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ASIA EDITION

Are you Ready for EU FMD? Urgency, Consistency and Planning are Key

29 August 2018 | News | By Vikash Pushpraj, SVP, rfxcel

With the deadline looming for enactment of EU FMD and US DSCSA, Vikash Pushpraj, SVP, rfxcel, explains how achieving compliance is about much more than technology. Companies not yet set up for serialisation will need to adopt best practices and leverage the know-how of implementation experts in their methodology to go-live on time.

Singapore - In February 2019, the Delegated Regulation to the Falsified Medicines Directive (FMD) comes legally into force in Europe, mandating Marketing Authorisation Holders (MAHs) to serialise individual medicine packs for authentication at the point of dispensation. With just months to go, it's a tight deadline to meet. But an even tighter deadline is just around the corner. In November 2018, DSCSA requirements for package-level serialisation finally come into play, midway through a 10-year roadmap for end-to-end traceability across the US supply chain. These new regulations reflect a global direction towards serialisation as governments look to protect the supply chain from counterfeit drugs. The question is: are you ready for it? And if you're not, how can you get there before it's too late?

The answer lies not only in good technology that assures data integrity, connectivity and integration – but also in collaborating with expert partners with a global reach, who can bring a proven, full service methodology to assure the rapid and effective deployment of serialisation solutions within testing timescales.

The current landscape

Despite the proximity of the regulatory deadlines, a surprising number of companies have not yet established the infrastructure and processes required for serialisation. While it's not unusual for organisations to wait as late as possible before adapting operations to meet compliance obligations, it's easy to underestimate the complexity of adding serialisation capabilities to operations.

The regulations have implications – and therefore active requirements – for the full gamut of stakeholders; manufacturers, brand owners, CMOs, third-party logistics providers (3PLs), wholesalers and dispensers. It's therefore vital that pharmaceutical companies have a full understanding of the laws, the requirements and the associated responsibilities of all parties in the partner network. Moreover, companies must map their entire supply chain operations to design systems that

allow visibility, collaboration and agile workflow across a broad end-to-end process. It isn't easy. It takes time, knowledge and expertise. The former is ebbing away. The latter depends on engaging the right partner to expedite processes and get you to go-live via the shortest, safest route.

Serialisation Technology

Naturally, technology is an integral part of the solution. Serialisation and traceability require aligning processes and software to generate, capture, share and affix data related to products' unique identifiers (UIs). This data must also be accessible to downstream trading partners in order for them to receive, ship, authenticate and dispense products. If the data isn't in the system – or it isn't accurate or reliable – products will not get through the supply chain, with implications for both profitability and patient care. Effective data management is therefore crucial.

So what should companies be looking for in serialisation software that allows them to 'track and trace' products through the supply chain? The best solutions fixate on data quality and integrity, routinely monitoring information as it flows through the system to detect human error, inaccuracy and duplication. Robust validation is essential to prevent erroneous data from entering the differing international data hubs, including EMVO, DAVA and other national databases. Alongside it, connectivity is key. Solutions must ensure data flows securely, end-to-end, across the supply chain, connecting all parties to a single version of the truth.

Urgency, Consistency and Planning in Implementation

The opportunity of serialisation technology and the data it can unlock is only half the story. To realise its true value – and, crucially, achieve it in time to meet regulatory deadlines – the other critical factor in software selection is around implementation and speed-to-market. In the current environment, time is not only sensitive; it is urgent.

Solutions have to be not only custom-designed to provide access and visibility across the supply chain, they must also be securely implemented at speed and scale. The best partners will therefore deploy implementation teams spread across the globe to ensure 24/7 availability with expertise in setting standard artefacts, automating processes and applying industry best practices to ensure a consistent and planned approach. These 'hyper' care teams will mobilise Subject Matter Experts in multiple time zones to maintain continuous engagement and activity throughout the implementation process.

The deadlines for FMD and DSCSA compliance are rapidly approaching and companies that have not yet prepared for serialisation need to move quickly and urgently, but with care and precision.

It's time to factor time management into serialisation.