Serialisation: The SME and CMO Perspectives

Pharmaceutical Serialisation & Traceability 2016

Pharma iQ
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Software Best Practises - Implementation & Data Integration

In the pharma universe, the buzzwords 'serialisation' and 'track and trace' are entirely unavoidable. For a while the industry has participated in the cycle of regional deadlines being set in motion after requirements are published. All in pharma seem to have their eyes firmly set on the fight against counterfeit medicines and retaining market share through compliance.

Despite this, to Pharma IQ's surprise, some members in our 2016 serialisation and traceability industry report labelled themselves as not having thought about serialisation yet at all. Also, recent market intelligence has noted that CMOs are not moving fast enough for serialisation deadlines. A risky business when market share could be at stake. It seems that for pharma SMEs and CMOs the task of serialisation still stands tall.

The SMEs

The smaller margins and tighter cashflow cycles that fuel Small to Medium (SME) pharma can create difficulties in the implementation of new requirements. These players alongside SME biotechs and virtual entities are thought to be at the earlier stages of implementation – just grasping regulatory and business requirements and compliance planning. Some firms in this bracket are understood to have planned to outsource serialization efforts, however this notion has depleted in popularity as more understanding was gained on the internal requirements needed for this model and the risks with some forms of complete outsourcing.

Some of those that haven't undertaken a formal internal serialization compliance program at all maintain that the enforcement of these regulations will be delayed. Only a minority of our report participants labelled themselves as not having thought about serialization yet at all, - 5.4 % - which is in fact the lowest amount since the report's debut, however it is still slightly concerning that this level exists considering the progression of timelines.

CMOs

A recent report conducted by Tracelink 1 reported that some CMOs are not moving fast enough for serialisation deadlines in the US. This is concerning as the lifeblood of CMO future business within pharma rests largely on their serialisation capabilities. A lack of compliance is likely to equate to a loss of business to competitors. A pain point felt by SME pharma and biotechs is the fear that CMOs will not be compliant in time, as their own projects are being outsourced to these firms.

In a recent article Dirk Hendrik Kneusels, Branch Director, Antares Vision Germany, Bensheim,

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Germany noted that miscommunications and slack initiation seems to be prevalent causes of this issue. He said: "When discussing the situation with CMOs, they often tell me that they have asked their customers for their serialization requirements, but are not getting sufficient feedback. Additionally, they think that modifications to their machines and infrastructure can be completed within just a few months." 1

Pharma firms need to evaluate the readiness of their CMOs – regarding expertise, system, status and if they are already connected to some of the established cloud vendors. Honesty and evidential proof is needed, as pharma firms need to confirm the foundations are in place and that relevant stakeholders are informed and synchronised. This is a task that should not be confined to email exchanges, but physical meetings and site visits. Even though this may have a slight drain on resources, this step is a necessity in this risk identification strategy, it's important to be aware of the level of risk that exists to know if a system can respond to that risk.

The late adopters who have evaded until now are going to be critically reliant on excellence in project execution to get their programmes in place and delivered on time. Any implementation programme that is being initiated now faces a daunting amount of complex capability that must be delivered in a very short time with little or no opportunity to practice before the deadline hits.

In response to this state of affairs, Pharma IQ spoke to Mark Davison, Chief Executive Officer Blue Sphere Health Ltd to gain insight on his experience working with SME pharma & biotechs for serialisation. Also we spoke to Vetter pharma – a responsible CMO for their insight on how peer CMOs can scale the summit that is serialisation.

The SME Perspective

With Mark Davison, Chief Executive Officer
Blue Sphere Health Ltd

Where should SMEs or the smaller pharma firms be within their serialisation projects at the moment?

Mark: "There are two components to this. The first one [concerns] where should they be strategically? So asking questions like:

- Do we need to produce our products in the way that we currently do?
- So could we outsource the problem to a contract manufacturing organisation
- Could we rationalise to fewer production lines?

This kind of upstream thinking should have happened.

"[In regards to] the tactical implementation of serialisation, obviously they need to start thinking about vendor selection, surveying their lines, getting in the experts [and] that should really be well down the track. Time is very, very short now so if they haven't done this by now, then they need to start as soon as possible."

The main consideration that the SME market or smaller pharma market needs to take on board looking at successful serialisation implementation?

Mark: "I think it goes without saying that urgency is now built into the process so there isn't the time to consider the options in a relaxed manner anymore. They have to really get on with it and kind of compress the usual committee and consensus driven approach that pharma tends to have into a

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method that is a bit more dynamic.

