Serialization in the Pharmaceutical Supply Chain

Complying with the Drug Supply Chain Security Act Using a Mobile Data Collection Solution.

RFgen

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Introduction

The Drug Supply Chain Security Act (DSCSA) was enacted in 2013 with the stated goal of building "an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States."[1] It applies only to finished-dose, packaged drugs for human consumption that require a prescription. The DSCSA replaces individual states' drug pedigree requirements with one comprehensive federal solution that will:[2]

- Enable verification of the legitimacy of the drug product identifier down to the package level;
- Enhance detection and notification of illegitimate products in the drug supply chain; and
- Facilitate more efficient recalls of drug products.

The World Health Organization (WHO) estimates that counterfeit drugs in the supply chain cost manufacturers $40 billion annually[3], and prompt safety recalls minimize product liability and potential compliance fines.

It is expected that full implementation of the DSCSA will improve patient safety by creating a system that makes it easier to identify counterfeit drugs and quicker to remove them out of the supply chain. The same system will also speed up the process for pulling back a legitimate drug from the supply chain in the event of a safety recall. Both of these benefit pharmaceutical manufacturers.

1 FDA, Drug Supply Chain Security Act website.
2 FDA
3 Karen Langhauser, "Serialization: 2017's Savvy Essential," *Pharmaceutical Manufacturing*, December 7, 2016.

Major DSCSA Compliance Milestone Rapidly Approaching

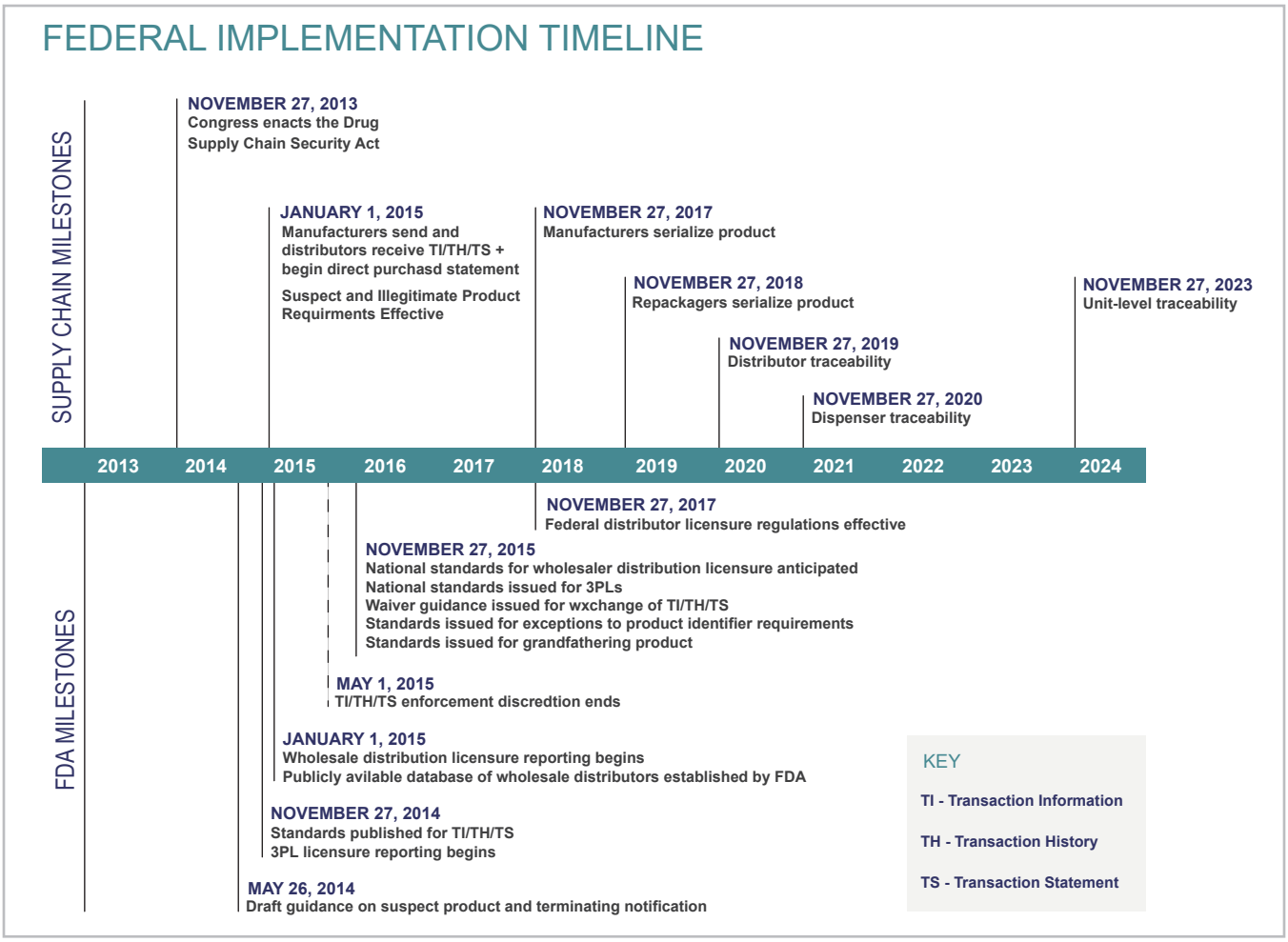
Compliance with DSCSA is serious business. Manufacturers, repackagers, and wholesale drug distributors that fail to meet product serialization and traceability requirements under the DSCSA can face costly penalties. These could include civil fines and possible criminal charges for executives.

