Countdown to Serialization:

Why CMOs Must Begin Working with Pharmaceutical Partners Now

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As the Life Sciences supply chain has shifted from predominantly local to increasingly global over the last decade, many pharmaceutical companies have virtualized up to 70% of their production and packaging in order to be successful in new markets. They have built relationships with local contract manufacturers and pharmaceutical companies for production and distribution efficiencies, allowing them to capitalize on the global market by cost-effectively producing and distributing product around the world.

The last decade has been marked by increasing drug integrity concerns, as well, prompting more than 40 countries to introduce track and trace laws to help regulate product as it passes through the supply chain. By the end of 2018, it's estimated that more than 75% of the world's prescription medications will be protected by legislation. For the industry, these regulations introduce a web of challenges: most regulations mandate some combination of generating and managing serial numbers; exchanging data in diverse formats with trade partners; tracking product through the supply chain; verifying data; and reporting associated events to government authorities.

With contract manufacturers and packagers handling large volumes of product, their readiness for serialization is critical to the industry's overall success. Serialization deadlines are fast approaching in three key markets: Brazil Phase One in December 2015; US DSCSA in November 2017; and the European Union's Federated Medicines Directive in 2018. Why should pharmaceutical companies, CMOs, and CPOs start talking now, and what do they need to achieve?

The challenge is twofold, and the stakes are high

Two primary tasks need to be accomplished in order for pharmaceutical companies and contract partners to continue successfully working together in a serialized world: lines must be upgraded, and data exchange must be achieved. Without the first, serialized product cannot be produced and packaged; and without the second, required serial number information cannot be passed between them or to downstream trade partners.

If CMOs and CPOs cannot produce serialized product and exchange the data when the deadlines arrive, then they will not be able to produce compliant - and saleable – product. Pharmaceutical companies risk drug shortages with patient impact, and contract manufacturers and packagers risk losing business to competitors who are better prepared.

Negotiations can take months

Pharmaceutical companies have dozens to hundreds of contract partners, and vice versa. That's a lot of relationships to navigate. Communicating specific serialization needs, deciding when upgrades should begin, and agreeing on financial responsibility will take months. The upcoming Brazil, US, and European requirements already impose tight preparatory timelines; if you need to allow for a lot of communication back and forth, that's all the more reason to start early. In addition, if every pharmaceutical company begins working with their contractors at the last minute, CMOs and CPOs will be incapable of meeting everyone's demands in time. Not only will individual projects take many months to complete, but contractors are balancing dozens of different customers and each comes with not just diverse regulatory requirements but with different business and operational demands.

Line upgrades must be planned and executed

Right now, many pharmaceutical companies are focused on upgrading their internal packaging lines and aren't yet thinking about their external ones. At the same time, most contract companies are waiting on their pharmaceutical partners to start the conversation.

Because line upgrades may cost between $250,000 and $500,000 per line, CMOs and CPOs will likely be looking for pharmaceutical partner support. Many pharmaceutical companies, though, will have opinions about whether they should contribute at all, and how to split financial responsibility with both the contract firms and their other pharma customers. There is no established commercial model for shared lines – which partner should pay for how much of each upgrade – so shared line negotiations will take even longer. Start these conversations now: reach out to each of your partners to discuss needs, negotiate finances, and agree on a schedule.

The communications challenge is complex

Negotiating line upgrades is critical, but it's not the only thing that needs to be accomplished. The second – and equally important – component is communication. How are you passing compliance information back and forth? From a data perspective, serialization introduces two significant challenges for pharma companies and contractors: data volume and data exchange.

Data volume

As serialization requirements phase in, pharmaceutical companies will need to generate and transmit unprecedented volumes of data to their contract partners. A pharma company that produces 100 million items annually, packing 24 items per case and 120 cases per pallet – for a total of 4,166,667 cases and 34,722 pallets – will commission 104,201,389 individually addressable serial numbers each year. Assuming that the pharmaceutical company is generating all of these serial numbers, each of those will need to be sent to the contract partner who is producing and packaging their product.

