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The Serialization Challenge

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The Regulatory Landscape

Over the past several years, global regulatory agencies have introduced or expanded upon regulations and guidance for life sciences companies. Whether specifically addressing supply chain, quality, IT or marketing elements, the ultimate intent is to protect and empower consumers. Multinationals are perhaps most impacted by the regulations, particularly considering the infrastructure and resources available in certain markets and fluctuations within the global economy. To maintain product safety and efficacy throughout the global supply chain, the World Health Organization has been working with regulatory bodies to harmonize Good Distribution Practices (GDP) across nations.

Specifically within the United States, the Drug Supply Chain Security Act (DSCSA) requires that manufacturers, repackagers, wholesalers and third party logistics providers (3PLs) implement means to transmit product and transaction information and determine the validity of product over a 10-year period (2013 to 2023). By November 27, 2017, all manufacturers must ensure that each drug package and homogenous case carries a product identifier, including a unique standard numerical identifier (SNI). Manufacturers will also be required to provide transaction details in electronic form, verify suspect product at the package level, and maintain product identifier records for six years or more, by the deadline.

Many companies have begun implementing serialization solutions and are working towards integration with contract manufacturing organizations (CMOs), 3PLs and trading partners. As companies' respective deadlines approach, these efforts will drive investment in integrated supply chain and IT solutions, though many are struggling to determine which entity or departments will carry the costs.

The Serialization Challenge

For organizations that are just beginning their serialization initiatives, it is important to build initial strategies with a broad view. The main priority of the rollout strategy is to ensure compliance with the current regulations; the second should be to build a flexible plan and serialization solution that anticipates future needs – particularly those that can be addressed without foundational changes. New regulatory requirements and internal initiatives, such as new product launches or site level projects, can be incorporated to allow teams to adapt and adjust program priorities and influence line implementation decisions.

Even for those organizations that have begun serialization implementations, few have addressed aggregation as an immediate need and wholesalers in the United States are setting a clear position for this requirement. Many manufacturers are currently focusing on unit level serialization to meet 2017 Drug Quality and Security Act (DQSA) requirements and prepare for the European Union's 'serialize and authenticate' model—neither of which involve aggregation. Further, the resistance to aggregation appears to be based on (1) a literal reading of the DSCSA text, and (2) the additional cost involved in equipping packaging lines to accommodate aggregation and unit level serialization.

Clarkston is working with numerous pharmaceutical manufacturers and trading partners to develop and implement solutions that address DSCSA, as well as global serialization and traceability requirements. As such, our general evaluation and recommendations for manufacturers and suppliers are as follows:

- Wholesalers, such as McKesson, require aggregation in order to efficiently conduct business. Imposing such requirements (which expand upon the compliance requirements of DSCSA) eliminates unpacking and repacking at their facilities, and proposes a practical provision for partnering with them. Cardinal and Amerisource Bergen will have similar requirements.

- Manufacturers that decline to implement aggregation prior to the November 27, 2017 deadline will risk losing business to competitors who implement aggregation requirements.

- The cost of adding aggregation capabilities to lines will never be lower than it is now. In addition, wholesalers/distributors may begin to charge administrative fees to companies who do not address these "expectations" in an efficient manner. This would offset the additional labor and systems required to unpack, scan, and repack materials.

- Installing and validating aggregation capabilities now will allow companies to take advantage of the downtime already planned for unit level serialization. Otherwise, companies will have to schedule additional downtime during aggregation implementation, testing, training and validation in the future. Although more complicated to plan, one serialization implementation project is cheaper than two implementations.

- Third party logistics companies (3PLs) fulfilling orders to wholesalers will also have to capture any new aggregation (i.e., partial cases, mixed cases, cases to pallets) and provide them to manufacturers and wholesalers.

For companies that are installing a single serialization line at a plant to serialize the output of multiple non-serialized packaging lines, aggregation is especially wise. In other cases, installing the same solution capable of both unit level serialization and aggregation allows production planning to flexibly shift among packaging lines. This also enables them to meet the requirements of: countries which currently require aggregation (e.g., Argentina, Turkey), customers who request aggregation even though their country doesn't require it, and other entities, such as the European Union (i.e., unit level serialization requirements).