To establish better tracking and traceability of drugs throughout the supply chain, the DSCSA is being implemented via a number of milestones spread across a ten-year timeframe. These milestones impact drug manufacturers, wholesale drug distributors, repackagers, and many pharmacy dispensers.

Starting in 2015, pharmaceutical manufacturers, contract manufacturers (CMOs), wholesalers and repackagers had to achieve the first step—achieving lot level identification and traceability by including lot number when exchanging Transaction Information (TI), Transaction History (TH), and Transaction Statements (TS).

From 2015 until now, TI, TH and TS could be transmitted electronically or in paper format, but the upcoming 2017 deadline will mean that manufacturers must begin providing this data electronically.

Starting in 2017, manufacturers must transmit Transaction Information (TI), Transaction History (TH), and Transaction Statements (TS) electronically.



Source: Implementation milestones for the DSCSA, presented by the Healthcare Distribution Alliance[4]

The next step is serialization

By 2023, all companies in the pharmaceutical supply chain will be required to be able to trace individual packages of prescription drugs by serial number. Upcoming compliance milestones in the move toward full serialization are as follows:

- November 27, 2017 - Manufacturers must serialize pharmaceutical products.
- November 27, 2018 – Repackagers must meet serialization requirement.
- November 27, 2019 - Distributors must meet traceability requirements.

4 FDA, Drug Supply Chain Security Act website.

The 2017 Challenges: Serialization and Verification

The impending November 2017 deadline requires manufacturers (including CMOs) to label products with unique product identifiers. In the DSCSA, "product identifier" is defined this way:

> *"The term 'product identifier' means a standardized graphic that includes, in both human readable form and on a machine readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product."*[5]

By November 27, 2017 manufacturers must place a barcode that contains serialization information on every product package and each case of products.

The DSCSA goes on to say that the product identifier information will be included in "a 2-dimensional data matrix barcode when affixed to, or imprinted upon, a package."[6] A drug package can be thought of as the unit of sale.[7] The product identifier information must also appear on each package in "human readable form." The 2D barcode on packages must include:

- Standardized Numeric Identifier (SNI) consisting of the National Drug Code (NDC) plus a unique serial number assigned by the manufacturer
- Lot number
- Expiration date

Manufacturers must also label every case of product. When labeling cases, manufacturers may use either another 2D barcode or a linear barcode encoded with all of the same information as the 2D barcode. The same information must also be shown in human readable form on the shipment. Manufacturers and their trading partners must retain information about the assignment and shipping of lot and serial numbers for six years.

5 DSCSA Section 581[14], as reproduced by Dirk Rodgers, "The DSCSA Product Identifier on Drug Packages," May 4, 2015.
6 DSCSA Section 582(a)(9), as reproduced by Dirk Rodgers, "The DSCSA Product Identifier on Drug Packages," May 4, 2015.
7 "Q&A: Addressing Drug Supply Chain Security," *Pharmaceutical Manufacturing*, October 24, 2016.

