A DSCSA CHECKLIST — ARE YOU READY?

The DSCSA enforcement is fast-approaching and the pressure is on pharmaceutical manufacturers and distributors to adapt their processes.

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Substandard and counterfeit drugs are a major worldwide problem, with up to one in 10 medical products in developing countries being falsified. North America is also heavily affected, with over one-fifth of all reported cases of counterfeit drugs occurring in the region according to the World Health Organization. This is likely only a small fraction of the real problem, as many cases go unreported.

To address the growing problem of substandard and counterfeit drugs, the U.S. signed the Drug Quality and Security Act (DQSA) into law in November 2013, which calls for the serialization of prescription drugs. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA), outlines steps to build a digital system to calendartrack and trace prescription drugs distributed in the U.S. By implementing product serialization, prescription drugs can be more easily tracked with a comprehensive system throughout the entire supply chain. By November 2018, the government is requiring pharmaceutical manufacturers and distributors to update their processes to include serialization. This involves assigning a unique serial number to each salable unit of each prescription. The serial number provides information about the drug's origin, batch number and expiration date.

With just a few months to go, there are many companies who are still not ready to implement this process, and missing the November deadline can result in receiving a penalty from the government. Are you ready for serialization? See how you compare with the checklist below to find out.

Are your labels designed to support 2D barcodes?

To develop serial numbers, the FDA recommends using standard numerical identifiers (SNIs) combined with the national drug code (NDC) for a combined unique number called sNDC. Once the manufacturer develops this unique code, a 2D barcode needs to be printed onto the label of each sealed container, as well as the shipping case. While the FDA isn't specifying the exact means of incorporating the sNDC on the package, it's recommended that it's applied to each package in both a human and machine-readable format.

This new 2D barcode will require many manufacturers to redesign their labels. Adding the 2D barcode will take up more space, so it may also be necessary to adjust packaging design. Designing labels and packages to support 2D barcodes ahead of

the November deadline will save significant costs if down the road it's discovered current packaging doesn't have room for the required labeling.

Is your IT architecture up to date?
While serialization will impact manufacturing physically in terms of label design, it also will have major effects on data management and IT. Not only do the systems need to generate unique serial numbers in a different 2D format, but it also has to be able to read 2D codes and store, capture and transmit serial numbers that come in and out of the facility.

Because manufacturers don't currently track every single drug bottle, many machines aren't equipped to store the influx of data that will come in when serialization is enforced. Having an updated IT architecture and a data management strategy in place will ensure a seamless transition once the DQSA comes into play in November.

Does your system support in-depth reporting?
With the DSCSA in place, manufacturers and distributors will need to make pedigree documents available for customers. Pedigree documents include the origin of every drug, each prior sale in the supply chain and purchase or trade of drug including the names and addresses of all parties involved. While this is required today, it hasn't been enforced until the upcoming November deadline. Reporting this information can be a hefty task, and companies that have automated reporting in place will save significant time and resources come November when this is enforced.

Are you involving all departments in the transition process?
Employees involved in the packaging process may be the most affected by changes driven by the DSCSA, but many different departments need to collaborate in order for the changes to be successful. Departments including IT, project management, engineering and quality assurance must be aligned to ensure a smooth transition.

Involving all departments from early on in the process can help an education gap in learning the new system. Also, enforcing changes from the point of view of these different departments can help with seamless collaboration. If all departments aren't currently up to speed with the latest process changes, now is the time.

Do you have the man — or machine — power to maintain production efficiency?
Current production processes will be disrupted by the DSCSA. To accommodate changes to serialization, packaging, label adherence and product scanning, manufacturers have to be prepared to allocate more worker time to the packaging processes, or ensure that they operate on an automated system that's equipped to handle the changes.

Unplanned work stoppages or slowdowns due to a sudden change in processes can cost manufacturers significant time and money. What's more, disruption in manufacturing has ramifications throughout the entire supply chain. Considering the pharmaceutical industry is responsible for handling life-saving drugs, any slowdowns have significant implications. Diligent planning can help minimize disruption, and it's best done well before the deadline to ensure new, automated processes are up and functioning and that there are enough people in the packaging department to accommodate the new demands.

The DSCSA enforcement is fast-approaching and the pressure is on pharmaceutical manufacturers

and distributors to adapt their processes. If you meet the above milestones, you are likely in good shape to meet the deadline. For those who may be behind, this checklist outlines some of the top considerations that must be made when implementing the new system. Although changing processes is never easy, in the end, the DSCSA will make the distribution of drugs safer, easier to track and more thorough.