The DQSA, signed by President Barack Obama on 27 November 2013, preempts all state regulations pertaining to pharmaceutical traceability and ePedigrees, and creates a national standard for drug supply chain security by requiring a national pharmaceutical traceability system. As Figure 1 illustrates, the DQSA sets various timelines for compliance between authorized trading partners. For example, on 1 January 2015, a single paper- or electronic-based document must record the transaction history at the lot level back to the drug product manufacturer, provide specific transaction information, and include a transaction statement from the entity transferring ownership to certify that the transaction complies with the mandates of the law. The legislation also sets various serialization requirements on Manufacturers (2017), Repackagers (2018), Wholesalers (2019), and Dispensers (2020) to affix a unique product identifier, using specific data carriers (1D or 2D data matrix) on packages and/or homogeneous cases. Authorized trading partners must also be able to verify all transactions using human- or machine-readable methods. By 2023, tracing the drug product at the unit-of-sale or item level is required, including aggregation and inferences through an inter-operable electronic system. With final guidance for each phase being issued by the FDA, the pharmaceutical industry is now faced with a definitive decision – perform a major overhaul to retrofit technologies on existing packaging lines, and/or replace legacy packaging lines to comply with the DQSA requirements.

SERIALIZATION & THE DRUG QUALITY AND SECURITY ACT
A TOP-DOWN SYNERGISTIC APPROACH

Hang around pharmaceutical drug manufacturers long enough and the conversation will undoubtedly turn to the global dilemma of safeguarding the public from the proliferation of counterfeit drugs, and the Drug Quality and Security Act (DQSA). Now a law, the DQSA includes a phased timeline, extending to 2023, that requires U.S. prescription drug manufacturers to comply with a unified federal mandate regarding transaction history and serialization. While the law eliminates the “wait-and-see” attitude some manufacturers had taken, applying a synergistic approach to the forced system and procedural updates can garner overwhelming benefits.
DISADVANTAGES TO A DISJOINTED APPROACH

A large number of pharmaceutical companies have taken a fragmented approach to implementing serialization and ePedigree, keeping hardware vendors, systems integrators, IT consultants, and enterprise systems engineers very busy over the past few years. This approach has resulted in millions of dollars being spent on pilot projects to print a unique serial number on individual packages; not all of these projects have been successful. Some companies have not even started.

Using a patchwork of niche solutions that must be manually built frequently results in inefficiencies, such as higher than expected implementation costs, delayed implementation timelines, and longer-term maintenance and overhead costs. Adding further confusion to the process is varying global regulatory requirements and potentially unforeseen facility and equipment related capital projects. Some initiatives have become mired in the confusion and stopped development due to recent downsizing (e.g., doing more with less), leaving many wondering “Where did we go wrong? And How do we correct?”

VALUE IN SYNERGY

Organizations can take a number of approaches to address the requirements addressed in the DQSA, but identifying a clear, cost-effective, forward-thinking path is most beneficial. To that end, a strong “quasi-exclusive” arrangement between M+W Group’s Life Sciences, M+W Automation, and Systech has been established to combine key industry resources and products to offer a standards-based, holistic approach to serialization. This collaborative team offers:

- full-design and integration services with a serialization platform
- a single-source serialization program management that includes traditional cGMP facilities and packaging engineering

Figure 1: Drug Quality and Security Act Timeline
Global and local teaming arrangements, i.e. a ‘glocal’ presence
The depth of talent needed for software engineering & systems integration
Corporate-wide view from the factory floor to ERP systems for access to the business enterprise environment
A secure, controlled ability to connect to any PLC, HMI/SCADA, Data Historian, MES, or ERP system
De-coupling the serialization data from ERP system
A softer packaging equipment/device "partnering" arrangement with many suppliers
Commitment to stand behind our work to address customer uncertainty and risk

CONCLUSION

U. S. pharmaceutical manufacturers must now comply with the legislation aimed at protecting the public from illicit and counterfeit drugs. While the DQSA and other existing or pending global regulations are not necessarily harmonized, sales in existing and proposed markets may be jeopardized for non-compliance with localized requirements; adding another layer of complexity.

For this reason, a constant global theme has emerged – the need for product verification based on codification and serialization to meet aggressive timelines that presently extend through 2015 and beyond. Serialization and product tracing provides a near real-time opportunity to view and dissect product movement data to capture business value. In addition, it has the potential to enhance revenue and ROI while incorporating new technologies that can code, read, verify, and track the saleable drug product across the entire supply chain. In order to reap these benefits, a company must have the capabilities to plan, design, construct, automate and validate new or retrofit packaging lines and/or facilities on a ‘glocal’ basis; along with an enterprise-wide event-data-management platform that offers open, flexible and efficient real-time business activity transaction information, end-to-end transparency to all authorized trading partners in the supply chain, logistics management, and product authentication capabilities.

Serialization is a significant time consuming initiative, and with the passage of HR 3204, the U.S. pharmaceutical industry can no longer maintain the “wait-and-see” attitude. Partnering with the right team, to the right degree, at the right time, and for the right purpose, is vital to eliminating counterfeit products from the supply chain and protecting consumers.

For companies to develop and implement an effective serialization plan, and to be compliant with this regulation the time to act is now!

Need Help? Contact the Authors ...

M+W Group

M+W U.S., Inc. is a leading global engineering and procurement contractor (EPC) company, and M+W Automation is a leading provider of automation, manufacturing IT, and vertical integration solutions to FDA-regulated industries, specialty chemicals, and other process industries. M+W Group has more than 8,000 employees providing professional design, engineering and construction services, from offices maintained in 30 countries on five continents, with annual revenues exceeding $3 billion USD.

Systech

Systech International is the global leader in brand protection technologies with solutions that address the needs of Enterprise Serialization, Authentication, and Track and Trace, serving a wide variety of industries ranging from pharmaceutical, biotechnology and medical devices to food and beverage and healthcare. Systech has offices in the United Kingdom, United States, and Belgium, as well as dedicated sales and technical support teams serving customers in more than 26 countries worldwide.