Security and serialization: Streamlining the pharma supply chain

Compliance with evolving global serialization regulations such as the DSCSA provisions of the US FDA’s DQSA and the EU’s Falsified Medicines Directive has required the global pharmaceutical supply chain to take a new approach to label and data management.

Smart companies have recognized the strategic value in meeting these regulations: By building an integrated, interoperable supply ecosystem, they can capture better visibility to the supply chain, reduce waste in procurement and warehousing, bolster change management programs and streamline overall processes.

Having the right labeling system in place—one that is secure, proven and reliable, that integrates completely with existing systems and workflows to enable “single source of truth” data management, and that scales and adapts to evolving business practices—can be the difference between a successful serialization initiative that creates efficiencies and a complicated one that creates costs.

BarTender: The heart of your serialization labeling solution

BarTender® is a secure component of validated installations at pharma manufacturers and packagers around the world, delivering secure, auditable barcode and RFID labeling, all backed by industry expertise.

BarTender supports every level of regulatory mandate across the global supply chain: product code, batch variable, serialization, e-pedigree and aggregation. Seamless integration with ERP systems like Oracle, SAP, Epicor, IBM Websphere and HighJump enables automation at the enterprise level, providing increased levels of security and labeling accuracy while also improving efficiencies and promoting interoperability throughout the supply chain.

BarTender and pharma labeling

Pharmaceutical manufacturers choose BarTender for its unparalleled security and serialization capabilities. BarTender is scalable to any system requirement and adaptable to the entire spectrum of AIDC technologies and global pharma traceability regulations.

- Centralized control to lock down any part of a template. Configure access by product, container, geography, business unit, operator or other parameters, based on your business needs.
- Layered security features, ranging from basic print-only settings to complex role-based permissions with label format encryption.
- Share incrementing serial numbers across your network. Flexibility to meet your serialization needs: Per-label or per-job, or by data source or database field change.
- A seamless connection between your ERP system and your label printer, whether used with one printer at a single plant or thousands of printers at facilities around the world.
BarTender for pharma manufacturing:

BarTender and regulatory compliance
BarTender is successfully deployed in systems validated by the US FDA and European Commission. BarTender’s Security Center, included in Automation and Enterprise Automation editions, provides powerful capabilities that can enable compliance with the most stringent regulatory requirement.

Security
BarTender offers a complete spectrum of customizable security options, ranging from simple Print-Only mode, to complex role-based permissions: Control access to label design and modification, database setup, document saving, printing and more from a central location onsite—or at a facility on the other side of the world. Label format encryption can be applied to any of the security levels, providing an additional layer of protection against unauthorized use.

Electronic signatures and data logging
BarTender’s electronic signature feature and comprehensive data logging capabilities combine to bring full audit trail accountability to the entire labeling process, enabling compliance with high security standards, including the FDA 21 CFR Part 11 guidelines.

Serialization
BarTender supports the incrementing of serial numbers at a single printer or at printers across a network, and can share data sources among all documents through the system database, with support for unlimited ranges and unique, random or sequential serialization: per-label, per-job, when changes occur in a data source or database field, or when the time or date changes.

BarTender can help you meet your pharma serialization labeling requirements. For more information on BarTender in FDA-regulated environments, please visit the Seagull Scientific website.

Try BarTender free for 30 days:
www.DownloadBarTender.com