Countdown to the 2017 DSCSA Deadline:
Pharmaceutical Product Serialization
Regulations and Strategies for Compliance

June 2015
The Drug Supply Chain Security Act – DSCSA (Title II, Drug Quality and Security Act, 2013) has been signed into law, with full implementation phased in over the next 10 years. The next milestone for manufacturers, November 27, 2017, is the date by which pharmaceutical manufacturers are required to print a unique product identification code on all Rx units of sale and homogenous cases distributed domestically.

**Serialization: Delay No Longer an Option**

Starting November 27, 2017, prescription drug products can no longer be shipped without a DSCSA-required unique serial identification code. Although manufacturers already print lot and date codes on each unit of sale, either by a static or variable barcode, the reality of these new regulations goes far beyond printing a few more attributes and modification of the template on the manufacturers’ vision system. The core concept behind DSCSA is to develop and maintain a tracking system from the manufacturing floor through point-of-sale capable of 100% accuracy.

**Drug manufacturers are first in line to comply with the following by the November 2017 deadline:**

- Serialize units of sale and sealed homogeneous cases with a unique product identifier.
- Provide transaction data to trading partners in electronic format only. The Transaction Data (TD) set includes Transaction Information (TI), Transaction History (TH) and Transaction Statement (TS).
- Respond to verification requests from trading partners within 24 hours.
- Verify the unique product identifier of suspect products at the unit of sale level.
- Verify the unique product identifier of returned products intended for resale.
- Quarantine product determined suspect until it is cleared or dispositioned.
Will Your Manufacturing Operations Be Ready?

Each of the components required by the milestone is highly complex, technical, and must provide accurate interoperability among key stakeholders (manufacturers, wholesale distributors, repackagers, and dispensers). As with any major change, there are myriad risks, decisions, and planning steps that must be undertaken prior to implementation. Questions manufacturers must answer include, but are not limited to:

- What will your standard information system architecture look like for hardware and software? Have you accounted for backup and recovery capability? Are you engaged with cloud capability or local servers?
- How have you interpreted the standards for interoperable data exchange, and the legislative and regulatory requirements, and are they consistent with everyone in your supply chain?
- Have you coordinated with all of your trading partners and your CMOs?
- What are your budgetary and schedule constraints?
- Do you have the resources available to implement your enterprise-wide program?
- How will serialization impact your line efficiency, operations, and distribution?
- Does your current label or carton artwork accommodate the area required for printing of serialized information?
- What is your interpretation for an aggregation strategy - DSCSA does not require it for 2017, but will downstream trading partners interpret it differently and/or require it to manage their business processes and/or be in compliance?
- How do you plan on handling rework/returns and exceptions?

The answers to any or all of these questions could impact drug manufacturers’ ability to comply with the requirements and inhibit the shipping of products.

CRB has the Expertise to Help

CRB can leverage our pharmaceutical system project management and integration experience along with our serialization experience to not only guide you through a successful implementation, but also to help drive down your overall implementation costs. We’ll handle your serialization implementation for your bottles, cartons, labeling, tracking codes, aggregation strategy and case packing applications.

We provide complete turnkey integration services including:

- Serialization Strategies and Master Implementation Plans
- Vendor Analysis and Equipment Procurement
- Installation and Contractor Management
- Start-up, Checkout, and Validation
- Project Closeout
Serialization Program Implementation Plan

The four stages below illustrate an excellent starting point for planning your serialization program, but should not be considered all inclusive. As with any program, the emphasis is on the planning stages – planning is critical in the serialization space. Time is of the essence. No manufacturer can afford to commit to a pilot and discover that the system you’ve been working with doesn’t have the proper backup capability in case of a power outage, or any other unforeseen situation.

Where are you now?

- Identify stakeholders - Operations, Legal, Distribution, Labeling, Regulatory, IT, Engineering, Purchasing, Customer Service, Quality, etc. - and establish your team.
- Detail your product portfolio (identify which SKUs are required to be serialized and which are exempt), package configuration (bottle, carton, etc.), and packaging line configuration/equipment/print technology, IT infrastructure, etc.
- Be aware of DSCSA definitions for manufacturer, distributor, CMO, etc. and know if your products are potentially exempt.
- Map all of your current business processes impacted by serialization.
- Review level of GS1 adoption. Define business objectives.
- Review method for sharing transaction data (transaction information, history and statement).
- Define process owners and responsibilities of potentially separate systems.
- Define current IT capabilities.
- Identify current processes to identify and quarantine suspect/illegitimate products.

Where do you need to be by when?

