Incorporating comprehensive serialization in the pharmaceutical industry

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In any discussion of the complexities of serialization, it’s important to focus on the finish line as much as the bottom line. Let’s set aside the anxiety-inducing talk of deadlines and guidelines, of mandates and must-haves. Instead, shift your focus to the ultimate goal of track and trace: How it will improve the safety and security of the people who use your products.

As your company scrambles to meet pending regulations, it’s easy to forget that, in terms of serialization, our overall goal as an industry is admirable and forward-thinking. Not only are we building a safer supply chain, but we’re also creating a smarter, more precise and—potentially—more profitable one. This process has already begun in Europe, where many companies have a big lead over their US counterparts, not just in establishing serialization protocols, but in implementing them, too.

US companies are now racing to meet their obligations under the Drug Supply Chain Security Act. That means committing substantial capital and other resources to serialization (track and trace). Like any business venture, if you build a people-pleasing solution, profits will come.

Barriers to implementation

Let’s face it: Implementing track and trace technologies is costly, complex, and lacking in coherent or cohesive regulatory guidance (Figure 1). Nonetheless, companies must manage vendor’s lack of capacity, changes to the package and packaging line, identifying lines available for implementation, and data system integration.

But perhaps the biggest barriers are organizational in nature. Because the move to track and trace is new, few people are versed in the language or have the skills needed to help companies evolve their operating models. The new models must ensure more effective exchange across the organization and with its partners. Undoubtedly, this will improve over time, but time is of the essence.

Find track and trace solutions that are ready for immediate implementation and flexible enough to accept future upgrades.

Desirable solutions for the short and long term

Not surprisingly, over the next 2 years, growth in the market for serialization services is expected to skyrocket. As deadlines in the US and EU approach, the landscape remains a legislative labyrinth, and many organizations clearly need help. Meanwhile, the serialization requirements of many emerging markets have already taken effect or are now being enacted.

Domestically, companies are seeking partners to help them meet short-term serialization mandates on an expedited basis. They’re also considering the long term because what’s compliant today won’t necessarily be compliant tomorrow. The goal is to identify track and trace solutions that are both ready for immediate implementation and flexible enough to accept future upgrades.

To put it bluntly, this stuff is really complicated, it’s really crucial, and it’s really happening.

Promising technologies

Thankfully, innovation in the serialization sector is booming. New anti-counterfeiting and anti-diversion technologies are already helping thwart illegal activity. Layered technologies that combine overt and covert printed features show great promise. In addition to traditional UV inks, several companies have developed proprietary inks that are easy to add to some serialization systems. Beyond compliance, serialization should be an investment that adds value to your business.

Vendor selection

Keeping your company current, compliant, and competitive requires preparation and careful vendor selection. You need a provider that not only addresses the impact of serialization on your packaging lines, but also considers the often overlooked details, such as package design, standard operating procedures (SOPs), warehouse workflow, and re-aggregation. Look for an experienced provider who can minimize the timeframe for implementation, its cost, and the risks.

Seek companies with global track and trace experience that can deploy established solutions and balance regulatory compliance with ease of operation. Ideally, the vendor will provide a solution that works with existing equipment and has the flexibility to meet future needs, many of which have yet to be determined. Fast delivery, competitive pricing, and excellent customer and technical service also are must-haves.

My company, Antares Vision, has long anticipated today’s heightened demand for top-notch serialization solutions, and has invested in the engi-
neering, capital equipment, and technology needed to devise and implement serialization solutions. In fact, we've installed solutions on 750 production lines in 140 plants worldwide, with more than 5 billion SKUs serialized, aggregated, shipped, and notified using our systems and equipment.

One example is a well-known contract packager based in Philadelphia, PA. This customer selected us after evaluating several other serialization equipment providers and integrators as candidates to upgrade its global platform. Modularity and flexibility were the key factors, and the contract packager selected its largest operation center, in Illinois, for the first installation. Today, that site has successfully integrated our technologies into its high-speed, automated, and multi-step packaging lines. It also uses our equipment as an à la carte solution to handle packages of various sizes and configurations. This successful implementation provides a robust platform for additional installations both at the company’s North American headquarters and at several sites in Europe.

**Benefits for all**

Don’t let the mad rush to implement serialization blind you to the ultimate goal: the greater good. That’s why, as government, industry, and vendors drive track and trace forward, you and your colleagues are right to press vendors to deliver solutions that minimize the impact on operational efficiency and SOPs. Seek vendors that are ready and able to develop unique solutions to satisfy your specific needs.

At the same time, make sure your investment in serialization pays off. By complying with government regulations, you should eventually recoup the costs as losses from counterfeiting decrease, your visibility in the supply chain improves, and user feedback turns positive. In due time, the effort you make today will more than pay for itself through better business efficiencies, consumer safety, and customer satisfaction.

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