Drug Supply Chain Security Act (DSCSA)
Public Meeting Series

Enhanced Drug Distribution Security

December 5-6, 2017

White Oak Campus

Silver Spring, MD

Enhanced Drug Distribution Security Goals – 2023

Package level interoperable, electronic tracing of products in November 2023 is expected to provide:

- Electronic exchange of transaction information for each sale of certain prescription drugs
- Verification of product identifiers at the package level
- Prompt response to suspect and illegitimate products when found
- Improved efficiency of recalls

FDA DSCSA Public Meeting Series

Stakeholder input on strategies and issues related to the enhanced drug distribution security provisions of the DSCSA

3 public meetings

Dates	Topics
August 23, 2017	• Supply chain security in 2023 • Enhanced drug distribution security needs
December 5-6, 2017	• Electronic interoperability • Standards for data exchange • Data architecture • Aggregation and inference
February 28, 2018	• Further refinement of enhanced drug distribution security needs • Building capacity for a unit-level system

Vision of the 2023 enhanced drug distribution system

- Provide increased public health benefits
- Ensure diligence and vigilance by all trading partners
- Support FDA's compliance and enforcement efforts
- Be adaptable and flexible
- Longer term…Be compatible with the health care system and global marketplace

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Recap of August Meeting

- How will the 2023 **system and processes** protect and enhance public health?
- In what ways can the system and processes be used to **prevent, detect, and respond to suspect and illegitimate** products?
- What are the **roles** of manufacturers, wholesalers, repackagers, dispensers, FDA, and others in the 2023 systems and processes?
- Are there **opportunities for interoperability** of the 2023 system that can be leveraged within the health care system? What are the benefits and the risks?
- Where do the 2023 system and processes fit within the **global supply chain/marketplace**?
- What do we need to do to **improve the efficiency** of the supply chain?
- What do we need to do to **ensure and increase the security** of the drug distribution supply chain?

FDA Public Meeting
Enhanced Drug Distribution Security Under the Drug Supply Chain Security Act (DSCSA)
December 5-6, 2017

Agenda
Day 1: December 5, 2017

Time	Activity	Speaker/Moderator
8:00 – 9:00 am	Registration	
9:00 – 9:10 am	Welcome and Opening Remarks	Donald Ashley FDA/Center for Drug Evaluation and Research (CDER)
9:10 – 9:20 am	Goals of the Meeting	Ilisa Bernstein FDA/CDER
	Meeting Logistics	Connie Jung FDA/CDER
9:20 – 10:15 am	Standards for Data Exchange	Connie Jung FDA/CDER
	OPEN-Serialization Communication Standard – Overview	Dirk Rodgers OPEN-Serialization Communication Standard (SCS)
	Enhanced Drug Distribution Security under the DSCSA – EPCIS	Peter Sturtevant GS1 US
10:15 – 10:30 am	Break	
10:30 – 12:00 pm	Standards for Data Exchange (continued) • *Breakout Sessions* • *Large Group Discussion*	
12:00 – 1:00 pm	Lunch	
1:00 – 2:30 pm	Data Architecture	Dan Bellingham FDA/CDER
	Enhanced Drug Distribution Security under the DSCSA – GDSN	Peter Sturtevant GS1 US
	HDA Verification Router Service – Overview	Perry Fri Healthcare Distribution Alliance (HDA)
	NCPDP DSCSA Efforts	Michele Davidson National Council for Prescription Drug Programs (NCPDP)

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Day 1: December 5, 2017

Time	Activity	Speaker/Moderator
	Understanding Blockchain and DSCSA • *Breakout Sessions*	Robert Celeste Center for Supply Chain Studies
2:30 – 2:45 pm	Break	
2:45 – 3:45 pm	Data Architecture (continued) • *Large Group Discussion*	
3:45 – 4:00 pm	Closing Remarks	FDA/CDER
4:00 pm	Adjourn	

FDA Public Meeting
Enhanced Drug Distribution Security Under the Drug Supply Chain Security Act (DSCSA)
December 5-6, 2017

