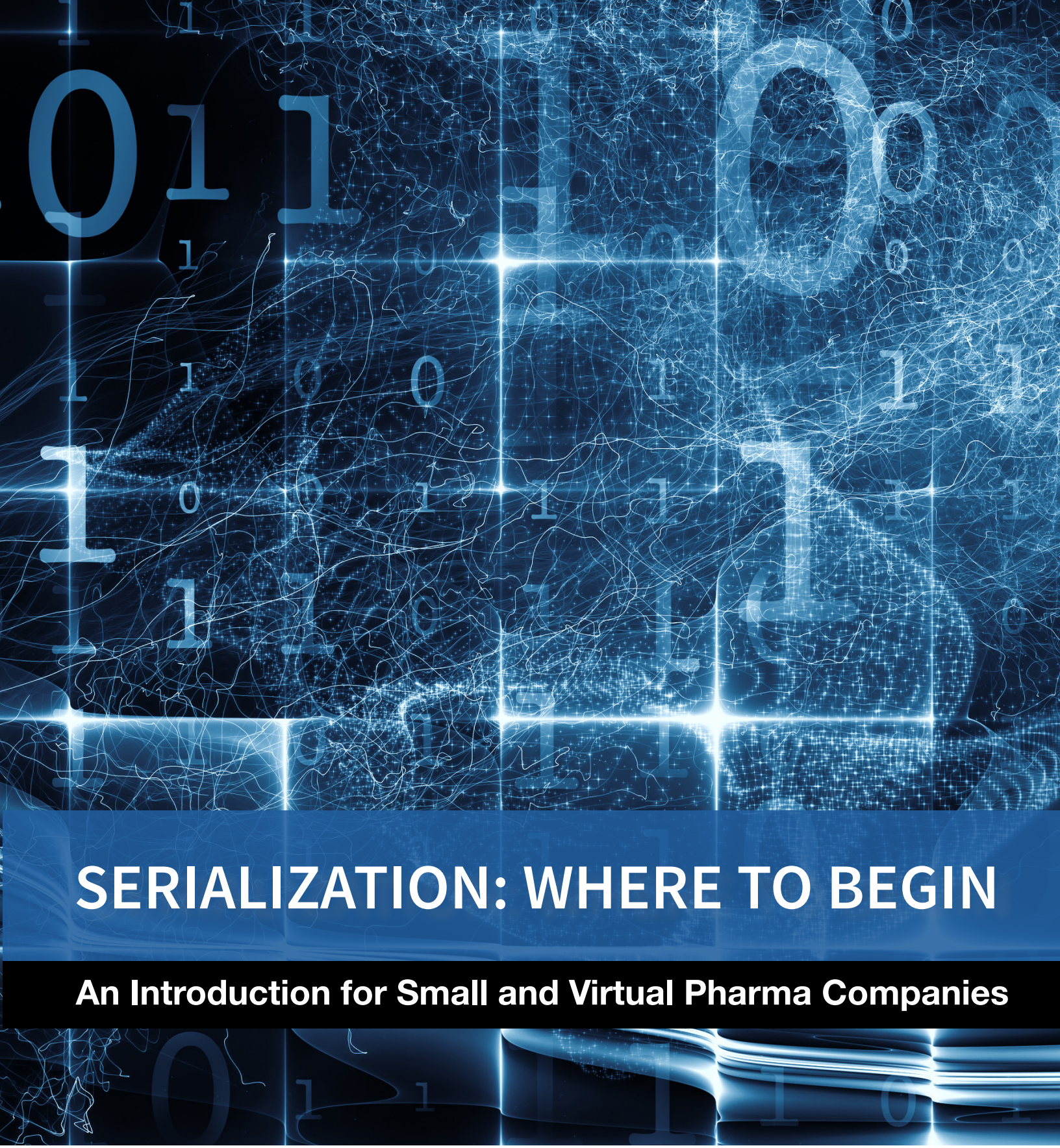

SERIALIZATION: WHERE TO BEGIN

An Introduction for Small and Virtual Pharma Companies

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Part 1: Introduction

In response to increasing drug integrity concerns, more than 40 countries have introduced track and trace laws to help regulate product as it passes through the supply chain. By early 2019, more than 75 percent of the world's prescription medications will be protected by legislation.

As a small or virtual pharmaceutical company, you will ultimately need to master the complex reporting and track and trace requirements in the U.S., implement a solution to generate, store, and manage unprecedented volumes of regulated data, and exchange that data with all of your supply chain partners. Overall, it's a daunting task. Where do you begin?

