Serialization: Moving Beyond Compliance

After delays in the U.S., federal DSCSA serialization regulations are now being enforced for manufacturers. EUFMD directives in Europe and other standards around the globe are advancing. The focus of Life Sciences manufacturers is shifting from planning and preparation for serialization to execution, management and business value.

With manufacturer requirements in place, serialization is now a standard part of designing, building and managing a pharmaceutical supply chain.

Converge Consulting helps clients design and setup serialization capabilities in conjunction with new product launch, as well as active program optimization to maintain compliance.

Ensuring Launch Excellence

Companies preparing for initial product launch are likely creating their first serialization processes and procedures. They must establish foundational infrastructure like packager codes, corporate entity structures, and GS1 identifiers with limited commercial supply expertise and scarce resources.

Regulations also require close coordination across business functions and with essential launch activities such as packaging line startup and validation, as well as 3PL selection and setup.

Our experienced practitioners understand the complexities of building out a first commercial supply chain, as well as the uncertainties of clinical and regulatory timing and legal entity/MAH status that will impact the buildout.

We work with these emerging companies on essential prerequisites for serialization such as defining configurations, designing labels, validating packaging operations, and selecting commercial GMP warehousing.

We also help clients define serialization and anticounterfeiting strategies, providing project management and guidance to ensure that biopharma companies implement solutions successfully and in compliance.

Enabling New Capabilities

For companies already serializing, focus shifts to system administration, user management, data integration, and data analytics. Growing organizations must maintain compliance as they increase the number of products, SKUs and partners.

Solution providers frequently release patches, upgrades and enhancements, forcing small and mid-sized companies to manage these changes and revalidate as required.

Some companies find their EPCIS/serialization solution unable to meet business needs as they grow, requiring replacement selection and implementation. They can avoid costly rework through requirements definition by a qualified team.

Converge works with clients to maintain, administer and optimize serialization programs by providing cross-functional expertise in critical areas including DSCSA, B2B integration, master data management, packaging, logistics and warehousing expertise.

Enhancing Business Value

As serialization requirements reach further across and down the supply chain, visibility to product and its status becomes more of a reality.

Leaders mine their data to improve on-time deliveries and recall management. Others look to predict and preempt supply shortages and replenishment issues. They see potential for monitoring single product units through the entire supply chain, ultimately helping enhance patient experience and improve outcomes.

We are able to guide clients in analyzing serialized data and identifying opportunities to capture new business value.

Our Services

We work independently and/or as advisor to our clients' teams to bring methodology, plans and tools to simplify and overcome the unique challenges of serialization in the following areas:

- Serialization strategy
- Partner and Solution selection
- Implementation project management
- Ongoing administration and management support

Converge Consulting serves the Life Sciences industry with strategy, operations and execution expertise. We collaborate with biotech, pharmaceutical and cell/gene therapy companies to achieve important business objectives. The Converge approach focuses on bridging the gap between sound strategy and reliable execution. www.convergeconsulting.com