Agenda
Day 2: December 6, 2017

Time	Activity	Speaker/Moderator
8:00 – 9:00 am	Registration	
9:00 – 9:15 am	Opening Remarks	Ilisa Bernstein FDA/CDER
9:15 – 9:45 am	A Safer Europe Without Falsified Medicines	Lorenzo Terzi Delegation of the European Union to the United States of America
9:45 – 10:15 am	Aggregation and Inference	Abha Kundi FDA/CDER
	Aggregation: Principles, Challenges and Solutions	Adriano Fusco OPEN-SCS
	Inference – Overview	FDA/CDER
10:15 – 10:30 am	Break	
10:30 – 12:00 pm	Aggregation and Inference (continued) • *Supply Chain Sector Breakout Sessions* • *Large Group Discussion*	
12:00 – 1:00 pm	Lunch	
1:00 – 2:30 pm	2023 Scenario Exercises • *Breakout Sessions* • *Large Group Discussion*	Eleni Anagnostiadis FDA/CDER
2:30 – 2:45 pm	Break	
2:45 – 3:45 pm	Large Group Discussion (continued)	
3:45 – 4:00 pm	Closing Remarks	Ilisa Bernstein FDA/CDER
4:00 pm	Adjourn	

Key Questions For Each Session

- What requirements, guidance, answers, other information is needed from FDA?

- What should be left for B2B?

Interoperability

Revised concept of “interoperability”:

Interoperability is the ability of systems to exchange information accurately, efficiently, and consistently in a usable format.

- Assumes that interoperability will be accomplished through electronic means, resulting in “electronic interoperability”
- Keeps concept broad to allow for flexibility in determining the system and processes needed for enhanced drug distribution
- Incorporates the need for accuracy, efficiency, and consistency, which are essential for any system involving data and the exchange of data
- Let’s discuss what FDA and trading partners will need to do and/or develop to achieve electronic interoperability (particularly the sessions on standards for data exchange and data architecture)

Meeting Logistics

- Housekeeping (pre-order lunch, restrooms)
- Participants have been assigned to specific groups to ensure representation of different trading partner and stakeholders.
- Breakout Sessions:
  - Sessions will involve smaller group discussions; Group assignments are on your badge.
  - Each group will have FDA representatives as a facilitator and a scribe to aid the discussion and capture participant input.

Group1	Group2	Breakout Session in:
Groups 1 - 4	A	Great Room
Group 5	B	Room 1406
Group 6	C	Room 1408

- Information captured will be aggregated and not associated with a specific individual or company.
- Press/Media representative(s) may be in attendance and have a separate assigned table.
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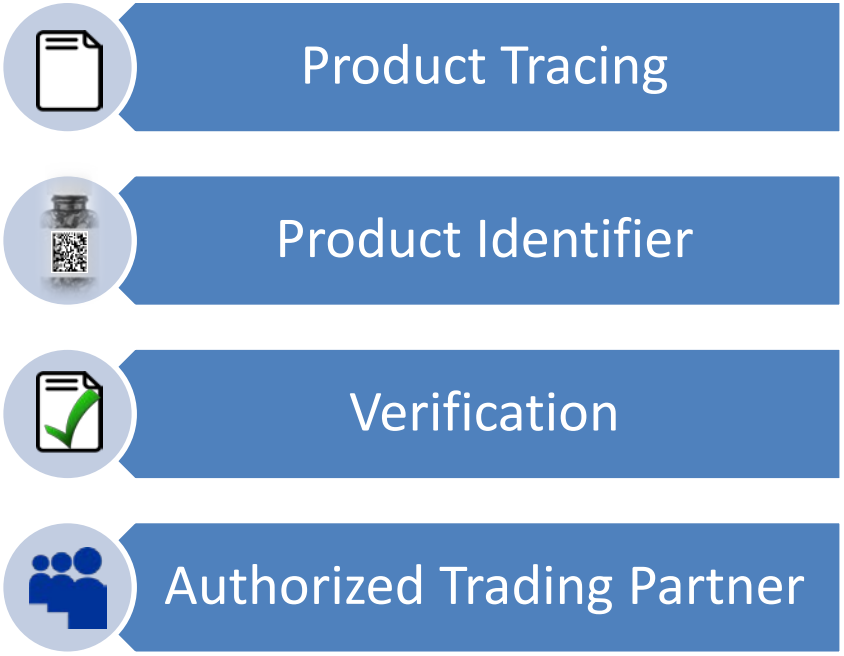
Standards for Data Exchange

Standards for enhanced requirements



Are the current standards sufficient or do they need to change?

