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### Serialization as a Foundation to Optimizing Business Practices -A Look beyond ePedigrees

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The pharmaceutical supply chain is undergoing dramatic changes as companies accelerate initiatives to comply with new pedigree regulations in support of improving patient safety, product integrity, supply chain security and at the same time protect product revenue streams, company image and brand.

As every participant in the pharmaceutical supply chain looks to serialize their warehousing and distribution operations, they find themselves facing several key challenges including incorporating serialized product into existing processes, supporting the additional data and complexities of serialization, establishing and maintaining serialization relationships through the distribution process, as well as generating and maintaining ePedigrees for compliance.

With regulations in the works, companies must find ways to continue operations in the meantime. The biggest problem manufacturers face today is that global standards have not yet been established. Yet manufacturers have the challenge to comply with a mixed bag of requirements. Companies are starting to address compliance as a global issue rather than focusing on a specific set of regulations such as California's ePedigree requirements.

With regard to serialization, there seems to be a shift from compliance-based thinking to a focus on business optimization that is currently underway for many manufacturers. Achieving a more granular level of data that shows product movement throughout the supply chain and then ties that data back into business management software such as an enterprise resource planning system (ERP), will help a company improve efficiency.

One such company that recognized this trend early on is Xyntek, a provider of high-end technical services and solutions to maximize the benefits of IT and automation technologies while ensuring manufacturers won't have to reinvest in all new systems and reinvent the wheel. Rather Xyntek has come out with a serialization solution that empowers manufacturer to be able to adhere with compliance and FDA mandates using their existing business systems and on hand automation systems throughout every stage of production. Xyntek launched its ITX-TraSer solution for optimized drug and packaging serialization that addresses regulatory validation and compliance. Leveraging web based communications, ITX -TraSer uses APIs to enable seamless interfaces between a manufacturer's existing ERP and its packaging line systems. The core infrastructure of the ITX-TraSer solution encompasses a single site server software and database module. Within that module, there resides a site server control and security component, which manages two interfaces, one for access to the line systems and the other for the business system. There is also a site server database that stores all the buffered serialization data during communication between the business system and the line systems to eliminate risk of errors that could occur during the serialization process.

Companies like having more detailed data. Forward-thinking companies look beyond the regulations and they realize that serialization is a foundation to optimizing business practices. Corporate Health Initiatives Consulting (CorpHI) is providing clients with a methodology to determine where their supply chain is most vulnerable, understand how and when this can occur and what measures they need to take to minimize their risk. CorpHI is currently partnering with hardware and software technology providers to construct robust serialization, track & trace and ePedigree solutions specifically for the food and pharmaceutical industries.

In today's economy, companies not only are trying to reduce costs within their supply chain but also are looking to streamline processes and reduce the number of hands a product has to pass through. Besides evaluating the overall operational efficiency, food and pharmaceutical companies pay equal attention to the supply chain's safety and security by leveraging serialization, track & trace and ePedigree solutions.

Axway, a provider of collaborative business solutions, sees a similar pattern among pharmaceutical manufacturers and the shift away from a purely compliance-based strategy. It seems that more organizations are focused on regulation strategies. However, as organizations delve further into the process, they realize there are other benefits such as gaining information about the cold chain and diversion, and they are shifting gears to a value-based approach. Axway offers a Synchrony solutions suite to provide community management, visibility, and policy-management solutions which include eSubmissions to FDA and EMEA, ePedigree, track and trace, and business activity monitoring. GE Healthcare chose the ePedigree component of the Synchrony solutions suite, and both AstraZeneca and Genzyme chose the supply-chain integrity suite. The software enables manufacturers to make data available to trusted partners, in all steps of the supply chain. This data can be used to secure the supply chain through enhanced visibility, to comply with global track-and-trace regulations, and also to optimize common supply-chain business processes.

Organizations are already starting to focus on serialization, data collection and management, track and trace, and optimization of supply chain activity to increase efficiency of manufacturing and distribution processes. There is a definite trend toward gaining more data about the supply chain. Companies today are starting to see the value in leveraging agnostic, scalable architectures to deliver significant improvements at the ERP, line, and plant levels to be able to create enterprise-wide visibility of packaging line data and empowering management to make better-informed business decisions.