Six Myths About Serialization

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It's coming

The global countdown to serialization compliance is well underway. Early adopters, such as Turkey and Argentina, required serialization as early as 2010, and were followed by others such as India, China and Korea. Over the next three years, many other major markets will require adherence to their own serialization requirements, including the United States and the European Union. Expect that by 2018, serialization mandates will govern most of world's drug supply. Biopharmaceutical companies that don't comply will find it impossible to market their drugs in countries that have instituted serialization regulations.

Despite looming deadlines and risk to on-market drugs, many companies lag in serialization planning and implementation. With regulators shifting dates, some may have waited for the dust to settle before moving forward. Others may have delayed due to cost concerns or simple lack of knowledge about how to create an effective serialization program.

This article discusses six myths about serialization and what you need to know to move forward toward global compliance.

Myth #1: There's plenty of time.... Let's wait and see

If you are supplying the U.S. market, you probably know that by November 2017, all biopharmaceuticals sold in the United States must include a:

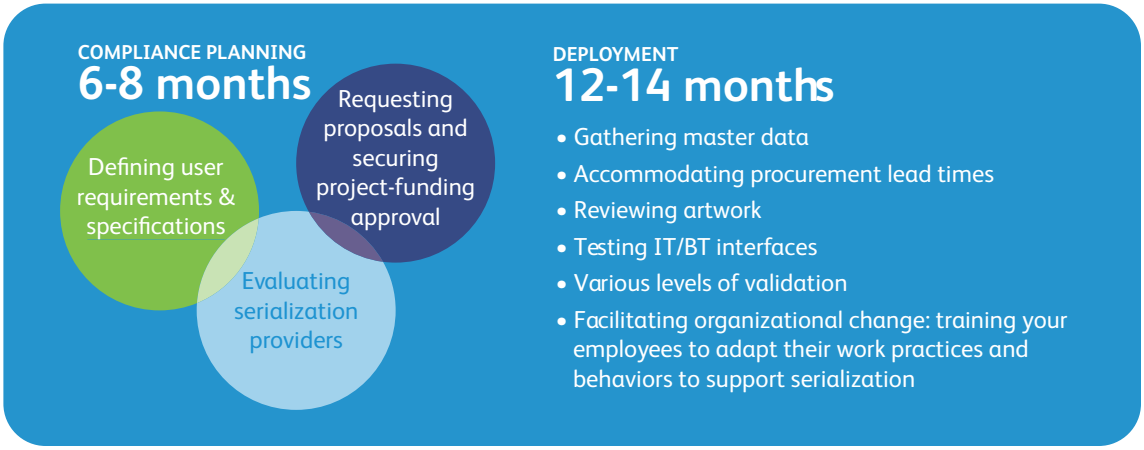
- Global Trade Item Number (GTIN)
- Serial number
- Lot number, and
- Expiration date, encoded both in a 2D data matrix barcode, as well as in a human readable form.

If you have at least started your serialization project, it's not too late to achieve compliance by the deadline – but you have to move quickly. Because initial serialization projects rarely go completely as planned, expect the total endeavor to take approximately 18 to 22 months:

Compliance planning: 6-8 months

Deployment: 12-14 months

There is a lot to do; you have no time to lose.



Myth #2: Serialization is simply setting up your packaging lines with some bar code printers and scanners

Line-level print and verification systems are fundamental to a serialization program, but they are only the first link in the serialized supply chain. The printer receives serial numbers from the line-level controllers, and the verification systems read and report the commissioned serial numbers back. This is the start of the serialized data flow. It then cascades up through a series of servers/controllers ultimately ending up in a secure, cloud-based repository. From this repository, products can be either authenticated or used to track and trace their movements through the supply chain.

Serialization master data is another important element of comprehensive serialization program. This is the common thread that binds the different systems up and down the supply chain that will be exchanging and referencing the serialization data. This data must be perfectly aligned in all systems. If a single data element is not aligned, data will not flow from one system to another.

Myth #3: Just give the serialization project to the packaging engineering team. They'll get it done.