If you're at the beginning of your journey, this guide is for you, it provides foundational content on serialization including what it really is, how it will impact your company, key terminology, and how to get started.

In the U.S., serializing product is the cornerstone of the Drug Supply Chain Security Act (DSCSA). Over the next few years, at least a few people in your organization will likely develop deep expertise on serialization. But if you're at the beginning of your journey, this guide is for you: it provides foundational content on serialization including what it really is, how it will impact your company, key terminology, and how to get started. Its goal is to teach you to walk, because with dozens of deadlines coming into effect over the next three years, you'll soon need to be able to run.

Part 2: Serialization, Track and Trace, and DSCSA Requirements

What is serialization?

Serialization is the assignment of unique, traceable numbers to individual items or saleable units. In today's society, we attach unique identifiers to many things: newborn babies receive a social security number, new cars are assigned a vehicle ID and then a license plate. There are hundreds of examples of unique identifiers across many different industries, all of which generally act as gateways to additional information on the primary item.

When pharmaceutical professionals first hear about serialization, they often think of it simply as the generation and management of serial numbers. While those are core tasks, the process of implementing serialization in your company goes far beyond creating a number and affixing it to the side of a package. Serialization introduces a paradigm shift for the industry. As a manufacturer, your company has been focused on producing identical units to an exacting standard. With serialization, the focus evolves to producing that same product, identifying each item with unique data, and then accounting for that data over the next several years.

What does serialization look like?

The majority of the world requires you to serialize product according to the GS1 standard of a 2D barcode. The 2D barcode contains a variety of data, including the company identifier, Global Trade Item Number (GTIN), a product identifier like the National Drug Code (NDC), expiration date, and additional fields.

As you begin to plan for serialization, one of the things you'll have to evaluate is product artwork. Many pharmaceutical companies are finding that label changes are required in order to make room for the 2D barcodes and any human readable components. When that's the case, you need to plan time for both the redesign work and the FDA approval of the revised layout.

What is the difference between serialization and track and trace?

You may hear the terms “serialization” and “track and trace” used interchangeably, but there is an important difference. In order to track and trace a product, it first needs to be serialized. This requires the assignment of unique, traceable numbers to individual items or saleable units. Track and trace systems begin with serialization but generally have additional components.

In the U.S. and other countries, additional requirements come into play, including:

Product Tracing or Tracking: Following the movement of product along the different hops of the supply chain.

Verification: The process by which product must be verified at one or more stops along the supply chain, comparing its serial number to other key data to ensure its legitimacy.

Reporting: Once a drug or serial number reaches certain milestones or events, many countries require that data be reported, at least to the responsible government agency and, in some cases, to other supply chain partners. There are often data retention requirements for all events for up to 12 years.

When does DSCSA take effect?

The full complement of U.S. requirements phase in through 2023.

With the 2015 lot-level traceability deadline behind us, pharmaceutical companies have turned their attention to full drug serialization. DSCSA requires that manufacturers mark packages with a product identifier, serial number, lot number, and expiration date by November 2017. Other milestones include the 2019 wholesale distributor requirement for serialization, followed by the full-scale convergence of track and trace and serialization requirements at the dispenser level starting in 2023.

Part 3: The Impact of Serialization on Your Company

Serialization is a complex process that will have a ripple effect throughout your operations. Its impact reaches far beyond the packaging line and requires extensive planning and an overall business strategy that considers all of the cross-organizational implications.

Below is a list of just a few of the many things you will want to consider.

Personnel: Who should be involved?

While you will want to designate a point person, no one individual or department will single-handedly take care of serialization. Representatives from different groups should be involved.

Internally, consider pulling in representatives from the following groups, where applicable:

- Regulatory or compliance
- Packaging
- Engineering
- Operations
- Supply chain
- IT
- Label control
- Quality
- Validation
- Training

You'll collaborate with external resources, also, including hardware and software suppliers, packaging equipment vendors, system integrators, and other consultants.

In addition, your small or virtual pharma company may rely heavily on CMOs and 3PLs to manufacture and distribute your products. While neither CMOs nor 3PLs have any legal requirements under DSCSA, your CMOs will play a critical part in your readiness for the November 2017 deadline, and both partners will impact your long-term compliance success.

Product: What are your volumes?

Serialization will introduce a massive volume of data, and with that comes storage and processing challenges. Calculating the projected volume of information you'll be managing is an essential planning step. How much product do you generate, and how many units do you

What is the total number of serial numbers you'll need to create on an ongoing basis, and how many associated events will you need to track and store? For many companies, the end result is billions of records—and terabytes of data—that will need to be retained and available in a retrievable state for many years.