In 2017, manufacturers will be legally required to supply transaction data to other supply chain stakeholders in electronic format. This electronic chain of custody documentation will include:

Transaction Information (TI) – basic data about the drug and the change of ownership. It should provide the following information:[8]

- The proprietary or established name or names of the product
- The strength and dosage form of the product
- The National Drug Code number of the product
- The container size
- The number of containers
- The lot number of the product
- The date of the transaction
- The date of the shipment, if more than 24 hours after the date of the transaction
- The business name and address of the person from whom ownership is being transferred
- The business name and address of the person to whom ownership is being transferred

Transaction History (TH) – the TI from any and all previous owners, going all of the way back to the manufacturer. For most manufacturers, most shipments will not require TH.

Transaction Statement (TS) – a statement, with seven components, made by the entity transferring ownership in a transaction, confirming that the entity:[9]

- Is authorized as required under DSCSA
- Received the product from a person that is authorized as required under DSCSA
- Received transaction information and a transaction statement from the prior owner of the product, as required under the law, section 582
- Did not knowingly ship a suspect or illegitimate product
- Had systems and processes in place to comply with verification requirements under the law, section 582
- Did not knowingly provide false transaction information
- Did not knowingly alter the transaction history

Starting on November 27, 2017, manufacturers must be able to respond to "requests for verification" from supply chain partners and regulators within 24 hours of receipt.

8,9 Kishore Sirigiri, "DSCSA – Transaction History, Information and Statement Tentative Formats," SAP blog, March 20, 2014.

Starting on November 27, 2017, manufacturers will also need to be able to respond to "requests for verification" by supply chain partners and regulators concerning drugs they have sold into the supply chain.[10] They will need to provide the response within 24 hours of the request, verifying that they did or did not produce the product with the serial and lot numbers in question. Requests will be made for all saleable returned drugs and "suspect" drugs. Dirk Rodgers, Pharmaceutical regulatory expert and author of The Drug Supply Chain Security Act Explained, said that while these requests should be rare, "in the event of a major scare in the supply chain, the frequency could increase quickly."[11]

To meet the challenge of serialization and verification, manufacturers need to adopt a system for collecting data, labeling products correctly, and transmitting TI, TH and TS to customers and possibly supply chain partners.

Beyond Serialization: The Value of Data Collection and Aggregation

Aggregation data is serial number-based containment hierarchy of a given shipment that can be used for sellers and buyers to know exactly which package-level serial numbers are contained in a given shipment without opening it. The DSCSA doesn't require manufacturers to provide aggregation data to customers (at least not through the current 2023 milestones). While there is no compliance requirement, aggregation data may represent additional value for manufacturers and trading partners.

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Thus far, RFgen Software has observed that many manufacturers have placed lot numbers on products (as required in 2015), but have not adopted full serialization. In fact, in the second annual RxTrace U.S. Pharma Traceability Survey, 58 percent of pharmaceutical manufacturers have the capability to put serial numbers on packages, but had chosen not to until the DSCSA November 2017 deadline arrives.[12]

According to Pharmaceutical Manufacturing, complying on serialization without investing in data aggregation may be short-sighted:

> *"Although regulatory requirements for aggregation at the case level—to infer serialization of individual product units—are not due until 2023, distributors will no longer be allowed to process saleable returns unless they are serialized as of 2019. The time and effort needed to open up each and every case is, in effect, forcing the aggregation issue early. It most likely makes financial and operational sense to do this now if possible, rather than wait until 2019."*[13]

10 Dirk Rodgers, "DSCSA – Have You Heard the Latest News," USDM webinar conducted June 26, 2014.
11 Dirk Rodgers, "DSCSA – Have You Heard the Latest News," USDM webinar conducted June 26, 2014.
12 Edward J. Buthusiem, "Drug Serialization Trends and Developments," *Pharmaceutical Compliance Monitor*, May 6, 2015.
13 "Q&A: Addressing Drug Supply Chain Security," *Pharmaceutical Manufacturing*, October 24, 2016.

When you consider that "saleable returns" equals approximately two percent of annual units sold in the U.S., this product is worth a lot of money.[14] According to Matt Sample, Senior Director, Secure Supply Chain at AmerisourceBergen—one of the three largest wholesale distributors of drugs—aggregation is a top challenge for wholesalers.[15] Wholesalers cannot process saleable returns unless they are serialized (starting in 2019) but many manufacturers do not plan to aggregate data before 2023.

Beyond DSCSA compliance, companies can potentially leverage serialization data to help improve operational efficiency and automation. For example, the same data collection solution used to implement serialization can be used to update real-time inventory data, helping to optimize inventory levels. It's also been suggested that serialization information could help reduce fraud in returns and chargebacks and eliminate duplicate payments during refunds. There's no question that automated data collection improves the speed and accuracy of a product recall. It may even lower the cost, if you are able to precisely target the recall to specific cases or packages, rather than entire lots.