"The actual doing takes quite a long time, so the thinking has to be done quickly and people need to get a move on."

Obviously with any firm, overheads and the bottom line are prime considerations, but with smaller pharma firms things will be a little bit tighter. So what do you think is key for serialising in a cost-effective manner as a smaller pharma firm, but keeping a focus on ROI potential also?

Mark: "It's important to think about total cost of ownership. It comes back to the strategic review before doing anything in terms of spending money on vendors, etc. Also, thinking about make versus buy, do I want to do this myself? Do I want to pay a contract manufacturer? Do I want to switch CMOs to [an entity which] is a bit more capable and therefore have a net lower cost even though it looks like a bit more initially? All of those thoughts need to be management level discussions around how the company does business rather than viewing serialisation as a bolt-on to things they already do because it fundamentally changes the way companies do business, especially small companies. It has a big impact so they need to think about that from first principles and not just delegate the job to somebody who is only solving the immediate problem of serialising boxes."

How can metrics be applied to help the smaller pharma firms sort of visualise this return from serialisation?

Mark: "The return on investment is a really tricky thing to catch because the upfront costs are hard and obvious: the production line equipment, the extra costs for CMOs. [However], the downstream benefits are soft and harder to collect - like improved efficiency of supply chain, improved handling of returns and potentially the option to engage with patients using codes, although that is probably in its infancy and for smaller companies that might not be so practical. It is quite tough to find [the] metrics.

"Obviously the bottom line is that this is a cost of doing business. It's not a choice. Companies who do not do this will have an immediate cost of not being able to sell product. So [in fact] the metric is: in business or not in business."

We have spotted a common thesis that quite a lot of CMOs aren't as ready as they should be/ Firstly, do you think this is a representative statement and also how should SMEs look to interact with their CMOs to test their readiness?

Mark: "[Do] I think is it representative? Perhaps it is in terms of the number of individual CMO entities. In terms of the proportion of CMO business conducted, I think the biggest CMOs are pretty well sorted as far as I can see. [Therefore], in terms of the volume of packs that go through the CMO market I would say that is probably less worrying.

"There are individual smaller CMOs who don't seem to be as on the ball as they should be and who knows we may see some of those smaller businesses go to the wall if they don't catch up quickly because this is going to be a cost of doing business. It's going to be a service that they will need to offer if they are doing final packaging, obviously not if they're just manufacturing ingredients. So, they will have to get to grips with this quickly, there are some who are not doing that and some who are running to catch up, but ultimately I think all will be well. [Although], I wouldn't be surprised to see a few people quietly decide not to do that business anymore and change the direction of their business.

"[Concerning] the second half of the question, I think it's important in that CMOs [are]able to demonstrate competence rather than just say that they are competent. They should have processes that they can show - They should have plans for converting equipment if they are not doing it already. So they should be quite well advanced, really.

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"So, [pharma firms should conduct] basic due diligence on 'Okay, you say you're ready for serialisation, now prove it' they should really shake that out."

What knock-on effect would be felt by an SME if their CMO of choice was not compliant in time. What sort of contingency strategy would be needed in this case?

Mark: "The worst case impact is that product is not sellable- so [the consequences are] quite brutal if all goes [wrong]. I think normal business caution rules apply. So, dual sourcing is probably not a bad idea. You may not want to split your production between two CMOs then serialise half each, but it's certainly a good idea to have a backup plan just for all the usual business reasons. In case [one provider's] equipment breaks or they have a fire at their facility, [pharma firms would need another firm] which is competent to serialise the product and get it to market.

"The important point to remember is that market authorisation holders carry the responsibility. It is not the entity which made the product on the [pharma firm's] behalf, unless their name appears on the box.

"You can delegate the [action] of putting numbers on boxes, but you cannot delegate the consequences of doing it wrong."

What are the consequences of an SME not fully grasping the urgency behind the approaching serialisation timelines?

Mark: "The obvious consequence, as we have said, is that if the deadline proves to be enforced on the date [claimed] and your product isn't ready, you cannot sell it - so you have lost money, that is the ultimate consequence.
"Particularly now post-Brexit, there are some companies thinking – 'Well, this is EU regulation, it's not going to be enforced on 9th February 2019, it might never be enforced. So why don't I take a calculated gamble and see what happens for a while.' Now, that is fine if it goes your way. However, it makes you look pretty [foolish] if it turns out you were wrong and are [unprepared] for this very, very predictable business time point.