Aggregation: What is your plan?

Even though aggregation is not mandatory in the U.S., some pharma companies are choosing to aggregate product for the business efficiencies it provides. However, aggregation does increase both the cost and complexity of serialization operations, so budget is also a decision factor.

Whether or not you aggregate product, and on which lines, will impact packaging processes, distribution operations, CMO conversations and more, so it's a determination you will need to make.

Packaging: How do you manage it?

When will you upgrade your internal lines, and what new equipment will you need? Will your current printers, for instance, be able to produce 2D barcodes? How much downtime will line upgrades require? And how do you need to adjust production to ensure you have enough stock to get you through that process? With unprecedented demand on many of the vendors, what are the lead times and resource availability for implementation projects?

If you rely on contract partners to package product, you'll want to initiate conversations with them right away. What are their plans and timelines to upgrade the shared or dedicated lines that produce your product, and what are their expectations for financial support from pharmaceutical partners?

Beyond line upgrades, how will you exchange required serialization data with them? If you work with CMOs, establishing point-to-point connections will require time and technical know-how. Is there a more efficient network approach? Start these conversations early.

Roles: Are you also a CMO?

If you serve as a CMO for another pharma company, you'll need to consider some of the same questions raised above from the opposite viewpoint. Will you upgrade lines used for your customers' products with or without a monetary contribution? What are their expectations for when those lines will be ready to serialize product? Are they providing you with serial numbers, or will they expect you to generate them? And how will you solve the communications issue? Will these transactions move through your core serialization enterprise system or communicate directly to your packaging lines?

Distribution: Where does it happen?

Serialization will impact distribution processes. If a serialized package is damaged at a distribution center, or pulled for quality sampling, your staff will need to decommission that serial number. And if aggregation is in play, you'll want to think through whether cases are typically broken down at distribution centers, and how that might impact exactly when you build your aggregation hierarchies.

Logistics: What's the impact on shipping?

Consider what impact serialization will have on your shipping and transportation services. Under DSCSA, you maintain ownership even when your product ships to a 3PL, and when it ships from the 3PL to a downstream customer. Since 3PLs don't specialize in serialization and DSCSA compliance, it's important to think about how your provider will support information exchange in terms of both infrastructure and expertise. How will they administer serial number exchange between your trade partners? Will they be ready to provide on-time verification information to wholesaler distributors? Will there be an increase in cost for their services?

Systems: What will you need to integrate?

If you use enterprise resource planning (ERP) software, you'll likely want to integrate it, and your warehouse management system (WMS), with the serialization solution you choose. This will allow your existing systems to trigger workflows in your serialization platform, for instance, when a shipping notification is received or another relevant event takes place. As you evaluate serialization solutions, consider which ones have pre-built integrations with your core business systems.

Providers: Who can help?

Just like no one person within your organization will take care of serialization, no one company can provide the entire solution set required for serialization. Solution providers specialize in the unique sub-projects required by serialization, such as packaging line serialization and warehouse edge systems. Your selected partners need to be able to demonstrate production integration with each other's systems.

You will also choose a serialization platform and overall compliance partner who will help you assess your network-level needs, meet all global requirements, and provide general subject matter expertise. Evaluating potential providers and selecting the right one for you is a critical part of your preparations: this will be a long-term partner who supports you through ongoing regulatory changes, new trade partner requirements, and all the uncharted territory that serialization will introduce.

Timeline: When do you need to get started?

With DSCSA just over a year away, begin right away to map out when you'll be required to deliver serialized product into the market. Then work backwards, taking into consideration all the things that need to happen in a very short period of time. What is your manufacturing lead time? And how long will it take for each line upgrade? Once you get your revised label artwork to the FDA, when will they give you their stamp of approval? These are just a few of the projects you need to factor into a fast-track timeline in order to start now.

Part 4: Next Steps

The advent of serialization and the larger track and trace laws will transform not just the pharmaceutical industry, but many core operations at your company. And all that change needs to happen in a very short time frame: if you are not prepared to serialize by the November 2017 DSCSA deadline, you may not be able to sell product in the U.S.

Now that you have a basic understanding of what serialization is and what some of the implications are for a small or virtual pharma business, you are ready to start planning in earnest. Explore additional resources on aggregation, CMO relationships, EPCIS, and more, and contact TraceLink for a personal consultation on your serialization needs.

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