Assessing Your DSCSA

Requirements, Supply Planning, and Next Steps

Preparing for November 2017 Serialization

tracelink
Life Sciences Cloud

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Introduction

When pharmaceutical companies hear the recommendation that serialization planning should start far in advance, some are skeptical. What could possibly take so long? Serialization is really just another packaging problem, isn't it?

The truth is, serialization will change the way you do business and have a ripple effect throughout your operations. It will require you to digitize your supply chain, prompting you to step back and reconsider how you not only package product but distribute it; how you manage the unprecedented volume of data that serialization will produce within your own organization; how you exchange that data across your trading partners; and how you stay in compliance with serialized product in an evolving regulatory landscape.

If you sell product into the U.S., you are subject to the first DSCSA serialization deadline as of November 2017. The requirements will impact your entire U.S. prescription drug portfolio, not just products that you consider high risk or high value. Because of that, you may already be at risk of missing that deadline - given all the decisions to make, conversations to coordinate, and new processes to implement - if your preparations are not well underway.

If you are just starting to think about serialization, the most important thing you can do is to jumpstart your planning and immediately take stock of the true scale and scope of your serialization challenge. This eBook will get you started, walking you through an assessment of your DSCSA requirements, the global demands that might impact them, and supply planning considerations. It will help you identify initial decisions you need to make so you can move towards a project timeline and give your company the best possible chance of achieving serialization and staying in compliance.

Evaluating Your Role in the Supply Chain

To begin to understand how the DSCSA serialization requirement will impact your company, you need to assess the role or roles you play in the U.S. supply chain, plus take stock of regulations in the other countries in which you do business.

What operations do you perform in the U.S.?

As a pharmaceutical company selling product into the U.S., you likely fit into one of the three following categories. Each of these groups will be impacted by the 2017 deadline in significantly different ways with the latter two dealing with much higher degrees of complexity and lower levels of control over the serialization program.

Brand owner producing your own product

As a brand owner of the NDA, ANDA or BLA who manufactures your product entirely on internal lines, you have tight control over your serialization infrastructure and processes, trade partner communication, and line upgrades. You still have a daunting list of tasks between now and November 2017 – and some dependencies on vendors – but your destiny is primarily in your own hands.

95% of CMOs are concerned about losing customers if their contract packaging operations are not prepared for serialization and data exchange by November 2017.

Brand owner outsourcing all or part of your production

Brand owners, as the legally responsible party, typically own the serialization infrastructure and are responsible for generating and storing serial numbers, managing the data flow with supply chain partners, and responding to regulatory inquiries. In the pharma-CMO dynamic, pharma companies typically control the production contract and set the terms for when they want their outsourced lines to be serialization-ready, how integration and validation specifics should be configured, and more.

While you're in the driver's seat as the brand owner, you will want to work closely will your CMOs to communicate your expectations and insure they can meet your timing and requirements. Most CMOs are working with many clients, so don't assume that your needs are at the top of their priority list. Start conversations now, especially if you rely on more than a few contract partners: negotiating the details as well as the commercial arrangements will be time-consuming for each partnership.

Brand owner who also acts as a CMO

If you act as a CMO you have no responsibility under the law itself for the product you produce on a contracted basis, but you likely have a formal agreement in place to

Source: TraceLink Webinar, Mastering Serialization for External Supply, September 2015.

manufacture customers' product as required. In this role, you are not your own master, but must contend with the demands of other pharma companies. For example, you may have decided not to enable aggregation on your packaging lines or implement rework stations but if a pharma customer wants their product aggregated, you'll need to address this. And to complicate things further, each of your pharma customers will likely have their own unique set of timelines, integration requirements, and validation specifications.

If you do provide CMO services, it's critical that you begin a dialogue with each of your customers now to ascertain their unique requirements.

What is your global landscape?

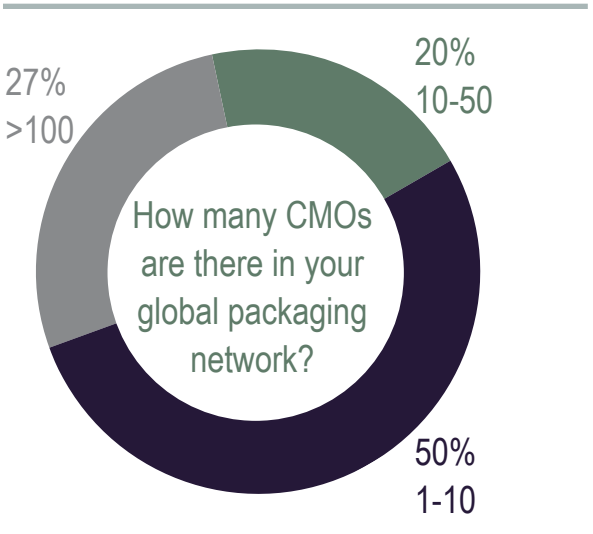
Today's pharmaceutical industry is an increasingly global one. Most companies either sell product into multiple markets or plan to do so in the near future. The advent of serialization is a good time to evaluate where your business is going in terms of market penetration and new product introductions. If your company has a global purview, you need to consider the serialization requirements for other pertinent countries on several fronts.

