialisation deadline in November 2017, and the European deadline looming in 2019, companies cannot afford to wait any longer.

Those trying to meet the deadline from a standing start today will face acute challenges. The transition to serialisation of products is logistically complicated during normal times. The coming months, in which an entire industry is seeking the equipment and expertise needed to serialise products, will not be normal times. Lead times are extending and competition for resources is intensifying just as companies need to move forward at full tilt.

Faced with this situation, there is value in looking to partners that have taken a very strategic approach to DCSCA readiness and timely implementation for lessons in how to manage the serialisation process.

PCI Pharma Services has been serialising commercial products for five years for US, European, and emerging markets. Along the way, PCI has adopted AntaresVision as its enterprise serialisation system at all its European and North American sites, and qualified supplier Marchesini for additional equipment solutions.

Q&A

Introducing serialisation across one of the largest packaging operations in the industry has been a challenging, but ultimately highly beneficial, experience according to PCI Pharma Services' Allison Gilpin and Ray Hook.

In this Q&A, they discuss the transition process, what they have learned along the way, and how companies that still have work to do to meet the deadline can prepare.

When did you first start with serialisation and how has the transition gone?

Hook: In the transition from our home-grown serialisation technologies to a scaleable enterprise level vendor solution, our first Antares-based serialisation line went live in 2014. It was a voyage of discovery. In the last three years we have gone from knowing the theory, to becoming an organisation containing expert practitioners in serialisation.

Gilpin: It was a very big learning curve. There's an incredible amount of information, knowledge and experience required. We take people into our team and, to a person they are stunned by how much is involved in serialisation. No matter how experienced they are as an engineer or how experienced they are as a project manager, this is a completely different world.

Can you give a sense of the scale of the serialisation transition?

Hook: Globally, PCI packages over 8,000 items. Most of those items that become serialised will effectively go through an entire launch process in the transition. The customer has to make their artwork serialisation-ready. They have to manage the inventory so non-serialised product goes out first. We have to go through a significant batch record and process change to move from non-serialised to serialised.

Gilpin: It's a huge amount of work and it's not just an engineering effort. It touches many functional departments, including marketing, purchasing, project management, quality, regulatory, operations, etc. We're all engaging with serialisation.

It's a huge learning curve for packaging teams, line leads, supervisors, quality inspectors, and everyone else within the facilities. Everything they do normally needs to be re-evaluated and thought about differently. Effectively, where we had been making a 100,000 units of the same product in a batch, now we are making and tracking 100,000 unique items in that batch. Serialisation is a major paradigm shift for the pharmaceutical industry.

How prepared is the industry?

Hook: A large proportion of the industry is not ready. Those people who have not started are suddenly waking up and realising the challenges and timeframe. Lots of people are starting to place orders for equipment. Their difficulty will be that

PCI partnered with industry leader Antares Vision for its global serialisation technology, including its Flexsuite™ technology for standalone serialisation processes to support clients with achieving advancing industry deadlines in the US and EU.

from starting to evaluate a solution, to putting the first line live, is a 12-month cycle. There is no time to spare.

Manufacturers of serialisation equipment, even though they've scaled up their build capabilities, are seeing an increase in lead times. We've seen delivery lead times increase from typically five to six months, to now seven months or more for a single piece of equipment, just over the last four months. So as time progresses, I can see that increasing to eight or even nine months. This is going to put late adopters in a tough position.

Gilpin: The staffing side is also a complex challenge. It's going to require a lot of resource, whether this is outside vendors or stepping up groups internally, to get everything in place for November. Many of our clients are relying heavily on consultant and contract resources to support their knowledge gap, but demand for those resources is also increasing exponentially.

What will be the consequences of failing to meet the deadline?

Hook: It will be illegal for non-serialised products to enter the supply chain on November 27, 2017. Any product going into a distribution centre is open for FDA or federal government sanctions, which could include fines for non-compliance.

The polls we've taken indicate that at least 50 per cent of businesses are not ready as of today.

What options are available to companies that are behind on preparations?

Hook: Customers can bring uncoded packages to PCI and we'll run them through our Flexsuite™. The Flexsuite™ is designed to receive cartons of a wide variety of sizes, from a matchbox to a shoebox. It serialises the carton, which is then aggregated to the case and onto the pallet.

What is the purpose of aggregation?

Hook: Operationally, at the end of a packing run, a critical step is to understand where 100 per cent of the serial numbers have gone – both viable numbers as well as those that were scrapped or not used. So conceptually, if you've got a packaging run of for example, 40,000 units, which is not atypical, then you have a responsibility to understand where every one of those 40,000 numbers has gone. If a few are missing, we would need to investigate and that happens immediately in the batch. With the advanced technologies involved, it is a very robust and controlled process to provide that assurance. Serialisation gives you that control and positive verification.

