

process of a label to a product. The challenge with serialization is storing the various pieces of information associated with the unique identifier that will be the drug's lot-level serial number. Each time the product moves in the supply chain or product ownership transfers, the pertinent chain of custody information must be captured. This increases the complexity of both the capture and storage requirements exponentially as the product moves in the supply chain farther and farther toward the ultimate consumer, the patient.

There are a number of serialization companies domestically and internationally that provide the product identifier on the label or "license plate" for the drug product and cases. For simple products, current barcode labels will suffice. For more complex drug products, the 2D barcode with its greater storage capacity will be needed. The challenge will be for these providers to readjust their equipment to meet the upcoming regulations. However, to do a pilot, the serialization technology to affix the product identifier is already in existence.

THE SILVER LINING: TRACK AND TRACE TECHNOLOGY

A good analogy for serialization is that all cars, trucks, and motorcycles on the roadways are now required to have license plates. All packaged drugs now have or will have a serialized label. This is a solid start. What is the next step?

It is absolutely critical to have a track and trace system that will be able to receive input data from the serialized labels on pharmaceutical drug packages, track the pharmaceutical drugs through the supply chain, and trace these same drugs back through the supply chain when issues arise. This is no easy task!

There are several companies that claim they have the supply chain track and trace solution to meet the requirements (or yet to be determined requirements) for the Drug Quality and Security Act. IBM and SAP are marketing their solutions to pharmaceutical supply chain participants. Bosch Packaging Technology is also marketing its solutions, with a stronger focus on its serialization capabilities.¹⁹

Tracelink offers a cloud-based solution that, through its network management services, allows the entire supply chain participants to connect with one another. It offers product tracing, product and transaction verification, product serialization, and compliance data archival services