"Some companies are very much winging it at the moment, but that is a really unwise business strategy for a number of reasons. This will ultimately be a cost of doing business, whether it's in 2019, 2020. Ultimately, I think there is so much momentum behind serialisation and the concepts that underpin it in terms of a traceable modern supply chain for pharmaceuticals that it would be really [mindless]to assume it is all going to go away.

"Small companies should not feel they have to start from square one, there are resources which can help with the really early stuff. There are very good contract manufacturers who are ready and can support a production switch to facilities which are ready to go."

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The CMO Perspective

From Daniela Guttmann, Product & Service Manager
Vetter Pharma International GmbH

Pharma experts have noted that a common perception is that most CMOs aren't as ready for serialisation as they could be. What do you think the reasons are behind this supposed trend?

Daniela: "If this is indeed the case, one could look to several reasons as to why it might be true. The first is the high level of investment that a contract and manufacturing organization needs to pre-invest in serialisation itself. Second, the overarching risk that deadlines can be delayed, or even eliminated as we have seen in recent cases in California and Brazil. Third is the general lack of knowledge about the topic itself. And, finally, the high-level of detail that continues to be missing in legislation leading to uncertainty for CMO's, particularly smaller ones."

What do you think is the key to serialising in a cost effective manner?

Daniela: "Cost efficiencies begin with knowing your strengths. That means having a good understanding of your packaging lines, technologies and batch sizes. Consider, are you packing small or large batch sizes? Armed with this knowledge, smart decision making regarding serialisation upgrades can be made as needed. For example, a decision to work with a portable or in-line installed serialisation solution to achieve a more specific, cost-effective serialisation."

Is it easier to retain pharma business by offering proof of your compliance? How are you doing this?

Daniela: "There is no such thing as 'easy' in this business. For Vetter, our serialisation project started as a systematic process prior to official regulatory deadlines. We began with a concept study which included questions such as:

- "What is our plan?"
- "Which lines should we upgrade first?",
- "What suppliers should we work with?"
- "What are the costs involved?" and,
- "Which people do we need involved as part of the project team?"

"Only after carefully answering each of these questions could we begin our IT project; upgrading our systems and then the pilot line, which is already validated. That led to our first customer project. Today, Vetter is compliant with the serialisation requirements for different markets. Our next step will be to systematically upgrade further lines. Without having the IT and technical elements implemented, one could say that a CMO remains non-compliant. Vetter, on the other hand, has already established the basis for serialisation."

Do you think the market will shrink in the number of CMOs once major serialization compliance deadlines are enforced? And, if so why?

Daniela: "This is always a difficult question to answer. However, I believe it is a certainty that some pharma companies will need to rethink their secondary packaging strategy and partnerships. This will include identifying which service providers they can trust with their products, selecting only those with the necessary expertise and capabilities; not just for today, but for the future as well."

How significant are the opportunities to pick up clients resulting from CMOs that are not fully compliant?

Daniela: " The answer to that question will lie in how the market responds. Over the short term, I think that pharma companies will have interim solutions. They will not have the time needed to shift from CMO 'A' to 'B'. If the contract manufacturer 'A' is not ready, the pharma company may very well shift these volumes in-house. Over the mid-to-long term,

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however, they will most likely look for an established outsourcing partner with the necessary serialisation capabilities."

What is your best advice for other CMOs in the industry in regards to serialization?

Daniela: "Quite simply, carefully define your strategy. For example, begin your project with a concept study and then establish a strong project team with all the necessary departments involved. These include IT, Engineering, Production, Supply Chain, Quality, Regulatory Affairs and Project Management. These projects can take years to implement, so you need to have an established project team with the right expertise. It is also important that you have management's commitment and involvement since it is a costly and long-term project. Consistently inform and update management on the team's progress, the opportunities involved, and what it means for the business. This is of vital importance."

To gain more insight into how to optimize your serialization strategies, attend the 2016 Serialisation and traceability conference.

Resources
1. https://www.securingindustry.com/pharmaceuticals/cmos-still-not-stepping-up-to-serialization-challenge-poll/s40/a2803/#.V1A4sOlrLIU

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- **Supply chain standards, regulatory requirements (IDMP) and the link to FMD implementation**

- Dedicated streams for: **IT integration and implementation & Data management and security.** *Christian Hay, Senior Consultant Healthcare, GS1 Global Office*

- Challenges of serialisation and track & trace applications on company level: How to make a serialisation strategy future-proof. *By Michael Urso, Product Manager Pharma & Packaging Solutions, Atlan*

- **Implementing a sustainable serialisation strategy.** *By Christoph Staub, General Manager Track & Trace, Laetus*

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