- The deadline is November 27, 2017, but realistically you should be six months ahead of this to account for any unforeseen difficulties in implementation?
- Collect requirements specific to your situation and develop a user requirement specification, to include domestic and global requirements.
- Coordinate with and utilize your trading partners, CMOs, and industry organizations (GS1, HDMA, FDA Serialization Workshops, etc.) on timelines and requirements.
- Determine aggregation strategy – temporary code, FIFO, none (wait for FDA guidelines), etc.
- Refine method of sharing transaction data (transaction information, history and statement) via EPCIS.
- Define business use and test cases (returns, rejects/rework, quality samples, etc.).
Serialization

Serialization Program Implementation Plan (cont.)

2 SOLUTION DESIGN STAGE
- Define scope, schedule and budget (pilot and rollout)
- Determine internal and external resource requirements
- Determine IT infrastructure for operations, backup and recovery, and risk of data breach (site server or other)
- Evaluate and select serial number management system and serialization provider (floor through enterprise)
- Design scalability and flexibility into your solution
- Determine and procure required equipment, hardware and software
- Determine print technology and coordinate with CMOs

3 BUILD PILOT STAGE
- Pilot line installation
- Operations – modify SOPs
- Training, Training, Training
- Evaluation and adjustments
- Coordinate with trading partners to assure accurate transaction data transfer via Electronic Data Exchange (EDI)

4 DEPLOYMENT STAGE
- Determine rollout strategy for product introduction to the market (once serialized, remain serialized; or convert lines but wait to implement serialization)
Case Study

By the end of 2015, CRB will have provided project management and engineering for serialization of nine lines at a large pharmaceutical manufacturer in the midwestern United States. Although the next deadline for the DSCSA regulations is not until 2017, this manufacturer has opted to develop standards early to avoid issues that could arise during implementation.

For the first phase of this project, CRB supported implementation of printing and verification systems and upgrades to equipment to allow for serialization and aggregation on one fully automated carton packaging line. Equipment included an upgraded cartoner, case packer and palletizer. A serialization system has been designed for an additional line and is scheduled to be installed. The design for two more fully automated carton lines, including aggregation, is in process.

CRB also implemented new print/verify/check-weigh systems and manual case packing with serialization and aggregation capabilities for two manual pack stations.

On another line, CRB designed a manual work center to serialize and aggregate products from six low-volume production lines. Equipment included a labeler, manual cartoner, print/verify/check-weigh systems and manual case packing with serialization and aggregation capabilities.

One of CRB’s current projects is to provide project engineering for a new high-speed packaging line (700 vials/minute) that will include complete serialization and aggregation capabilities.

Future Application

CRB’s serialization efforts for the lines above have been for cartons where serial numbers are placed in a consistent, repeatable location. A more complex application in design is to serialize a round container. The challenge with round containers is that the serialized code is never in a consistent orientation or location due to the rotation of the bottle. CRB will leverage previous experience with round containers to minimize any issues and a 360-degree vision system will be required to locate and confirm the serial number.

CRB will be providing additional project management and engineering in 2016 for several more carton and bottle lines for this client.
About the Authors

Steve Peterson, PMP

Steve Peterson is a certified Project Management Professional (PMP) with more than 25 years of experience in project and program management. Over the course of his career, Steve has worked on multi-discipline projects with a concentration in integration, installation and start-up of food, beverage, consumer and pharmaceutical product packaging lines, electrical and control systems, sanitary process systems, utility support systems and building/civil/structures.

Steve has successfully executed projects for many of the industry’s biggest clients, including serialization program management for Mallinckrodt Pharmaceuticals and pharmaceutical tech transfer for multiple lines for Bayer Healthcare. Prior to joining CRB, Steve worked within the Program Management Office at Mallinckrodt Pharmaceuticals, leading large multi-discipline life science capital projects. He also served 17 years with Barry-Wehmiller Design Group as Director of Projects - Life Science and Consumer Projects and Project Manager. Steve began his career with Sverdrup Corporation, where he spent six years as Packaging Engineer and Project Manager.

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Mike McKillop

Mike McKillop is an experienced project and process engineer with more than 24 years manufacturing experience in new process implementation and validation—improving design and contributing lean manufacturing knowledge to increase program profitability and efficiency. Mike has worked in a number of industries, implementing automated manufacturing and packaging lines. These industries have included; Automotive, Consumer Products, Food and Beverage, Medical Devices, and Pharmaceutical.

Mike has provided project engineering services to implement serialization on existing packaging lines and has provided project management for new equipment and modification of existing equipment that performs aggregation of serialized product. This new equipment is incorporated into the existing lines, some of which also required relocation. Mike was has been responsible for developing new line layout and location and coordinating with mechanical and electrical services for the new location.

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Additional Resources

There are a number of resources available for you to get on track and provide the assurance that you’ll be able to ship your serialized products:

- CRB
- Healthcare Distribution Management Association (HDMA)
- Global Standards (GS1)
- Global Track & Trace (GTT)