TEGO
Powering Assets with Intelligence

Achieve Compliance with Asset Intelligence

Summary of the Legislation

In November of 2013, the federal Drug Quality and Security Act (DQSA) was enacted, addressing the oversight of compounding of human drugs. Among its numerous provisions, DQSA includes Title II, the Drug Supply Chain Security Act (DSCSA), mandating a full supply chain traceability system from pharmaceutical manufacturer to pharmacy dispenser for prescription drugs distributed in the United States. Section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA), also governs the actions of compounders qualifying as outsourcing facilities.

DSQA, including DSCSA and 503B, will help protect patient safety by enabling verification of products, improving the detection of suspect ones, and facilitating product recalls. This legislation also puts a significant burden on entities operating under its provisions.

Compliance Requirements

Drug manufacturers, wholesale distributors, repackagers, and dispensers that work with prescription products in the U.S. must comply with DSCSA's complex drug tracking, verification, and serialization regulations:

- Track and receive lot level compliance data and transaction history
- Verify "T3" compliance data and quarantine any suspect products
- Store "T3" compliance data for at least six years
- Retrieve and respond to request for information from FDA or other regulators.

Compounders registering under Section 503B must:

- Comply with CGMP (Current Good Manufacturing Practices).
- Consent to FDA inspection according to a risk-based schedule.
- Report adverse events and provide FDA with information about the products they compound.

The Challenges for the Affected Entities

Full supply chain traceability is a significant challenge for many manufacturers, distributors and dispensers. End-to-end visibility is hampered by the complexity of heterogeneous systems and the lack of interconnectivity from the packaging line to the distribution center to the pharmacy and ultimately to the bottle in the patient's hand.

DSCSA imposes numerous deadlines, some of which have already passed and others that will be phased in between now and 2023. As pharmaceutical companies and contract manufacturing organizations (CMOs) feel the pressure mounting from impending deadlines, they may be tempted to implement anything that solves the problem at the moment. The result can be layers of serialization that are tactical in function, but not scalable, maintainable or cost-effective.

Some additional challenges companies face as they struggle to comply with DSCSA requirements, and especially the Nov 27, 2017 deadline include:

- **Falling behind deadlines:** While many companies were able to meet the 2015 DSCSA requirements on time, some remain noncompliant.
- **Outdated paper tracking:** Not all companies are storing DSCSA transaction documents electronically; some remain reliant on paper records;
- **Reliance on partners to meet Nov'17 deadline:** Not all companies using contract partners to package drugs are confident in their ability to meet the November 27, 2017, deadline to apply serial numbers.
    - Few packaging lines owned by contract partners of companies targeting the U.S. are converted to apply serial numbers.
    - Only some companies have begun adding the components necessary to serialize; most of the others will only start this year.
- **Slow adoption across the chain:** Wholesalers and third-party logistics providers are receiving only a small percentage of product with serial numbers today;
- **Lack of standardization:** Wholesalers and third-party logistics providers will use a wide range of techniques and technologies.
    - A wide range of technologies used to exchange DSCSA transaction data, with no clear standard.
    - Wide range of processes and techniques to verify saleable returns after 2019, no clear standard.
    - GS1's EPCIS standard is expected to play a major role in the exchange of non-serialized and serialized DSCSA transaction data between now and 2023.
- **Requirements interpretation:** There is still no consensus understanding over "aggregation data."
- **Hasty, check-the-box approach:** Without a long-term vision many companies are hastily considering the cheapest available options failing to derive additional value from those investments.
- **Meeting only minimum requirements:** Various paper-based or bar-code systems may provide the basic identification and track-and-trace functionality but fall short in seizing the opportunity to transform business processes.

A Strategic Approach to Compliance

Safety and quality is and will remain one of the top concerns and priorities in the pharma and health care industry. Depending on where you sit in the organization however, safety and quality concerns can seem as a pesky compliance mandate or a real business risk that requires active management. Compliance activities should not be isolated 'checking-off-the-box' activities with minimum investment, but rather an opportunity to rethink and restructure smarter ways of doing business, solve operational risk concerns, drive improvement and extract additional value. Strategically-minded companies will seek new ways to manage business risks, make control frameworks and processes more effective, and in the process influence best business practices

Digitizing track-and-trace and transaction documentation for compliance is one example of the bare minimum mandates. Many technologies will suffice in only achieving the regulatory requirements. However, the promise implied in digitizing information on assets – from drug products and biospecimens to medical devices and equipment - goes beyond compliance and simple product identification. Being able to capture information, data and documents on the assets themselves is what makes assets smart. Embedding them with intelligence as they travel through the supply chain allows them to tell their story. This digital storytelling delivers greater business value and reduced risk, through improved visibility, agility, better measurement and benchmarking, and value-added collaboration with supply chain partners. Visibility and agility help avoid common problems like stock-outs while minimizing inventories. The possible improvements in these critical measures alone are enormous - a typical pharma or medical device company has 150 – 250+ days of inventory, and manufacturing lead times of 75-180 days. Thus, improvements in the 2x – 20x range are possible, freeing up operating capital while preventing revenue loss from stock-outs.

From the prevention of counterfeiting to better management of recalls and the automation of processes, advanced digital asset technologies can unlock enormous hidden value throughout the supply chain while also bullet-proofing safety and quality processes.

