



Serialization: Where to Begin

An Introduction for the Life Sciences Supply Chain

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Introduction

In response to increasing drug integrity concerns, over 40 countries have introduced track and trace laws to help regulate product as it passes through the supply chain. By the end of 2018, more than 75% of the world's prescription medications will be protected by legislation.

As a pharmaceutical company you will ultimately need to master the different reporting and track and trace requirements for each country in which you do business; 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?

While no two countries have passed the exact same requirements, they all rely on one core component: serialization. Serializing product in one manner or another is the cornerstone of all the regulations. 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.

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Part I: Serialization, Track and Trace, and Market Requirements

What is serialization?

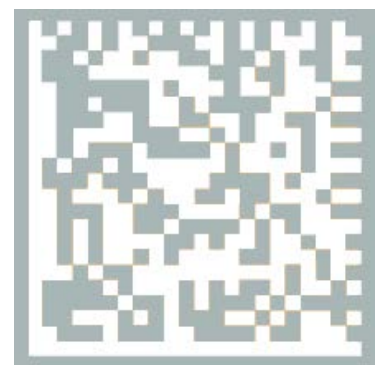
Serialization is the assignment of unique, traceable numbers to individual items or saleable units. In today's society, we attach unique identifiers to many things: newborn babies receive a national identification or social security number; new cars are assigned a vehicle ID and then a license plate. 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 as simply 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 Number (GTIN), a product identifier like the 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 build in 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. Track and trace systems begin with serialization but generally have additional components. Every country that currently has a law in play has at least one additional requirement, including potentially:

- **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 to at least the responsible government agency and, in some cases, to other supply chain partners. Often there are data retention requirements for all events for up to 12 years.

DIAGRAM 1

Country	Government Agency	Serialization	Tracking or Tracing	Verification	Reporting
Argentina	ANMAT	X			X
Brazil	ANVISA	X	X		X
China	CFDA	X			X
European Union	At Country Level	X		X	X
India	DGFT	X			X
South Korea	KFDA	X			X
Turkey	ITS	X			X
United States	FDA	X	X	X	TBD

How do serialization requirements differ by market?

Serialization will impact every segment of the supply chain, but manufacturers are the only ones who have requirements under every country’s track and trace laws. Your company’s specific requirements are determined by which countries you sell product into, not by your geographical location.

You may be based entirely in the US but if you ship product to the US, European Union, South Korea, and Brazil, you are responsible for following each of those countries' requirements for the inventory you provide to them.

Specific serialization requirements can vary on several fronts, including:

- **Serial number format and origins** – Format-wise, many countries will follow the GS1 standard but others – like Brazil – will dictate their own. And while most countries make generation of the numbers the manufacturer's responsibility, China requires companies to request them from the government.
- **Packaging levels** – Countries have different guidelines around what packaging levels must be serialized. In the European Union, for instance, serialization is required at the unit level only. In India, though, primary, secondary, and tertiary packaging must all be uniquely identified.
- **Aggregation** - Aggregation is the process of building a relationship between unique identifiers assigned to packaging containers. If you have a case with a serial number and within that case, saleable units with their own unique serial numbers, aggregation enables you to associate "child" items with their bundle or case "parent." Having aggregation in place lets you scan the case's bar code to get its serial number and then infer the identity of all the contents. Without aggregation, you would need to open that case and scan all of the individual products.
- **Product scope** – Most track and trace laws cover all prescription drugs, but some countries have specified only certain drug classifications and others may include pharmaceutical samples or certain over-the-counter products.
- **Segment requirements** – In some markets all supply chain segments are involved with serialization and in others, the burden falls on select groups. As a pharma company you have a requirement in all markets, but the specific requirements for other segments will impact with whom you're most closely collaborating.

Once you determine which country's laws you must follow, there are several resources for the requirement details. Within each country, a government agency is at the helm of track and trace efforts (see Diagram 1). And ultimately, whatever solution providers you partner with for your serialization needs should have deep knowledge about the regulations.

Part II: The Impact of Serialization on Your Company

Serialization is a complex process which 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. Here are 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 your regulatory or compliance group; packaging engineering; operations; supply chain; IT; label control, quality; validation; and training. You'll collaborate with external resources, also, including hardware and software suppliers, packaging equipment vendors, contract packagers and 3PL's, system integrators, and other consultants.

Markets: Where do you do business?

Figure out what market requirements you need to worry about, either because you sell product there now or because you plan to in the near future. And then become well-versed in the regulations themselves. From a planning perspective, it's important to note that in many countries, different requirements phase in at different times. In South Korea, for example, the first serialization deadline took effect in 2015 but reporting does not phase in until 2016.

Product: What are your volumes?

Serialization will introduce a massive volume of data, and with that come 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 ship each year? 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?

Aggregation is mandatory in some markets and not in others. Even for markets that do not require it, 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 a decision factor, also.

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 insure 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 on which your product is produced, and what are their expectations around financial support from pharmaceutical partners?

Beyond line upgrades, how will you exchange required serialization data with them? If you work with more than one or two CMOs, establishing point-to-point connections will require a lot of time, technical know-how, and a high budget. 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 if cases are typically broken down at distribution centers and how that might impact exactly when you build your aggregation hierarchies.

Systems: What will you need to integrate?

You'll likely want to integrate your ERP and WM system with whatever serialization solution you choose. This will allow your existing systems to trigger workflows in your serialization platform when, for instance, 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 generally provide 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 market requirements, and all the uncharted territory that serialization will introduce.

Timeline: When do you need to get started?

Based on your deadlines, map out when you'll be required to deliver serialized product into each of your markets. Then work backwards, taking into consideration all the things that need to happen. 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? Those are just a few of the projects you need to factor into an overall timeline that will dictate when you need to get started.

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 product by the time a country's deadline takes effect, you may not be able to sell into that market.

Now that you have a base understanding of what serialization is and some of the implications for your 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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