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Keeping Track

Serialisation has become essential to maintaining compliance with regulatory bodies, but this is, by no means, the limit of its potential. How can this one-size-fits-all solution provide benefits to supply chains, anti-counterfeiting and timely delivery to end users?

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As the global pharmaceutical industry implements serialisation to meet governmental regulatory requirements, other opportunities exist for companies to realise business benefits. The main driver for serialisation is to provide greater integrity to the supply chain, but other meaningful advantages can also be obtained.

Combatting Counterfeits

In addition to tightening up the supply chain and channels of trade, serialisation can provide great efficiencies for processing shipments and knowing what specific packages are included in shipments down to the lowest saleable unit. Tracking information can be updated continuously and provided to brand owners and supply chain partners on dashboards or on mobile applications.

These developments in enhanced track and trace can be employed to more quickly and accurately detect diversion of product to unauthorised regions. To combat counterfeiting, new authentication technologies now exist for linking serial numbers to security features that are unique to each package to detect possible replication of serial numbers by counterfeiters.

Despite increases in the quality of pharma manufacturing, there will periodically be a need for recall. Serialisation can be used to provide more selective identification and notification of product to be recalled and can also be used to investigate the causes of the manufacturing problem more quickly.

The expired product is returned for credits in accordance with supplier contracts, but, in some cases, it is difficult to accurately associate the selling prices with the specific product. Interfacing serial numbers with ERP systems can provide accurate pricing and shipping information for specific products. Serialisation can also help to verify that the goods being returned are authentic.

Ensuring Adherence

Statistics on medication adherence have revealed that, on average, 50% of medications are not taken as prescribed, thus severely limiting the therapeutic effect of drugs. Applications employing serial numbers can be used to establish a means for patients to record that a medication has been taken, and, if not, the prescribing physician or designated care giver can intervene. Compliance during clinical trials is necessary to ensure the integrity of the drug trial. Patients enrolled can be provided with an easy-to-use mobile application that is programmed to remind them when medication should be taken, and data can be collected to determine overall adherence of all patients. Given the cost of drug trials, brand owners can use this methodology to ensure that patients are adherent.

To enhance the overall experience and outcomes of a patient, communications programmes can be developed that require them to register for product promotion programmes, such as coupons. Webinars can be made available in exchange for patients providing serial numbers of their current prescription. Brand owners could benefit



from this direct communications channel with patients, given the amount of unfiltered information that can be obtained.

Supply Chain Solutions

More attention is now being given to the concept of “The Connected Enterprise”. In pharma, great advantages can be obtained by linking units of an organisation, including manufacturing, packaging, supply chain, finance and sales/marketing. A serial number can be used as the critical enabling technology to provide information such as:

- The name of the product
- When it was made
- Which raw materials were used
- When and where it was packaged
- When and how it was shipped
- At what price was it shipped and to what region

Additionally, with end user patient communications programmes, timely and accurate marketing data can be obtained directly rather than via purchase from market research companies. Now that much of the pharma industry is well on its way to implementing serialisation of its packaging lines, a return on investment can be obtained by developing business benefit programmes. These would use the same serial numbers that are printed on packages to comply with regulatory requirements.

Facilitating Efficiency

Advances in technology have certainly increased the efficiencies of today’s businesses, but too many organisational units have become increasingly isolated in silos, limiting opportunities for cross-collaboration and timely information from customers, suppliers and distribution partners. Companies are encouraged to hold meetings with cross-functional groups within an organisation to stimulate thought and discussion about these possible benefits. Serialisation can be a highly effective solution for facilitating the transfer of timely and comprehensive information throughout the many functional units of an enterprise, its market and external partners and, most importantly, its customers.

About the author



Steve Wood is the President and Chief Executive Officer (CEO) of Covectra and holds a Bachelor of Science degree from the US Naval Academy and an MBA from Yale, US. He has over 25 years of experience in processing and packaging machinery, pharma security technologies and integrated systems. Steve is the co-founder/CEO of five different companies and is currently serving as Director of PharmoRx Therapeutics and MedSentry.

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