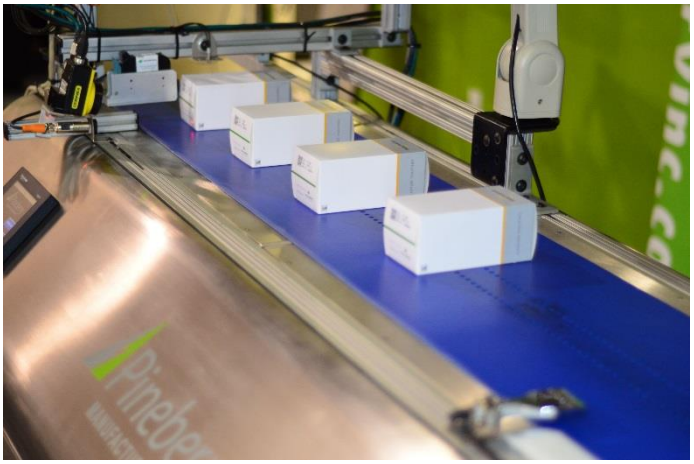
4 Reasons Why Serialization Must Be Incorporated in the Pharmaceutical Industry

Do you rank among those who need to respond to the difficult task of implementing serialization of pharmaceutical's?

Pharmaceutical Executives are hustling to finalize plans to execute the Drug Quality & Security Act, which became law on November 27th, 2013. The supply chain for genuine pharmaceuticals has grown longer, and every step in the chain offers an opportunity for counterfeiters. The problem of counterfeit drugs and drug adulteration has been a worldwide issue for decades. Driven by e-Commerce sales, unsecured physical and cyber global supply chains, and minimal criminal charges, counterfeit prescription drugs have become an exploding industry with an estimated market worth of $75 billion a year worldwide. *

Four reasons why serialization solutions are important to the pharmaceutical supply chain.

Track and Trace Pharmaceutical Products Throughout the Supply Chain



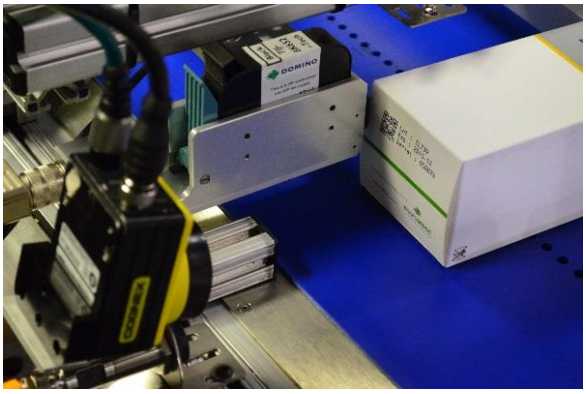
The Drug Quality & Security Act requires product serialization codes to be added to each pharmaceutical package for unit level traceability. These measures are positioned to deal with suspicious and illegitimate products. Manufacturers, wholesale distributors, dispensers and repackagers must pass, capture, maintain and update information with respect to each transaction. Information that must be recorded includes the name of the product, strength and dosage form, NDC, container size, number of containers, lot number, transaction date, shipment date, and the name and address of the business previous and subsequent owner. To elaborate, product tracing requirements are triggered by changes in ownership/transactions between trading partners. Each business is required to provide the transaction information, history, and statement to the subsequent owner for each transaction, and capture and maintain for six years.

Reduces Counterfeit and Drug Adulteration

80% of counterfeit drugs come from overseas, most of them manufactured in India and China. With the high price of prescription drugs and the relative ease of duplication and diversion make them a prime target for counterfeiters. Pharmaceutical companies and governments worldwide believe that counterfeiting can be reduced significantly by implementing product serialization, hence the Drug Quality & Security Act. The act requires pharmaceutical products and packages to be equipped with product serialization codes for ease of traceability. Serialization requires a comprehensive system to

track and trace the passage of prescription drugs through the entire supply chain. Serialization identifies every product within a supply chain by a unique serial number, in addition to the origin, shelf life, and batch number. Serialization can also trace the pharmaceutical product from production through distribution to patient.

Provides Visibility and Full Traceability



Substantiation of pharmaceutical products at various levels in the supply chain becomes very difficult without data sharing across the supply chain. Controlling and monitoring a highly complex distribution network from manufacturer to consumer in which products change hands as many as 10 times is easier said than done. Serialization requires collaborative action from partners throughout the supply chain for accurate recordings, tracking and managing data as the product moves from manufacturer, to distributor, to the consumer.

Reduces Overall Cost of Pharmaceutical Products and Medications

Current business processes in the pharmaceutical and its supply chain industry is very labor-intensive. As a result, the price paid by the consumer for pharmaceutical products is very high. Automating greatly reduces labor costs, and improves efficiency, cutting costs. We at Pineberry Manufacturing offer many automated serialization and track and trace options for the pharmaceutical industry. Visit our Pharmaceutical Packaging & Serialization webpage for more information.

As part of a long-term strategy, the United States has been trying to move to implementing technology and systems that would discourage the introduction and distribution of counterfeit drugs. In November 2013, President Obama signed into law the Drug Quality and Security Act. This act is the result of a multi-year effort to produce balanced legislation taking into consideration stakeholder priorities. Implicit within the Drug Quality and Security Act outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the U.S.

For a detailed timeline, please visit the article, Understanding When the New Drug Quality Safety Act (DQSA) Will Start to Impact Manufacturers of Drug Product by SCN.

*BioSupply Trends Quarterly, 2014