Packaging lines

As a global company, you probably already think about where it makes sense to produce and package product for different markets. With the advent of serialization, additional considerations come into play. You may have a line in the U.S. that's producing primarily for the U.S. market, but has excess capacity for other markets. If you don't factor in serialization requirements for those markets when planning upgrades at the line and site level, you may not be able to utilize that capacity, or you may find that you have to duplicate your investment to later serialize that line for another market. If, however, you know the full universe of your market needs and discuss them with vendors as you plan upgrades, you should be able to update so that you can meet multiple countries' specifications.

Solutions

One of the most important decisions you'll make is selecting your serialization infrastructure. Meeting the U.S. requirement might be your immediate focus, but if you have other market requirements, you will want to select an extensible global solution that can meet all your track and trace needs in order to simplify your implementation process, partner relationships, and staff training.



Source: TraceLink Nexus '15 Survey, September 2015.

As you evaluate platforms, consider which ones offer a proven global approach, a global master data management design, expertise in each country's evolving regulations, and built-in configurability and modularity to handle market-specific regulations without one-off customizations.

Timing

When do your other markets' serialization deadlines fall, and how will they impact your U.S. preparations? Do the serial number formats and packaging hierarchies, serialization attributes, and related compliance events align tightly with U.S. requirements or will they require special upfront preparation? For example, serialization programs supporting U.S. DSCSA, India, South Korea and the EU FMD require extensive flexibility. Plotting out which regulations you need to comply with and when will help you plan your resources and upgrade projects accordingly.

Defining Serialization Readiness

The law stipulates that manufacturers must serialize product for the U.S. market as of November 27, 2017. Specifically, this means that manufacturers need to apply a serialized product identifier on each unit of product intended for commerce. But what, exactly, does that mean?

To date, the FDA had yet to publish guidance on grandfathering for non-serialized product that is in the pharma supply chain. These issues are driving ongoing conversation in U.S. industry groups with pharmaceutical companies asking, "By the November 2017 deadline, do I need to be *producing* only serialized drugs, or *selling* only serialized drugs?" In the absence of clear regulatory guidance, there are two ways that companies are approaching serialization readiness:

- *Serialization packaging readiness:* All products destined for the U.S. market will be serialized across all internal and external packaging lines on or before November 27. By that date, there is no non-serialized, non-compliant product coming off of my lines.

- *Serialized product inventory readiness:* All products being sold and shipped into the U.S. market on or after the deadline is serialized, compliant product. My company has no non-serialized, non-compliant product in our internal network, having flushed it all out prior to the deadline.

There is no "right" interpretation of the law and deadline at this point, but your company will need to determine what state of readiness you are aiming to achieve. That decision has significant ramifications for your project plan and timelines. For instance, if you decide you want to flush out all non-serialized product from your internal network – including at your own distribution centers, at 3PL partners, and at finished goods inventory warehouses at packaging sites - you'll need to determine by when your existing lot level product needs to be bled out, and when serialized product needs to begin to replace it.

Taking Stock of Your Supply Planning

Your serialization planning and project timelines need to take into account not only the impact on production, but also supply and demand planning. Key issues include:

Product velocities

How long does each product sit in the finished goods inventory channel before it moves into the supply chain? Fast moving products or those with very predictable demand and short production cycle times may only sit on the shelves for a week or two. Others with high production volume, uncertain demand or long shelf lives may be made to stock and only turn over twice a year. Products with international production and complicated internal distribution paths, including customs entry, may also have a lengthy internal inventory stay. This is particularly relevant if you decide that you want to achieve serialization product inventory readiness, where you've flushed all non-serialized products out of your internal network prior to the November 2017 deadline.

Planned production times

Supply planning and related production runs may be timed to meet continuous demand as discussed above or there may be seasonality factors to consider. Flu vaccines and other specialty products may be produced only once a year on a very fixed schedule. If that's the case, then you need to work back from that production date and determine when serialization needs to be in place. It may be sooner than you originally expected if you want to maintain your general production order and still meet the compliance deadline.

