

## Effective Strategies for Global Serialization and Track & Trace Implementations

*Valuable Questions from Leading Pharmaceutical Companies*



The global regulatory landscape is continuously evolving to protect patients and ensure supply chain visibility. GS1 has published standards on processes and data exchange to provide direction and enable a clearer path to compliance for pharmaceutical companies, manufacturers and trading partners. However, country-specific regulations will require manufacturers to proactively monitor regulatory changes, considering which specific solutions they will need – and when – to meet various market requirements. Regardless, companies will need flexible implementation plans and increasingly agile systems to meet the varying country and trading partner requirements over the coming years.

In our experience, as companies are planning to meet global serialization and track & trace requirements, there are a range of questions that frequently arise.

A few of these questions are highlighted below, with strategic guidance for how companies – like yours – are managing these implementations.

### *What drivers should organizations focus on as they develop their serialization strategy?*

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.

### *How do you integrate your trading partners, such as Contract Manufacturing Organizations (CMOs), into your rollout strategy?*

The manufacturer should ensure open communication with their contract manufacturers before, and as they develop their internal solution and rollout strategy. Determining scope and aligning an implementation with CMOs can be a difficult process, particularly because they are receiving serialization requirements from multiple organizations for one packaging line. Since neither the company nor the CMO can dictate implementation requirements, the two parties should designate key leaders to determine agreeable goals. We've found that a single point of contact for each party works best. These two resources should be responsible for setting key milestones, and establishing methods by which they will escalate risks & facilitate issue resolution across organizations.

### *When a regulation changes or a new regulation is introduced, how should an organization adjust their rollout strategy?*

The organization should identify a single point of contact (or contact team) to monitor all serialization regulations, and put a process in place to evaluate the impact to each business unit. Supply Chain, IT, Quality Assurance, Regulatory, Packaging, Operations, Procurement, Legal, and Commercial will need to be included in the assessment. Initially, the responsible point of contact should work with the Supply Chain lead to determine the products, packaging sites and lines affected. Once this analysis is complete, the impacts to the program and timeline can be determined. Discussions with other companies and industry organizations to evaluate legislative interpretations can help organizations fully assess any new requirements. Once all of the

information from internal and external entities is gathered and synthesized, the scope, solution and baseline of the project plan can be updated and presented to executive leadership for evaluation.

*A challenge many organizations have faced is managing packaging shutdowns. How do you mitigate packaging line shutdowns before, during and after implementation?*

A packaging line can usually be out of production for only a limited period of time – and it could be months before the line is available for shutdown again. Once project management determines the high level rollout timeline, the plan should be shared with site resources to secure time for line shutdown. If the site already has the line scheduled for shutdown, all required activities will have to occur concurrently, if possible, or the implementation timeline will have to be adjusted. During implementation, the agile methodology has proven most effective for managing complexity and risk because of the continuous feedback loop.

Post-implementation, management again must work with the site resources to plan for line availability should another shutdown be required. Strategies for limiting downtime effects are: (a) building up inventory to lessen downtime impact; (b) testing the solution offline using simulation; (c) using a standard solution so that after the first line other lines are streamlined; (d) build a solution that is almost complete offline, fully test, then do a replacement of the components that limit the additional validation testing required.

*As companies complete serialization implementations, how should they prepare to transition from project mode to production mode?*

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.

Before go-live, work with Supply Chain, IT and Quality to develop standard operating procedures (SOPs) to manage the entire serialization process. Collaborate with Supply Chain personnel to establish clear business roles and responsibilities and to train staff on system functionality and SOPs. Companies should also set up clear lines of communication with trading partners, confirming standard procedures and the process for managing exceptions. Additionally, proper IT policies and procedures should be in place to guarantee networks and systems are operating unconditionally.

After go-live, develop a training program for new hires (as a part of orientation) along with follow up training courses for continuous improvement that involves impacted employees. Along with Human Resources, this process should involve Supply Chain, IT, and Quality. Also, Supply Chain, IT and Regulatory teams should stay abreast of GS1 standards, modifica-

tions to US DSCSA regulations and evolving global requirements. Finally, Supply Chain and IT teams should dedicate business staff to manage serialization processes and communications with trading partners, and IT resources to ensure connectivity and integration between the various systems and trading partners.



#### About the Author

David Treadaway is a senior manager and serialization expert with Clarkston Consulting.

He has over 25 years of information systems experience in the consumer products, pharmaceutical, medical device and high tech industries. For the last three years, Mr. Treadaway has managed Serialization and Track & Trace projects involving pharmaceutical anti-counterfeiting efforts and regulatory compliance for the Americas and the European Union. Mr. Treadaway is also working with several clients to design and develop their serialization strategies, preparing them for compliance with worldwide serialization regulations. He and his team also developed a serialization training course for both Clarkston stewards and their clients.

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