Manufacturers faced with the prospect of significant costs to meet the impending deadline for DSCSA compliance can achieve savings and peace-of-mind by outsourcing to serialization-ready third party logistics providers.
Logistics services providers with DSCSA-compliant equipment and technology eliminate serialization headaches for manufacturers.

Many pharmaceutical manufacturers choose not to make the significant investment to upgrade hardware, software, equipment and training for pharmaceutical serialization requirements. In addition to realizing cost savings compared with outright equipment purchase, these programs appeal to manufacturers with a limited number of products that fall within DSCSA requirements and also for manufacturers working with contract manufacturers that are at risk of non-compliance after the legal deadline of November 27, 2017.

As progressive third party logistics providers have expanded their service offerings to increase integration with manufacturers, a few of these companies have added on-site packaging and labeling capabilities. Initially, these programs were designed to re-package and re-label medications to help clients meet current and expected product demand.
When the Drug Quality Security Act was passed into law in 2013, reputable third party logistics providers with packaging lines committed to early serialization of equipment, processes and training to accommodate manufacturers requiring compliance assistance.

Non-serialized products received at 3PL firms are re-packaged and re-labeled for DSCSA compliance and forwarded to trading partners.

Manufacturers entrusting their products to 3PL Serialization-As-A-Service programs solve different problems but all save time, increase efficiency, minimize the burden of compliance and reduce cost. The complete program begins with receiving non-serialized product at the 3PL facility, disassembling original packaging, then re-packaging and re-labeling onsite with serial numbers from the manufacturer’s own Level 4 repository set up by the 3PL and managed for the client on their behalf. These specialized third party logistics providers are not only providing serialization, but also managing the trading-partner data transfers that will be part of later DSCSA compliance requirements.
Manufacturers outsource serialization to reputable 3PL firms to reduce expense and assure products move legally within the pharmaceutical supply chain.

An example of this new joint manufacturer/3PL program involves WDSrx – Woodfield Distribution and Cameron Pharmaceuticals. WDSrx President Adam Runsdorf states, “Our serialization-ready warehouses, packaging and labeling lines are ready to assist manufacturers regardless of their level of DSCSA compliance.” According to Michael Venters, Chief Executive Officer at Cameron Pharmaceuticals, LLC, “At Cameron, we stress fiscal responsibility. The cost of complying with the DSCSA serialization requirements is a material expense for a generic pharma company still in the emergent phase of its life cycle like Cameron. We wanted to ensure that we chose a serialization provider that gave us an exemplary level of service and met the DSCSA requirements but did not require a material up-front cash outlay that could negatively impact available cash for growth opportunities. WDSrx provided the solution we were looking for at reasonable cost and with full DSCSA compliance.”

Another program benefit for manufacturers is that the Level 4 repository created for clients by the logistics services provider is owned by the client compared with many contract manufacturing firms that own their
repository and contract serial numbers out to their accounts. Using a 3PL-based solution, brand owners maintain complete transparency of ownership within the pharmaceutical supply chain and minimize any potential complications when tracing issues arise.

The WDSrx Serialization-As-A-Service program was developed with TraceLink, creator of the TraceLink Life Sciences Cloud, the world’s largest pharmaceutical track and trace network. The collaboration with WDSrx is the first undertaken by TraceLink with a third party logistics provider.

Serialization services enable manufacturers to rely on 3PL partners to transmit compliant data and products at reduced cost and with increased efficiency.

Adds Runsdorf of WDSrx, “WDSrx serialization services address a significant need in the marketplace for small and mid-size manufacturers who don’t want to spend the money to serialize themselves but who also want to maintain business operations in a post-serialization environment.”

For further information about WDSrx Serialization Services, contact Larry Hotz (561) 998-3885 x304 or lhotz@wdsrx.com.