In addition, for each of these numbers, a range of serialization events – generated, reserved, commissioned, decommissioned, destroyed as well as potential aggregation events – may need to be tracked. These, along with their associated serial numbers, will need to be shared between the pharmaceutical company and their CMO or CPO partners in order to insure the integrity of the serialization data.

Data exchange

Pharmaceutical companies and their contract partners will need to determine how they exchange this critical compliance information. Analysis indicates that at least 21 of the top 30 global pharmaceutical companies have complex and unique data exchange requirements, and many pharma companies beyond this top tier likely do, as well. The goal is to insure bi-directional, real-time data exchange that is tightly integrated with the packaging processes such that compliance is achieved without compromising operational efficiencies.

Doing this electronically with traditional technology means establishing individual, custom point-to-point connections with each partner. There is a high cost and level of effort associated with these - particularly since the regulations are still evolving and frequent changes are necessitated – and each one takes approximately 9 months to establish.

Factor this in with the number of customers you have and the tight deadlines for readiness, and you will be performing many complex data exchange projects in parallel.

Also, point-to-point connections make it exceedingly difficult for either party to establish a repeatable, reliable serialization process. Because serialization in today's global supply network is inherently a network data exchange problem, it requires the development of a network data exchange solution.

What is the shared platform that you and your partners are using? You need to start discussing that as well, and planning for end-to-end, comprehensive pilot testing with all of your partners.

The bottom line

For CMOs and CPOs, the ability to remain a valued partner to the pharmaceutical community hinges on their readiness for serialization. And being ready on time may also open up opportunities to win business away from competitors who haven't planned ahead, and allow them to turn the regulatory burden into a competitive advantage. CMOs and CPOs need to aggressively pursue line upgrade conversations with their pharmaceutical partners and select an industry-leading serialization platform that the majority of their partners are likely to use.

For pharmaceutical companies who are working to comply with upcoming deadlines, it won't be enough to address just you own internal production facilities. Your outsourced lines are equally – if not more – important to plan for early. If your CMOs and CPOs haven't upgraded in time, you won't be able to ship your non-compliant product. That will have a painful impact on your bottom line, but it could also lead to drug shortages for patients. Get the ball rolling with your CMO and CPO partners now, before your competitors get in line ahead of you and time before the deadlines runs out.

What CMOs should ask pharmaceutical partners

As they prepare for upcoming serialization deadlines, including the November 2017 DSCSA one, many pharmaceutical companies will focus on their internal lines first. But if you are going to continue to serve customer needs without interruption, you will want to start a conversation with your pharmaceutical partners now. The following questions will help you gather the majority of information you'll need to make your preparations:

Regulatory and Business Requirements

- Which country regulatory requirements do we need to address?
- What are your CMO readiness deadlines for each of those countries?
- How many products will you be serializing with us?
- What is your estimated annual number of saleable units per product?
- Explain the levels of aggregation hierarchy you will want us to support for each product (ex. X blisters into a carton, Y bottles/cartons into a shipper, Z shippers on a pallet).
- Will you generate serial numbers centrally and distribute them to us?
- Do you expect us to generate serial numbers on your behalf?
- If you will generate them centrally, how will you be sending them to us?
- What Track & Trace system are you using?

Serialization Preparedness

- What is the schedule by which you want us to have serialization ready for testing?
- What about in production?
- Will you want us to participate in any pilot projects with you?
- What are your technical integration requirements, including transaction interface specifications, so that we know how to exchange serialization information with you and can prepare to implement to your schedule?
- When will you provide new FDA-approved artwork with the 2D barcode?
- What are your validation requirements?
- What is your proposed commercial arrangement for upgrading the lines (dedicated and/or shared) we will be using to serialize your product?
- Are you proposing any modifications to our existing contract?

To learn more about TraceLink's serialization solution, contact us.

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