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Seven Things to Consider When Looking for a Serialization Solution

With less than a year to go before the November 2017 deadline for serialization, manufacturers don't have a lot of time left to explore compliance options. Here are seven characteristics to look for in an automated data collection solution to help you implement serialization:

1. **Rapid deployment** – There's no time to lose with the deadline less than one year away. You'll need a solution that can reliably deploy in weeks rather than months. Solutions that require heavy customization or lengthy implementation roll-outs will not guarantee your compliance by the deadline.

2. **Integration with existing systems** – Some drug manufacturers quickly rolled out standalone systems for capturing serialization data in the pharma industry, but it can be difficult to leverage the information in these systems beyond simply meeting DSCSA compliance requirements. It's far better to feed this data back into your ERP and core manufacturing and distribution processes.

14 Matt Sample, "DSCSA Serialization and Pilot Programs," AmerisourceBergen presentation, slide 24, May 24, 2016.
15 IQPC, "Anti-Counterfeiting in Pharmaceuticals: How Serialization Challenges Play a Part," white paper, 2017.

If you choose an automated data collection solution with full integration to your ERP, you can centralize the data, use it inside your operations, provide it throughout the chain of custody, and include it in your company reporting and analysis. In this way, you'll have the same system of record for production, packaging, inventory control, warehousing and sales orders, as well as product verifications and recalls.

3. **Value beyond compliance** – First and foremost, you have to meet the DSCSA's compliance requirements, but the right vendor can help you achieve greater operational efficiency to deliver long-term value beyond compliance. Use this compliance requirement as an opportunity to introduce better, more effective data collection throughout your supply chain processes.

4. **Mature platform** – Anytime government regulations create an imposed compliance deadline, you'll find lots of come-lately vendors quickly bootstrapping solutions to meet the artificially imposed wave of demand. Usually, it is better to find companies with established, proven solutions that were created before the regulation. These vendors have helped companies in your industry achieve all sorts of meaningful operational goals through data collection; their solutions will be more advanced and robust, have better integration and fewer bugs, and provide more additional value than more recently developed systems.

5. **Future-proofed** – Don't settle for just serializing your products and collecting and transmitting TI, TH, and TS. Instead, choose a solution that is future-proofed and can help you turn serialization information into an asset for your inventory control, production, and customer support operations. You'll be ready for every aspect of DSCSA compliance this year and also be able to reap additional benefits of serialization in your supply chain operations.

6. **Support for mobile devices** - Give your plants and warehouses an efficiency boost with a solution that supports mobile data collection devices and mobile barcode printers. With your production workers untethered from ERP workstations, they can perform their jobs in the most efficient location and using the tools that best fit your environment, including mobile barcode scanners, tablets or even wearable devices. When you add mobile barcode printers, labels can be created within your natural workflows at the point of activity, rather than making workers trudge back and forth to stationary printers.

7. **Low cost of ownership (TCO)** – Some vendors are hosting cloud-based solutions that will require ongoing subscription fees. Some charge fees by the transaction. Some software solutions can be purchased and implemented in-house. Think about your transaction volume, your IT security preferences, and what other uses the solution might have in other areas of your operations. Choose your solution based on the best value with the lowest total cost of ownership.

How to Achieve Compliance Quickly and Effectively with an RFgen Mobile Data Collection Solution

For pharmaceutical manufacturers, RFgen provides a rapidly deployable, highly effective solution to the serialization challenge—and much more. For decades, RFgen data collection solutions have helped manufacturers in critical industries, such as Pharmaceutical & Health Products, Food & Beverage and Defense & Aerospace, achieve full tracking and traceability compliance throughout their supply chains.

RFgen has worked with pharmaceutical and health product companies that manufacture their own products, as well as those who use CMOs. Some distribute their own products, some use 3PLs and some employ a combination of distribution strategies. Despite the wide variety of business models, all RFgen customers needed a reliable, automated data collection system to help them improve tracking and traceability in the supply chain.

Advantages of RFgen data collection solutions for pharmaceutical manufacturers include:

- **Ready-made, proven solution.** RFgen is a Mobile Application Development Platform (MADP) that can be used for all mobility and automation needs. It's trusted by companies in 35 countries, with over 2,800 installations globally. Thousands of hours of research and development went into RFgen's automation and validated integration with major ERP systems.