Digitizing the Life Sciences **Supply Chain**

Improves Safety

- Prevents suspect, illegitimate and counterfeit drugs and medical products
- Prevents medication errors

Achieves visibility and agility

- Enables significant improvements in days inventory, manufacturing lead times and minimizes risk of stock-outs or product obsolescence
- Enables better forecasting across complex supply chains by selectively sharing more detailed operational information across the chain
- Eliminates unnecessary costs

Drives coordination and collaboration

- Supports industry-wide supplier controls and auditing practices
- Decreases dependencies

Stops revenue leakage due to counterfeiting

- Prevents drug counterfeiting. With the global counterfeit market estimates ranging between $75B and $200B+ an enormous amount can be re-directed back to legitimate manufacturers
- Prevents revenue loss to counterfeit products in medical supplies, components and equipment as well

Dramatically improves recall processes

- Allows for granular-level product details, to support easy identification and removal of unfit products ensuring early and contained recall

Automation of processes, driving costs down

- Improves efficiency by advancing from paper tracking processes and human inspection, to automation along multiple supply chains and across value-added business processes

Existing Solutions vs. The Power of Smart Assets

Simple ID Solutions are Falling Short:
Today the standard digital technology employed to address compliance mandates includes simple identification numbers and little more. Those solutions rely on backend databases and sharing of information throughout the supply chain so that the important details about the product must be extrapolated. Latency for decision making and costs to manage the shared data infrastructure are inherent and accepted as the cost of doing business. Once written, identification data cannot be updated to reflect changing conditions and chain of custody updates. Furthermore, in many cases those solutions cannot survive sterilization, refrigeration or other typical conditions in life sciences.

Digitizing Assets Ensures Compliance and Delivers Data at the Point of Use:
In contrast, Tego's solution is an interoperable platform for critical data sharing, capturing noteworthy manufacturing, regulatory and lifecycle data on the products themselves, at the shipment, pallet, carton and/or item level. Critical safety and business data travels with the products and is available locally to authorized users - wholesalers, distributors, re-sellers, pharmacies or patients to take action. By embedding digital information into the products themselves each stakeholder has improved visibility into the medication's or medical product's safety, compliance and chain of custody for ongoing real-time management.

Valuable Data and Documents Move Securely with the Asset and Benefit Entire Supply Chains:
Tego's Asset Intelligence Platform (AIP) embeds digital data directly on the product, carton, pallet or shipment in a reliable and secure manner. The solution is rugged enough to survive gamma and e-beam sterilization and other rigorous manufacturing processes so that end-to-end safety details and electronic chain of custody can be captured. Shipment information, detailed documents, safety warnings, all these can be written and read, and secured directly on the item, pallet or shipment. Access to parts or all of the information is controlled using tiered access privileges at both the item and account level.

Tego's solution makes products compliant and smart, thus enabling the entire value chain to operate more efficiently and safely. With Tego's AIP life sciences companies get critical data visibility across the entire ecosystem, sidestepping interoperability issues and the need to share enterprise-based information through a centralized data repository. And rather than relying on costly, rigid, back-end infrastructure, constant connectivity and unnecessary data overload, life science companies deploying Tego's AIP can take advantage of the right asset data at the point of need. With the interoperability of Tego's built-in operating system, data can be securely or easily accessed on any mobile device or RF reader, or integrated into a larger enterprise system.

Top Use Cases

Tego's AIP addresses the following top use cases:

- **Visibility into manufacturing events, distribution pedigree, and safe use advisory for components, drugs, biospecimens, medical devices or products**
- **Compliance and risk management**
- **Management of components, drugs, biospecimens and medical devices and products**
- **Creation of electronic pedigrees, or e-pedigrees, to help improve drug safety**
- **Digital signatures and NSA-level encryption to eradicate drug counterfeiting**
- **Value-added activity and data sharing for partners up and down the entire value chain**

Let Tego help you outline the possibilities of transforming your assets with embedded intelligence. Ensure compliance and move beyond to deriving extra value from high impact business processes. To learn more about the Tego Asset Intelligence Platform, please visit ***www.tegoinc.com.***

Simple to Deploy and Use, Minimal Infrastructure, Interoperable Platform:
With much less infrastructure and no enterprise systems requirements, manufacturers, wholesale distributors, re-packagers, compounders and dispensers will easily meet the compliance challenge with Tego. In addition, Tego's AIP enables products, boxes and pallets to maintain their own unique "storylines". Those stories can range from e-pedigree to critical transaction details – events and processes endured at a certain time and date – gathered sequentially and added in real time during manufacturing and distribution, augmented and accessed when needed in the supply chain, to validate compliance with processes, guidelines and manufacturing best practices.

With minimal infrastructure footprint and ease of scalability, Tego's Asset Intelligence Platform (AIP) delivers local intelligence and compliance information on any asset with an immediate ROI. When companies turn to Tego for help with streamlining processes and controlling and protecting valuable inventory, they can reduce operating expense by slashing the time needed to assure supply chain traceability, validate chain of custody, and query and certify asset history.

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About Tego

Tego powers assets with intelligence. Tego's Asset Intelligence Platform makes businesses smarter by embedding digital information in assets and components in the aerospace, life sciences, healthcare and manufacturing industries. Insights about assets' lifecycle history, regulatory compliance and integrity drive operational excellence and new revenue models. Smart asset data is available for the right people and systems, including IoT, EAM, ERP, and Analytics applications.

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