In order to effectively meet DSCSA and wholesaler and distributor requirements, manufacturers should strongly consider installing aggregation capabilities, in addition to serialization capabilities, on the packaging lines they will use for serialized products. Doing so will not only ensure flexibility, but will also reduce overall serialization costs, positioning forward-looking manufacturers with a considerable advantage over competitors who choose not to do so.

Best Practices for a Successful Serialization Strategy

Pharmaceutical serialization requires a global approach. Based on our experience working with some of the world's leading pharmaceutical companies, we have built a program management approach that provides business guidance, governance, budget oversight and project coordination on a global, corporate level. Serialization implementations are then managed locally in alignment with the global program.

The Global Serialization Steering Committee (GSSC) is composed of senior executives representing the business as a whole. The committee meets periodically to review reports on serialization progress and to provide overall business direction. It establishes the corporate budget for serialization and authorizes the release of funds from the serialization budget for individual serialization projects. The Global Serialization Program Management Office (GSPMO) is then comprised of a program director, program management, finance management, IT management, and business management.

The Global Serialization Business Coordination Team is a multidisciplinary team that forms the bridge between the global serialization program and ongoing business practices. During the global serialization program, its members work with the various serialization project teams to schedule product artwork, labeling, production scheduling, regulatory filings, and other work mandated to meet serialization regulatory and business requirements. As the program nears its end, these team members build on the knowledge gained through the program to manage serialization within daily business operations.

Serialization equipment and systems implementation and testing are performed by multiple Global Serialization Project Teams in accordance with overall program governance provided by the GSPMO.

Operationalizing a Serialization Program

To ensure the success of serialization programs, companies must involve leadership and business units when discussing project goals, milestones, and organizational impacts. As the project moves towards completion, continuous communication and education will remain critical.

Well before go-live, planning should begin for the transition from serialization project mode to serialization production mode. This should happen no later than midway through the serialization implementation project. The first key decision is whether to (1) incorporate serialization responsibilities within existing business and technical organizations or (2) form a serialization center of excellence which would interact with existing business and technical organizations. The benefit of the first approach is that serialization is regarded as part of existing operations and minimal impacts to cost and headcount are incurred. The challenge is that the distribution of responsibilities would be spread among multiple business and technical organizations and would require a larger training effort. The benefit of the second approach is that there is one source of knowledge available to all departments, a clear definition of responsibilities and a minimized training effort. The challenge is the added bureaucracy, added cost, and a specialization of knowledge. Regardless of the approach taken, the following are critical paths to ensure long-term success.

During the implementation, the project team must create documentation that is readily available and can be used by business and technical personnel to manage serialization operations and to onboard new plants, CMOs, and trading partners once the implementation project has been completed. The responsibility for maintaining and expanding the documentation in response to new or evolving regulatory requirements must be assigned to the correct resources based on the approach that is chosen.

In addition, a change management exercise should be conducted to confirm the readiness and ability of business, operations, and, if chosen, COE personnel to understand and accept serialization responsibilities.

The change management assessment should include analyses of additional headcount that may be necessary, followed by a budget planning exercise to sufficiently address any headcount needs in advance. In addition, a knowledge transfer period should be planned during which implementation project team members coach and guide the operational support team of their new or additional serialization responsibilities.

Lastly, planning to accomplish serialization work for additional plants, CMOs, or trading partners after the implementation project is complete should be initiated during the latter phases of the implementation project in order to take advantage of the experience of the implementation project team members.

Looking Ahead

Over the next five years, while increased healthcare spend will likely lead to higher revenues for manufacturers, life sciences companies will focus heavily on addressing regulatory requirements, industry and consumer influences, pricing, and demonstrating comprehensive therapeutic value. Many organizations will adopt or invest in data-driven technologies to monitor and improve treatment efficacy and long-term patient outcomes. Furthermore, some may integrate new business units, or implement new, or more agile, processes, which will deliver both organizational efficiency and profitability. Companies that successfully leverage technological advances, partnerships with industry organizations and academia, and internal resources will see a definite impact throughout the value chain.

This eBook has been created from the insights provided by Clarkston Consulting.

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Clarkston Consulting provides management, operations, and technology consulting services for life sciences and consumer products companies. Clarkston has achieved a 15-year average client satisfaction rate of 95% by continuously pushing for success for our clients, our consultants, and our company.

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