Security and serialization:
Streamlining the pharma supply chain

BarTender® is at the heart of FDA-validated pharmaceutical manufacturing installations around the world, providing legendary ease of deployment and acclaimed technical support.

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.

Built-in security, compliance and agility

Built to help meet the security demands of the pharma printing environment, BarTender provides full audit trail capabilities throughout the entire labeling process. Layers of configurable settings add broad protections to the printing environment, with security features ranging from basic print-only settings to complex role-based permissions with label format encryption.

Regulatory and production landscapes will continue to change. And BarTender's Intelligent Templates™ provide the agility and security companies need to meet evolving interoperability standards—use them to rapidly perform and deploy design, data and format changes.

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.
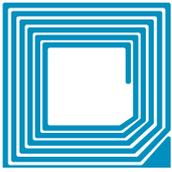
BarTender for pharma manufacturing: Dependable. Scalable. Adaptable.

BarTender enables the entire pharma supply chain—manufacturers, contract packagers, repackagers, kitters and 3PL providers—to meet global serialization mandates. But there are also strategic benefits inherent in a well-deployed label serialization program:

Process improvement
- "Single source of truth" data management supports change management protocols.
- Better visibility into the supply chain enables waste reduction in procurement and warehousing.
- More precise transportation planning captures resource efficiencies.

Brand protection
- By tracking drugs through the supply chain, companies add layers of protection against tampering, counterfeiting and sale of expired product.
- Serialization enables rapid recall in case of an adverse circumstance or event.

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

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.
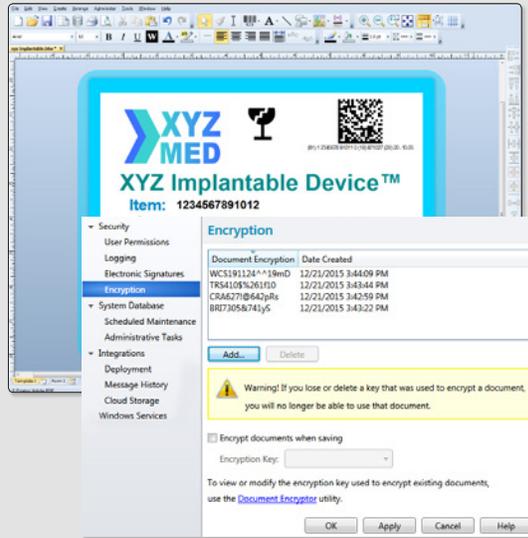
Electronic signatures and data logging

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
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Integration with SAP Applications

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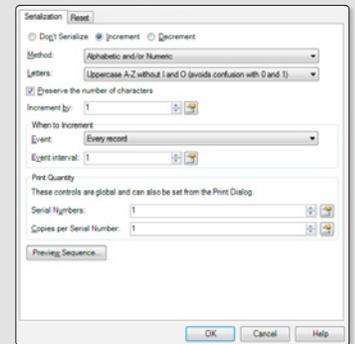
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