



Complying with pharmaceutical serialization regulations

Pharmaceutical counterfeiting is a major problem. The National Crime Prevention Council shared research from the U.S. Food and Drug Administration and the Center for Medicine in the Public Interest highlighting the cost and danger of intellectual property theft and bad drugs. Global sales of counterfeit pharmaceuticals reach \$75 billion every year and account for 10 percent of all the products in the market. In fact, in certain countries, the majority of pills that reach consumers are fake.

These fraudulent products cost companies dearly and put the public in danger. The risks involved with the global supply chain forces businesses and regulators to come up with solutions for traceability and verification. In 2013, President Barack Obama signed the Drug Quality and Security Act into law. To stay compliant with the new rules, Pharmaceutical manufacturers must enable verification of merchandise unit of sale packaging level.

Serialization is the process of assigning unique markings on the packaging design of each product. As companies adjust and optimize their processes to overcome the obstacles of modern serialization standards, they can partner with Nos-

co for the experience and technology necessary for complete serialization optimization.

Global compliance

While organizations prepare for the DQSA regulations to go into effect, many are beginning to serialize now to comply with upcoming laws and standards put forth by consumer health organizations. Nosco has experts with decades of compliance experience ready to create products and manufacturing packaging processes that will follow rules dictated by the Health Industry Business Communication Council and international standards put forth in unique territories.

Nosco provides pre-serialized packaging for compliance in all governed regions around the world. Nosco has created products and processes for companies in China, South Korea, Saudi Arabia, the EU and more. Whether a company needs linear code or data matrix serialization, Nosco has the tools and services ready to create unique business markings.

Avoiding duplicates

The Nosco pre-serialized print methodology allows the service to offer the serialization component instead of forcing clients to do it on their production line. Letting a packaging partner take control of the process eliminates common mistakes.

By utilizing a Vision inspection model, Nosco can grade codes, check for duplicates and match multiple codes. The risk of pharma companies having a duplicate code in the supply chain is by far the greatest concern, especially when codes are created and allocated by the Government - as is the case in China. The ability to match data to two different bar codes through electronic or visual inspection reduces risk and ensures compliance for regulatory standards around the globe.

Superior quality of barcodes

Thanks to our On-Demand Solution Center, Nosco can provide unique codes printed by our HP Indigo 30000 press for each of our clients. An organization can employ serialization at the item, case or pallet

level. The Digital Printing process is quick and accurate, prioritizing optimal grading so serialization is easy to read and scan with inventory equipment.

Most pharmaceutical standards call for C in-line grading for barcodes or better. Nosco offers package printing quality with the consistency necessary to provide B and A level grades for clients based on their needs. Obtaining pre-serialized products with outstanding code grades allows businesses to process work on the packaging line without worry or concern about the serialized data and its readability.

By partnering with Nosco, companies gain the tools, knowledge, education materials and strategies they need to stay compliant with changing regulations. Nosco solutions are also cost-efficient and prevent companies from wasting resources on mistakes. Employees can easily read and scan codes to make daily tasks simpler. By partnering with Nosco, Pharmaceutical companies can help reduce fraud and keep consumers safe.

Sources: <http://www.ncpc.org/topics/intellectual-property-theft/counterfeit-drugs-1>
<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/>

Drug Quality and Security Act of 2013 Timelines & Summary Requirements

