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Asian pharma companies prepare for Russian regulations

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Asian companies that want to do business in Russia will have to comply with that country's new serialization requirements

Most pharmaceutical companies in India, China, and Asia-Pacific Economic Cooperation (APEC) countries are complying with serialization and traceability laws that mandate product serialization and traceability to combat problems in the pharma supply chain, such as counterfeit drugs. Most notable are the Drug Supply Chain Security Act (DSCSA) in the United States and the Falsified Medicines Directive (FMD) in the EU.

Soon, however, Asian companies that want to do business in Russia will have to comply with that country's new serialization requirements, which will be the most comprehensive in the world. The complex regulations will go into effect on January 1, 2020 — just five months from now — so companies that have not begun preparing need to start now.

Russia's pharmaceutical market is expected to reach $38 billion by 2021, so it should come as no surprise that the country is working to enhance its oversight of the pharma supply chain. Not complying with the new regulations would be disastrous for any Asian company's bottom line, as they would be denied access to this lucrative market. Furthermore, the regulations will cut into the market for counterfeit and falsified products as more efficient logistics management lowers operational costs for compliant companies.

However, being compliant is not a simple task. Successful and timely compliance will require three things: a dedicated project team, designing and conducting a pilot phase, and finding a trustworthy technology partner to help navigate the process.

Establish a project team and manager

The road to compliance is often demanding, so it's essential to have a project manager and team in place to maintain momentum and keep your plans on track.

Project managers should be well-versed in the regulations in question, and be skilled in managing and appointing a team that understands the importance of serialization. Project teams must have a comprehensive understanding of drug supply chains, including where ownership is passed from one party to another.

It's also important for companies to have a clear vision of their IT landscape and data flow, and appoint team members who are responsible for these facets of the process.

Design and conduct a pilot phase

Running a pilot is crucial to make sure formal implementation goes smoothly. It can uncover potential setbacks and provides a chance to discuss the actual functional requirements needed to be compliant. A pilot will also allow Asian companies to ensure they have all the necessary equipment for labeling. For example, companies should look at the needs for Data Matrix Codes and Electronic Data Interchange (EDI) labels, as well as assess if they'll need an Electronic Document Management System (EDMS).

To launch a pilot phase properly, it's also vital to have the right labeling and scanning equipment, cash software, and accounting systems, as well as a sophisticated IT solution. You should review what type of cash register and related software you're using and verify how — and if — they will work with the new marking requirements..

Find the right technology partner

When deciding on a technology partner to help meet regulation deadlines, be sure to choose one that has your best interests in mind and is willing to work collaboratively to ensure flexibility to meet the final details of the regulations, which have yet to be announced.

Your partner should be an experienced service provider that can adhere to tight timeframes, keep you in the loop about changing global regulations, and work with you to customize solutions that adapt to changes in the industry. Proactive, two-way communication is also a priority, and technical jargon should be kept to a minimum. It's also important that your technology partner is committed to cybersecurity and data management, as you will be sharing large amounts of data.

Some Asian pharma companies may regard preparing for Russia's serialization requirements (or any new pharma regulations) as daunting, but it's a worthwhile investment in time and resources. If you haven't begun, there's still have time to be ready by January 2020. But you need to act now. Start by building your team, planning a pilot, and finding your technology partner, and you'll have taken the first critical steps.

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