By reading boxes at every stage of the packaging hierarchy, we know which cases are correctly built and can discount them as being the cause of the missing numbers. This process, known as aggregation, allows us to focus on the areas of the packaging suite that may have caused the issue.

When we're aggregating, we close a line down in five to ten minutes. Whereas not aggregating, it can take over an hour. That's lost production time.

Gilpin: The other significant benefit from aggregation is in the broader supply chain. With aggregation, you know specifically what is on each pallet, what is in each case, etc, due to the electronic verification and parent-child data pairing. This benefits the manufacturer, the wholesaler, and the downstream trading partners. Without the benefit of the electronic aggregation, the supply chain participants are left to 'infer' what is contained on a pallet or a shipping case, which has been proven to be extremely problematic.

What are the operational benefits of serialisation?

Hook: There are multiple benefits. Primarily, serialisation provides control and positive verification. For example, when serialising, if a creased label gets put onto a case so you can't read the barcode and the case is rejected, the contents of the case become available for repacking, whereas previously anything that came off the line was rejected and repacked. The rejection and repacking process destroyed cartons and some leaflets. As such, serialisation reduces waste and saves time.

Serialisation also supports automation. At the front end of the line, software has replaced manual entry of lot numbers and expiry dates. This has increased quality standards, while cutting resource use. Similar benefits are realised by deploying cameras at the back end. There's no need to weigh a case to check it contains 24 packs. The camera keeps count and the system labels accordingly.

Product aggregation yields substantive benefits for both the product supply chain traceability as well as adding positive operational process controls in packaging operations.

How are post-packaging modifications for sampling, damage, and rework handled?

Hook: Our Antares platform supports post-production interference with serialised material after packaging for situations such as sampling, damage, or rework. If a customer asks for ten additional samples after a batch has been completed and closed, we can go back and open a pallet, take ten units out of a case, reseal the case with a new partial case label, and reseal the pallet with a new quantity using the Antares system, while amending the aggregation data set. This can all be done in the warehouse rather than needing to create a special operation.

The same system handles damaged products and ensures that pallet-level and aggregation hierarchy data that we send to customers is accurate, not a theoretical figure based on production output.

What effect has serialisation had on overall equipment effectiveness and productivity?

Hook: There is a lot of evidence that early implementation of serialisation had a negative 20 per cent or 30 per cent impact on productivity. We can agree with that from our earliest lines. But now, with the experience we have, we're not seeing a great downturn in the productivity of a line. In some instances we are seeing the new equipment and processes are improving control and efficiency.

How do the incoming US requirements differ from those adopted in the European Union?

Hook: The US uses a true track-and-trace system. Products are verified at each step in the supply chain. This will enable the US

Serialisation requirements vary by country and region, including the US DSCSA, the EU FMD, as well as in emerging market countries such as China, Brazil, Turkey, South Korea, Saudi Arabia and others.

to address counterfeiting and help the FDA eliminate bad actors from the supply chain.

Gilpin: In Europe with the Falsified Medicines Directive (FMD), the process is very different. The manufacturer tells a European government the serial numbers they're entering. They don't tell a distribution centre at all. The next normal verification step is when a pharmacist is about to hand a pack to a patient. Other than some special auditing, which is relatively low level; there are no checks throughout the supply chain in Europe.

Instead, Europe is mandating the use of tamper-evident technology on serialised packaging. These technologies, which destroy packs that are opened illegally, substitute for the step-by-step verification of the US approach.

Most people either love the US model and dislike the European model, or vice versa. Yet both are valid ways of managing supply chains.

What other approaches are companies using to prevent counterfeiting?

Hook: Layering of anti-counterfeiting technology is popular, particularly in Europe. Companies are adding features such as photo-reactive elements to packaging so they can verify product authenticity by exposing it to light of a particular wavelength. People might also add microcode or intentional design defects that a counterfeiter may overlook when copying product packaging and leaflets.

Gilpin: A multifaceted approach is necessary because serialisation alone cannot stop counterfeiting. Layered technologies and a rotational approach to their strategy, paired with effective serialisation, significantly increases the chances of mitigating counterfeiting and diversion activity.

Allison Gilpin

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Allison Gilpin is responsible for leading programme management across PCI's global serialisation initiative, working with clients to assure success in achieving US, EU and evolving emerging market requirements. Gilpin features an extensive background in project and commercial business unit management for PCI's commercial packaging operations, having supported a multitude of emerging pharma, mid-tier and large multinational pharmaceutical clients.

Ray Hook

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Ray Hook is responsible for leading technical evaluation and implementation of serialisation technologies across PCI's global supply network. Hook features a diverse background and technical expertise in machine automation and vision inspection, including founding his own vision inspection company prior to joining PCI.