New-to-market products

Is your company planning to launch new products, product line extensions, or new packaging configurations into the U.S. market? If so, does your product launch team have serialization on their commercialization prep list and do you know their supply chain fulfillment plans?

Mergers and acquisitions

The rise of M&A activity is putting pressure on serialization planning as well, with acquisitions and spinoffs often taking serialization teams by surprise. Check internally to see if you can get a heads-up on potential new products, packaging facilities, or even new enterprise systems from acquired companies that you'll have to incorporate into your serialization planning. Ultimately, you'll also want to understand into what other markets newly acquired products have traditionally been sold.

How Will Serialization Complicate Production Management?

Serialization puts pressure on how you produce drugs in several different ways, including:

Determining Product Destination

Most pharmaceutical companies already do packaging runs for a specific market. Maybe that particular drug formulation or packaging configuration is only approved for one country or labeling and handling characteristics make it impossible to change post packaging. Some companies, though – particularly in Europe – produce "bright stock" where labeling is postponed until they determine, post-production, exactly where the product will ship. With serialization, it becomes harder – if not impossible – to make bulk amounts of product where the destination is not known upfront or where you want to gain some flexibility to shift product between approved markets where demand is uncertain.

Managing Inventory in the Transition Phase

While you are gearing up for serialization, inventory management will become more complex on several levels. For instance, performing the necessary line and equipment upgrades and associated validation testing will impact supply and demand planning. How long will each line be down? It may take one to three months to bring that line back up and thus you'll have to plan to have that amount of extra stock in reserve. How many lines will you take down in parallel, versus upgrading them one at a time? Do you have enough time left to just do one at a time? How about your CMOs? What's their upgrading schedule for the lines your products are packaged on and – if they are shared lines – how will your needs be prioritized compared to their other customers?

Maintaining Efficiencies in a Post-Serialized World

Pharma companies and CMOs who have experience serializing for the U.S. and other markets have analyzed downtime and operational efficiency. Initial results indicate that the efficiency of the packaging line post-serialization typically does not return to the pre-serialization level but instead experiences a degradation of 5-10%. Aggregation is one of the big causes of packaging line decreased efficiency. It's a complex process that results in more errors, so it's hard to regain pre-aggregation levels of efficiency.

If your company ultimately has a similar experience, you will have a capacity issue if your packaging lines were originally scheduled to be as efficient as possible with no excess capacity. If your efficiency will be 5-10% reduced post-serialization, how will you plan for extra capacity or otherwise compensate?

Making Initial Key Decisions

To begin drilling down into the details of what must happen by when for serialization readiness, use this checklist to answer some key questions, identify a subset of dates, and work backwards to start building out associated timelines.

- ☐ *Identify your overall target date*
  When are you aiming to be serialization ready? Are you targeting the November 2017 deadline as a pharmaceutical company, and do you perform CMO operations that have a different timeline based on your customer needs? Are you targeting just-in-time readiness or building in a several-month buffer to allow for unanticipated issues?

- ☐ *Define serialization readiness for your company*
  Will you plan to "produce" only serialized product or "sell" only serialized product by the deadline? And might you adjust your approach when grandfathering guidance is issued?

- ☐ *Assess your non-U.S. market requirements*
  What other countries do you sell product into, and what is the scope and timing of all of their serialization requirements?

- ☐ *List your full universe of U.S. product*
  Take into account your current drugs, soon-to-launched ones, and newly acquired product.

- ☐ *Identify product-specific launch dates*
  For each product on your U.S. list, what should the serialization launch date be given velocity, seasonality, and other supply planning factors?

- ☐ *Pinpoint the relevant lines*
  What internal and external lines do you rely on for each of these U.S. products?

- ☐ *Define your universe of relevant CMOs*
  How many and which CMOs will you need to work with to ready the relevant external lines?

- ☐ *Evaluate resource and budgetary constraints*
  How many of these internal lines or external CMO lines can you afford to upgrade simultaneously based on resource availability?

- [ ] *Evaluate downtime considerations and production impacts*
  How will your retrofit requirements impact supply capacity given line downtime?

- [ ] *Determine internal line-specific readiness dates*
  Given the launch dates of the products you produce on each internal line, when does each line need to be serialization ready so it can start producing serialized product?

- [ ] *Identify external line-specific readiness dates*
  Given the launch dates of the products you produce on each external line, when does each line need to be serialization ready so it can start producing serialized product?