- **Rapid, easy deployment.** RFgen was designed to be highly flexible and adaptable. It's typically deployed at an initial company site in 6-8 weeks, then rolled out to other locations at a rate of one site every two weeks thereafter. Rapid deployment, combined with easy customization, enables RFgen to offer customers a very low total cost of ownership for robust automation.

- **Integration with ERP systems.** RFgen provides validated connectivity to most ERP systems, including: SAP, Oracle's JD Edwards, Oracle E-Business Suite and other back-office enterprise systems. RFgen facilitates bi-directional exchange of real-time enterprise data with your ERP, while leaving zero footprint on your ERP server.

- **Flexibility to work with CMOs.** If you are using CMOs to produce your products, each additional step you ask them to take in the serialization process can raise your costs. RFgen can help you quickly get serialization information into your ERP system with minimal effort by your CMO. For example, one RFgen customer provides its CMO with preprinted barcode labels and a barcode scanner that operates RFgen in a disconnected mode. The CMO simply applies the label during the manufacturing process, and then scans the packages, automatically storing the information on the mobile device. The CMO delivers the device along with the product back to the pharmaceutical company. Once in the connected RFgen environment, the device automatically uploads the serialization information to the pharmaceutical company's ERP system.

- **Superior tracking and traceability.** RFgen empowers you to respond to traceability audits or verification requests in hours rather than days. You can trace products from your inputs to finished drugs. You'll be able to accurately label products, provide chain of custody information, track products as they travel throughout the supply chain, and achieve full compliance with DSCSA requirements.

- **Support for aggregated data.** With the RFgen Solution, you can give customers accurate aggregated data about shipments before they unpack the first pallet. Send information in advance via EDI and customers can simply swipe the barcode label or RFID upon receipt. License plating collects all of the data needed to produce an Advanced Shipping Notice (ASN) for your customers, including: part number, quantity, inventory status, location, lot number, creation date, and expiration date.

- **Mobility and device agnostic.** RFgen can be used on any mobile device—from barcode scanners to tablets and phones—running Microsoft® Windows® Mobile, Microsoft® Windows® CE, Android™, or iOS™ operating systems. RFgen can be used on ruggedized or consumer-grade devices, giving you the freedom to choose the best devices for your business needs.

Conclusion

When it comes to serializing your prescription drug products, there is no time to lose. The deadline for packaging these products with serial numbers is November 27, 2017. Manufacturers will also have to provide transaction information, history and statements electronically to customers and be able to verify that a product is genuine (by serial number) within 24 hours.

Automation goes a long way toward meeting these requirements. With an automated data collection solution like RFgen, production and warehouse workers can quickly capture serial numbers and other information by scanning barcodes and then exchange that data bi-directionally with back-office management systems such as ERP systems. With serialization information centralized inside your ERP, instead of trapped in a standalone system, you can leverage automated data collection to achieve greater operational efficiency in receiving, production, inventory control and beyond.

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RFgen Software—The Mobile Data Collection Experts

RFgen Software helps organizations reduce supply chain implementation costs and increase accuracy and efficiency with the industry's most reliable and flexible wireless and mobile automated data collection (ADC) software and industry standards based supply chain solutions.

In business since 1983, RFgen is known in the manufacturing and distribution industry for its solid, high-quality products and high customer satisfaction ratings among its more than 2,800 customers. With a global reach and local touch, RFgen and its network of more than 140 certified solution partners can service and support your organization no matter where your operations are located around the world.

Using RFgen, businesses are able to quickly take their current manual processes and turn them into real-time mobile applications using barcoding, RFID, mobile and wearable technologies. RFgen's Mobile Foundation Suites accelerate the integration of mobile and barcoding technologies into your environment providing certified solutions that can simplify existing processes as well as combine multiple ERP operations into an optimized workflow.

Whether you are looking for solutions to automate your warehouse and better manage your inventory, comply with government regulations, ensure 24/7 warehouse operations, track and trace your products, voice-enable your warehouse, or manage your remote inventory, RFgen is the smart choice.

To learn more, please call us at 888-426-2286, or visit our website at: www.RFgen.com.

Reduce supply chain implementation costs with RFgen Software—one of the industry's most reliable and flexible mobile and wireless automated data collection solutions on the market today.

1101 Investment Blvd, Suite 250
El Dorado Hills, CA 95762
(888) 426-2286

www.rfgen.com