While engineering plays a key role in implementing a serialization program, they provide only one element of what must be a cross-functional team effort for you to achieve success. That means active leadership at the top of the organization down to precise orchestration at the floor level. One model for consideration:

Program governance: provides oversight, guidance, points of escalation and leadership visibility

- Executive sponsor: Overall champion of the serialization program, generally executive manufacturing leadership. Underscores importance of project success to the executive leadership team. Sponsors the program and receives routine communication about progress, impacts to business as well as any potential issues.
- Program governance committee: Confirms/endorses overall program scope, approves program resourcing levels and monitors program threats and risks. Meets quarterly to approve scope changes; monitor and mitigate program risks; and secure program resources and investment.
- Supply chain security leadership team: Takes a holistic view of enhancing the security of products as they flow across supply chains, from sourcing of materials to delivery of finished goods. Serialization is a key supply chain security tool, but its coordination with other supply chain security tools is the focus of this team.

Program operations: creates program plans and drives execution of planned activities

- Serialization project management office (PMO) steering team: Oversees implementation of the serialization program across the company's internal and external supply network. Establishes core program strategies and monitors program plans.
- PMO program leads: Accountable for a successful implementation of the serialization program with minimal disruption to drug supply. Manage day-to-day operations of the programs underway on the packaging lines; and drive the activities of multiple work streams being performed by numerous cross-functional teams, including finance, logistics, quality, supply planning, capital controls, and supply network enablement.

Implementing a serialization program in any size organization requires commitment and collaboration across the company. Entrusting only one team with the job will lead to failure.

Myth #4: One size fits all

With the long list of countries instituting serialization regulations, biopharmaceutical companies will need to comply with a myriad of different coding and reporting requirements if they seek to expand their global footprint.

There are two schools of thought on the best way to meet multiple mandate requirements within a given operation. One method is to design your program and run your operation consistently to meet the most stringent requirements. This creates a uniform approach that is less confusing to the packaging operations teams. The second method is to build a modular, flexible program that allows operators to activate specific functionality/reporting requirements to meet a given country's regulations.

Myth #5: Once you have achieved serialization compliance, your job is done

Implementing serialization will have significant impact across all areas of your organization – packaging, warehousing, quality, distribution and logistics. It will also affect interactions with your downstream trading partners and customer-facing teams, who could be fielding questions on product security issues. It is important to help educate your key stakeholders on the ramifications of working in a serialized environment, such as potential pinch points created by the new system, as well as identify creative solutions to address these impacts.

New and additional support areas will be needed across your organization to deal with these impact areas as you transition from a program/project support model to business as usual. As serialization is one of the final steps in the manufacturing/packaging process, any issues or deviations requiring time to rectify can impede the product release process. You will need effective support staff and processes to solve problems as efficiently as possible to minimize any threats or delay to supply.

With adequate planning and the strategic implementation of those plans, you can achieve the transition to a sustainable serialization platform.

Myth #6: A CMO manufactures my drug, so I don't have to think about it.

It can take several years for a CMO to become fully serialization-ready. If your CMO is behind the curve, it could be hard for them to procure the hardware they need or find an available software vendor, given the demand across the industry to meet compliance deadlines. Early, open dialogue with your CMO regarding their serialization implementation plan is critical in ensuring continuity of supply for your product. As discussed previously, serialization requires ongoing investment in resources. Make sure your CMO has the capital not only to put an initial serialization program in place but also maintain it over time.

Regarding implementation, serialization is by necessity a collaboration, not a "plug and play." Your CMO needs to work closely with you, from evaluating the level of serialization you require – unit, box, pallet and possibly other configurations – to determining where the serialization code will be printed on drug packaging, which could trigger a full redesign. Significant customization on the IT side, should you require it, can take several hundred hours of additional work. Beyond logistical decisions, you'll need to determine who "owns" the serialization data and provides reports required by regulators. These are only a few of the activities involved in working with your CMO partner. Discussions should begin now, if they haven't already.

The right move for all of us

A biopharmaceutical company is no longer just selling their product; they are selling assurance that the product is genuine. Serialization is not an easy process, but it will pay dividends for us and for the patients we ultimately serve. Biopharmaceuticals are one of the most targeted categories by counterfeiters, putting almost any brand at risk. This means we have a responsibility to make sure our drug supply chains are safe and secure. Any deviations not only potentially put patients' safety at risk, but also the reputation of our company and the brands we manufacture.