MANUFACTURER DATA QUALITY

Best Practice Considerations for DSCSA

HDA
Healthcare Distribution Alliance
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About the Healthcare Distribution Alliance

The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA Research Foundation, HDA's nonprofit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues.

CONTENTS

INTRODUCTION

This document provides information for manufacturers on practices that can improve data quality which will, in turn, aid in implementation of and compliance with the Drug Supply Chain Security Act (DSCSA). The DSCSA amended the federal Food, Drug and Cosmetic Act in 2013 and by November 27, 2023, manufacturers and their wholesale distributor and dispenser trading partners must be able to send, receive and maintain data in a secure, interoperable, electronic manner each time covered prescription drugs change ownership in a covered transaction [see, e.g., 21 U.S.C. § 360eee-1(g)(a)(A)-(B)]. Ensuring that prescription drug transaction data are accurate and can be provided to and received by trading partners is a key part of the DSCSA and an important component of successful implementation is manufacturer confidence in the quality of their data.

These best practices were compiled by HDA's Exceptions Handling Work Group. The work group was convened as a forum for manufacturers and wholesale distributors to identify common pathways to handle data and product exceptions that are expected to occur when trading partners begin exchanging serialized transaction data on November 27, 2023. With resolution of some exceptions likely to be very challenging, the work group concluded that the most significant measure to prevent exceptions from arising at all was to proactively address data issues at various steps while the product is still in the possession of the manufacturer.

The manufacturers participating in the work group identified practices that helped them to accurately capture and aggregate product serialization data. Those learnings are described here for the benefit of other manufacturers seeking to provide accurate product serialization data to downstream trading partners to meet the 2023 DSCSA requirements. These considerations are not trading partner requirements, are not presented as necessary for meeting legal requirements and are not legal advice; though, where appropriate, specific DSCSA or other legal citations are noted. A trading partner must consult with its own regulatory advisors and legal counsel to decide what is appropriate and necessary for its own business.

FOUNDATIONAL ELEMENTS

- Establish a top-level, cross-functional steering committee or project team. This could be focused on the U.S. market or for all market implementations. The team could include representation from quality assurance (QA), regulatory affairs (RA), legal, operations, sites, supply chain, external supply, commercial operations and external and internal manufacturing, global serialization, product security, information technology (IT) and local market teams to ensure appropriate levels of considerations are given to team members, strategy, issues resolution and compliance.
  - Establish a cross-functional core team to align on deliverables, report progress, brainstorm on cross-functional challenges, strategies and effort.
  - Educate business leadership — what is needed, why, risks, legal requirements, what happens when it doesn't go as planned, etc.
  - Engage site leadership to assist in DSCSA product and data serialization and committed to reducing exceptions.
- Develop a master data strategy, including: material master set up; how information is communicated to downstream partners [Global Data Synchronization Network (GDSN), HDA new item form, spreadsheet]; who is responsible and accountable for ensuring the data is shared; and aligning with downstream trading partners to make sure that they have right master data [Global Trade Item Number (GTIN), Global Location Number (GLN), Global Company Prefix (GCP)].
- Consider:
  - A validation approach to equipment, systems and processes.
  - Training programs and organizational change management. Change management could consider customer complaints, quality and other key areas impacted by DSCSA-required product serialization.
  - Integration with existing customer complaint processes.
  - Establishment of a DSCSA or serialization center of excellence for larger organizations.
- Think about who is responsible for data regarding co-licensed partnerships, other alliances, mergers, acquisitions and divestitures and document that responsibility with each arrangement or contract.
  - Issues to be addressed in these scenarios may include who is responsible for responding to verification requests, who is responsible for sending EPCIS data and other matters.
  - Respective responsibilities as well as ongoing maintenance and updates may need to be documented and memorialized in an alliance contract to make sure all systems consuming the data are aligned.

MANUFACTURER INTEGRATION WITH UPSTREAM SUPPLIER PARTNERS

- Describe your company's requirements in a formal document to be shared with new suppliers as part of the business development process.
- Establish a team to manage business-to-business systems integration with suppliers.
- Integrate business-to-business onboarding with new product launch processes.
- Integrate label verification processes to ensure compliance to industry and internal labeling requirements for bundles, cases and pallets.

Note that the above items do not comprise an all-inclusive list — a company will need to talk to trading partners so that business requirements are identified, communicated and met.

MANAGING PACKAGING OPERATIONS

Manufacturers in the Exceptions Handling Work Group reported that it took considerable time and effort to ensure that their packaging operations successfully implemented DSCSA serialization and accurately captured product identifier data, including child-to-parent aggregation. The following "lessons learned" may be helpful for other manufacturers and repackagers.

- Confirm that labeling formats, barcode data and quality are accurate.
- To ensure serialization is being accomplished appropriately during packaging operations, commissioned serial numbers should be reconciled to physical product.
  - Reconciliation can be done at various points, including: CMO sites, packaging on line systems, quality release (could be singular or multiple checks), and against data repository (at whichever system level is appropriate). Importantly, working group manufacturers reported value in frequent checks at appropriate points to identify issues closer to the site of a problem.
  - Sites should ship only after confirmation of successful reconciliation.
  - As part of the batch release, the serial number data can be reconciled to the physical count to achieve 100 percent match. The supply site may decommission additional samples and damages prior to shipping from their warehouse.
  - As part of the quality release process (at internal and external supply sites), serialized data is properly notified to the manufacturer's data repository.

