



GRANTEK

Serialization in Pharmaceutical Manufacturing:
*Serialization Requirements for Pharmaceutical Production,
Looking Beyond Compliance*

Serialization Requirements for Pharmaceutical Production

Are you ready for pending regulatory changes and government enforcement?

Globalization, criminal activity, lax regulation and traceability requirements, less-than-stringent production protocols – all have increased the incidence of potentially dangerous counterfeit medication in the marketplace. It is estimated that 10% of all medications sold worldwide are counterfeit— placebos at best or dangerous substances at worst. This poses a risk to consumers, patients and manufacturers.

Congress passed the Drug Quality and Security Act (the Act) on November 21, 2013. Title II of the Act, the Drug Supply Chain Security Act, requires manufacturers to affix or imprint a product identifier to each package and homogeneous case. Enforcement activity is scheduled to begin in November of 2018. The Act requires serialization of each unit of packaging for pharmaceuticals, and requires traceability of the packaging from manufacturer to customer (typically commercial pharmacies).



Advantages of Working with Grantek

Pharmaceutical manufacturers are concerned about meeting the compliance dates for enforcement of the Act (which have since been delayed until November 2018). Companies with a pharmaceutical packaging line, such as contract drug manufacturers, generic drug manufacturer, or new drug manufacturers are subject to enforcement of the Act. The new regulations require serialization of all packaging units, from the smallest unit of packaging (generally a bottle, carton, bag, etc.) all the way to the shipping pallet. The parent-child relationship of each packaging unit must be identifiable and

traceable: for instance, a pallet may contain cartons, the cartons may contain bundles, and the bundles may contain bottles. This provides traceability and genealogy for products at all levels of packaging.

When overseeing a solution for a client, Grantek strives to go beyond compliance of regulatory concerns and design solutions that will improve the overall efficiencies of site operations. These efficiencies not only lower overall costs, they can also reduce downtime across other systems because of an implementation strategy that considers the site as a whole. The expertise Grantek also has outside of serialization factors into overall strategy decisions.

Grantek can help implement compliant serialization systems for existing or new production lines to help manufacturers meet the new requirements. Since Grantek is a system integrator, we design custom serialization systems for our clients that not only ensure compliance with the requirements of the Act, but also tie into the facility's ERP system to obtain serial numbers and to provide reporting that complies with the EPCIS (Electronic Product Code Information Sharing) requirements. The use of EPCIS helps enable disparate applications to leverage data. Data can also be exported in standard comma-separated variable (CSV) format for use elsewhere in the enterprise or other formats that may integrate into a specific site's business management software.

In addition to developing the serialization system, Grantek offers several services that are outside the scope of some of our highly specialized competitors. As integrators, we have the skills and experience to tie the serialization system into the facility's ERP system and provide seamless integration with production systems and MES. Fully integrating serialization data systems into the facility's ERP and planning systems provides value by maximizing use of the data acquired by the serialization system to facilitate shipping, tracking, supply chain, and other factory systems. Our competitors may offer a readymade reporting solution, but it may not be truly integrated with existing plant systems. Our engineering expertise allows us to fully integrate the serialization system with existing equipment and systems to realize maximum benefit for our customers.

Grantek can design a labeling serialization system that includes the GS-1 required data elements and company-specific identification. We develop recipe-based systems, in which the contents of a

product's labeling are encoded in a 2D DataMatrix barcode assigned by the number manager. The information is programmed for the packaging unit's size and shape, and printed in a format appropriate for each product's packaging, at all levels (individual unit up to shipping pallet or other bulk container). The labeling can be programmed to include additional information such as warehouse, ordering customer, production line, etc. The assignment of serialization data can be controlled by the ERP system or locally, and products can then be verified throughout manufacturing and shipping by scanning.

Pharmacies, the eventual customers, benefit from an improved ability to detect counterfeit medications and improved traceability of drugs. The Grantek Recipe System defines recipes that contain what to print, the printing orientation, size, and formatting of the label for the specific container. The system provides configurable options for each of the different products on a given line. When the manufacturing facility specifies a drug, the serialization system provides the recipe for its labeling at each packaging level in the manufacturing process.

For facilities that may already have a proprietary system in place, Grantek attempts to maximize reuse of existing components, but limitations may exist with some hardware/software due to obsolescence, security, and functionality. Grantek has experience retrofitting and reprogramming vision systems and can help our customers determine whether their existing equipment is capable of supporting



serialization requirements imposed by the Act. We thoroughly evaluate existing systems and software and map a path forward to align with the new requirements.

Grantek develops systems that provide visibility to everything on the line. Batch report data can be exported to an ERP system or to a local file for the facility's use. Grantek supports the SAP ATTP module for pharmaceutical manufacturing, providing data compliant xml tagging requirements.

Unlike some of our competitors, Grantek takes a holistic systems approach to serialization, rather than a specific PC-based approach where the data is visible on the line, but is not readily available to other systems in the facility. For additions or upgrades to existing production facilities, Grantek evaluates existing systems to determine whether the hardware is non-proprietary and capable of handling the new serialization requirements. We work with customers to reuse existing equipment when practical to do so.

Proven Methodology

After analysis of existing systems (if any) or plans for new construction, Grantek can develop or provide insight into a detailed user requirement specification, defining the requirements for the serialization system. Based on this, Grantek develops the functional requirements specification, system design, and is able to assist with acceptance test protocols, instruction manuals, and qualification testing.

Grantek can design and implement a recipe-based labeling system that generates a unique label appropriate for each unit of packaging, for each product being manufactured. Label content, label size, and encoding parameters are programmable by the facility. All identifiers are compliant with GS-1 requirements. Labeling may also contain the intended customer, warehouse, and manufacturing production line, allowing traceability of each packaging unit back to its source.

Grantek provides 24-hour customer support, and as a system integrator with over three decades of experience in the pharmaceutical industry, Grantek is used to dealing with multiple equipment vendors, multiple machines, and multiple production systems. Grantek is vendor-agnostic—we are

not tied to specific equipment vendors and we are comfortable doing custom work with PLCs, software, labelers, shrink wrappers, palletizers, robots, case packers, cameras, scanners, and other components of a pharmaceutical manufacturing facility. We have experience integrating our systems to allow SAP or other for ERP systems to talk to the manufacturing floor.

As a systems integrator with over 30 years of experience with pharmaceutical manufacturing facilities, including vision systems and serialization, Grantek has expertise in a wide variety of manufacturing technologies. To comply with the coming enforcement of the Act in November 2018, companies should contact Grantek as soon as possible to ensure their facility is compliant before the deadline. Grantek would be happy to discuss your company's serialization system strategy and begin subsequent project planning. The deadline for compliance is quickly approaching.

For over 30 years, top manufacturers in Food & Beverage, CPG, Pharmaceuticals and Energy have called upon Grantek to solve their most complex business and manufacturing challenges. Grantek's team of professionals located in 17 offices across the globe deliver solutions to complex problems in Smart Manufacturing, Industrial Networking, Automation and Industrial Safety. Call 1.866.936.9509 or email info@grantek.com to learn more.