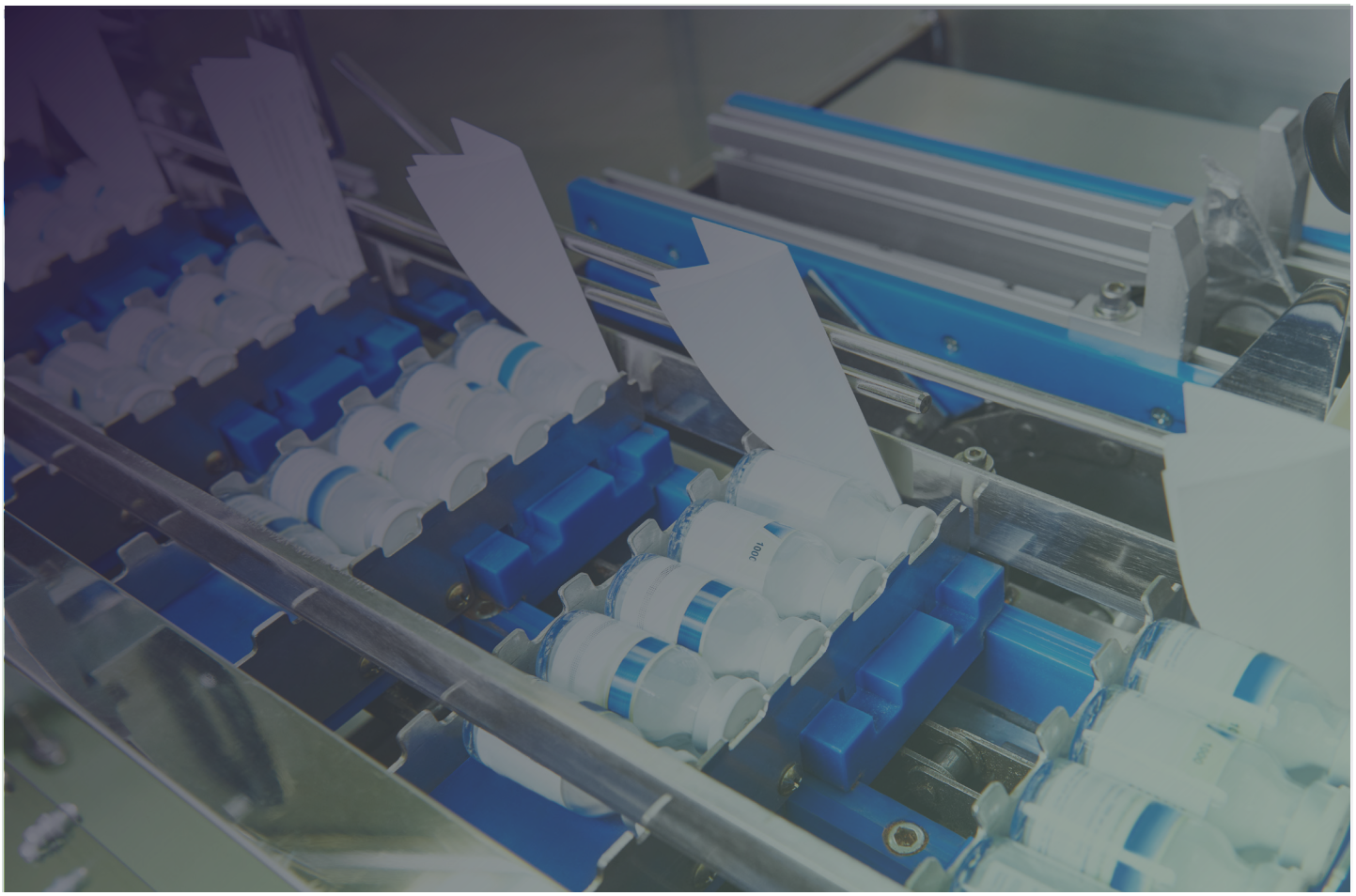
- [ ] *Brief your CMO partners*
  Communicate key timelines and other requirements to your CMO partners.

- [ ] *Communicate with pharma company customers*
  If you act as a CMO for other pharma companies, initiate conversations so you can factor their needs into your overall planning process.

Looking Ahead

Everything covered in this eBook is fairly operational and process-oriented. In parallel with this, you really need to take stock of the needs for your serialization information architecture. For instance, what are the outcomes and outputs of your global serialization program? Based on your target markets, do you have to report to multiple governments, send compliance documents to trading partners, and respond to verification requests on products and transactions? And what are the associated master data requirements? You'll also want to take into account the internal systems (ERP, WMS, and Edge) from which you might need to acquire master data, feed serialization information to, or receive serialization updates.

The bottom line is that we've looked at just the tip of the serialization iceberg in this eBook; there's a lot more to assess from a business and operational perspective. Stay tuned for upcoming DSCSA GPS content tackling everything else you need to consider on your journey to compliance.



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