- U.S. pharmaceutical products are aggregated to the Serialized Shipping Container Code (SSCC) at the pallet level (saleable unit-bundle/inner pack-shipper/case-pallet). The DSCSA requires manufacturers and repackagers to serialize the lowest saleable unit and the case level only. However, where a business chooses to serialize a bundle or an inner pack (or other intermediate level of product), that product should be aggregated to the higher level of packaging and the corresponding aggregated data should be provided to downstream trading partners that match the levels of serialized product provided.
- Accomplishing EPCIS messaging between a manufacturer and its external supply site or CMO can be challenging.
  - EPCIS for an external supply site or CMO is a GS1 US chain of custody guideline that includes a shipping event.
  - There should be systems and processes to verify the EPCIS message and data on the data carriers are correct.
  - There should be systems and processes to verify the EPCIS data is correct, including manufacturing date, expiry and batch information.
  - Create a strategy to ensure what data is sent internally, whether from internal lines or CMOs, e.g., are sites sending decommissioned and commissioned data?
- DSCSA requirements should be integrated into existing customer complaint and quality processes. For example:
  - Complaint processes should be updated so that customer service personnel are trained to recognize and respond to reported serialization problems.
  - Complaint handling systems and processes should be able to capture trends and address root causes.
  - Customer service teams and sites should be able to coordinate complaint responses. Site investigation teams should have appropriate training to assist in DSCSA-related customer complaint investigations.
- Manufacturers in the Exceptions Handling Work Group looked to FDA's Data Integrity and Compliance With Drug CGMP Questions and Answers for guidance. A determination should be made, after consultation with regulatory and legal advisors, on the extent to which FDA's GMP requirements and data integrity guidelines apply to a company's DSCSA product serialization data. Examples of potential compliance requirements include maintaining the raw data at the site for six years and a program to verify audit trail information on a schedule including meta data.

INVENTORY MANAGEMENT TEAM

Manufacturers in the Exceptions Handling Work Group reported on how they engaged their inventory management teams to implement DSCSA serialization to improve data quality:

- SOPs had to be enhanced to include decommissioning serial numbers for damaged/scrapped product.
- System and process enhancement to decommission/update serial number status directly from a transaction.
- Training for the inventory management team on new DSCSA systems and processes to ensure quality control processes are maintained.
- Systems, processes and training updates to control serial number statuses within the manufacturer. Noting that there may be multiple steps to this process.

DISTRIBUTION/3PL OPERATIONS

Manufacturers in the work group also identified intracompany distributions, with co-licensed partners, CMOs and packagers and third-party logistics providers as areas where data quality issues could arise.

Inbound

- Systems and processes should ensure integrity of inbound data: e.g., aggregated pallet scanned to confirm serialized data match product (quantity matched and data properly notified to the manufacturers repository). If they do not match or data have not been properly notified, the shipment should be put in quarantine and issues resolution analysis should be started to resolve the gap.
- Technical teams checking logs at least daily may ensure inbound files are being processed without error. This practice is particularly relevant and useful for inbound CMO shipments. Technical teams should aspire to automate checks/alerts when errors occur.
- Development of data quality metrics for inbound shipments is recommended. These metrics could then be included in supplier relationship manager scorecard reviews. There also should be a process for providing feedback to identify trends and address.
- The EPCIS event file should be sent with a shipping event so the product can be accepted in the manufacturer's distribution center and 3PL in a timely manner.

- Training the business teams who manage the relationship with the CMO in the importance of data quality and FDA compliance requirements will help to identify errors and communicate back to the CMO.
- Establish systems and processes around how exceptions will be handled and resolved.

Outbound

- Systems and process should be in place in place to ensure data integrity and shipment accuracy (e.g., during the pick process, verify scanned data against data in a manufacturer's repository). Physical quantities are reconciled to serialized data for shipments, prior to generating TI/TS data to customers. Checks here to ensure physical quantity shipped using Enterprise Resource Planning (ERP) system match the data generated by the serialization data repository.
- Technical teams check logs timely to ensure outbound files are being sent or systems are built to alert for exceptions.
- Technical teams should quickly address/resolve any outbound file failures in advance of the physical product being received by downstream trading partner.
- Systems and processes also should address how to make and document serial number status changes or decommissioning that may occur, such as for damaged product, sampled product, expired product, donated product, exported U.S.-labeled product, or product to be destroyed.
- Scan product to build a shipping event and reconciliation of the items in the event.
- Consideration should be given to establishing systems and processes that will permit and document warehouse personnel to manage serial number status information during the pick process.
- EPCIS event should be based on the DSCSA US GS1 Healthcare Implementation Guideline for the TI/TS.
- Sending TI/TS for aggregated product and TI/TS for serialized product during the transition between now and when serialized data is legally required in 2023.
- All EPCIS messages should be maintained for at least six years (based on last transaction date) in appropriate, secure systems that can be accessed in response to appropriate requests (e.g., an FDA inspection or audit).
- The EDI 856 Advance Ship Notice (ASN) will continue to be sent after November 27, 2023. However, this standard ASN will be for logistics purposes only and may exclude DSCSA required elements.
- Systems and processes should be able to identify and document product serial numbers for certain depositions (e.g. stolen or lost products).
- Establish systems and processes around how exceptions will be handled and resolved.

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