

DSCSA DEADLINES: IS YOUR SUPPLY CHAIN READY?

August 4th, 2019 • Pharmaceutical Executive • Gina Parry

While it's been several years since the Drug Supply Chain Security Act (DSCSA) was first enacted, the journey to compliance with the legislation has involved extensive time and resource investments for the biopharmaceutical industry. After taking full effect following a grace period late last year, the act aims to ensure security and traceability across the supply chain. With the introduction of further requirements, such as aggregation, many companies are feeling the operational burden as they seek to comply with these deadlines.

One of the next major challenges will be to distributors and dispensers, who will be required to meet the product identifier and serialization standards outlined in DSCSA by November 2019 and November 2020, respectively. Effective compliance is further complicated for global companies by the variety of serialization regulations coming into play, from the recently enacted EU Falsified

Medicines Directive to Russia's upcoming 2020 requirements and a number of nations in the planning stage.

With the industry feeling the pressure, biopharmaceutical companies are investing in technology to further digitize their supply chain. By utilizing technology solutions like enterprise resource planning (ERP) software, organizations can implement an efficient system to meet regulation standards while ensuring supply chain accountability and patient safety. Technology will be critical to meeting DSCSA deadlines, wherever companies are at in the compliance process.

Building an ERP for Compliance

An important component outlined in DSCSA is the product identifier requirement, or serialization, which calls for each product in the pharmaceutical distribution supply chain to have a unique product identifier. This identifier must contain the product's numerical

identifier, lot number and expiration date. Today, most companies lack the infrastructure to make compliance possible without implementing the right technology tools that will identify and report on every drug moving throughout the supply chain.

By using an ERP interface to collect and store unique identifier data, companies can manage the entire supply chain system to ensure every product is accounted for. Many supply chains have their data segmented and must manually transfer it between touchpoints, making accountability and transparency of products at each step a difficult task. But with IoT devices equipped with ERP software that automatically access one central database, these devices can accurately trace drugs throughout the entire distribution network. Reporting is also made easier with a central database system because the information is continuously updated and can be collected quickly.

Many companies have struggled to comply with each DSCSA standard mostly because they lack the tools to efficiently meet requirements without slowing business. But with the integration of technologies hosted by an ERP solution that

identify, track and report on each product, companies can streamline supply chain processes without having to worry about manual business labor. There's no need for companies to turn to fancy technologies in order to

meet DSCSA compliances by the deadline. The most vital step starts with ensuring your system is set up with the right solution to handle every requirement.