Standards for Data Exchange

What else is needs standards?

- **Serial number management** (includes generation or commissioning, sharing, applying to product or homogenous case using a the product identifier, decommissioning)
- **Master product data** (information about the product that remains unchanged throughout distribution)
- **Product data that may change** (e.g. status of a product through the use of the product identifier, such as “destroyed” or “expired”)
- **Transaction data for transaction information and transaction statement** for product tracing and verification at the package-level
- **Trading partner information** (the minimum information to identify an authorized trading partner)
- **Transaction data for distribution history of the product**
- **Other?**

Standards for Data Exchange

Data Format	• Data should be of the same format and structure
Data Communication	• Trading partners should use the same communication protocols/standards to ensure reliable and secure data exchange
Data Interpretation	• Trading partners should use the same interpretation protocols/standards to ensure that the data and associated messages are understood in a consistent manner

All facilitate interoperability !

Standards for Data Exchange

Speakers:

- Dirk Rodgers, OPEN-Serialization Communication Standard (SCS)
- Peter Sturtevant, GS1 US

Breakout Session
Standards for Data Exchange

- What standards are needed to accomplish the change from lot-level to package-level product tracing information? Are the initial standards used for lot-level tracing are applicable to package-level product tracing?
- Are there other currently available or emerging standards that could support the secure, interoperable electronic data exchange among the pharmaceutical distribution supply chain? Do these standards comply with a form and format developed by a widely recognized international standards development organization?
- Are there standards available to facilitate:
  - the creation of a uniform process or methodology for product tracing?
  - the creation of a uniform process or methodology for verification when investigating suspect or illegitimate product?
  - protection of confidential commercial information and trade secrets?
- What are the gaps?
- What do stakeholders need from FDA in regards to standards for data exchange?

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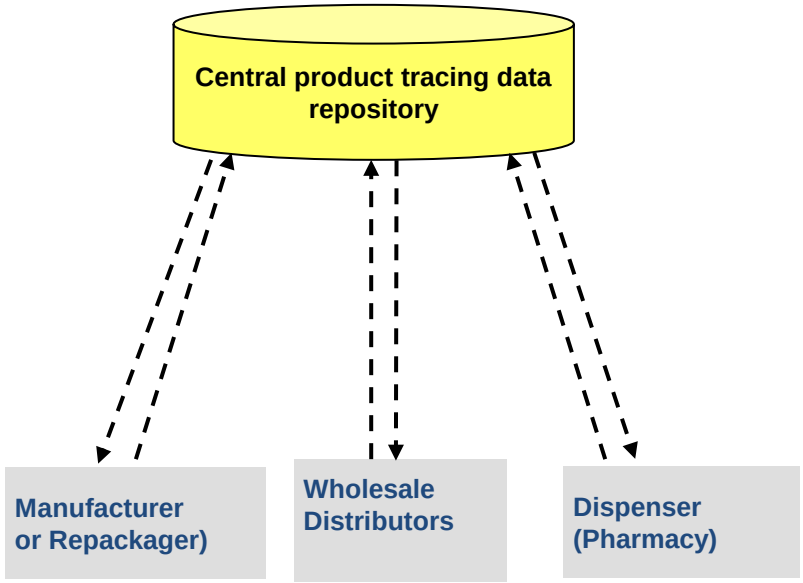
Data Architecture

- FDA's working definition for the concept of "data architecture" is:

  Data architecture is a set of rules, policies, standards and models that govern and define the type of data collected and how it is used, stored, managed and integrated within and between organizations and respective systems.

Data Architecture

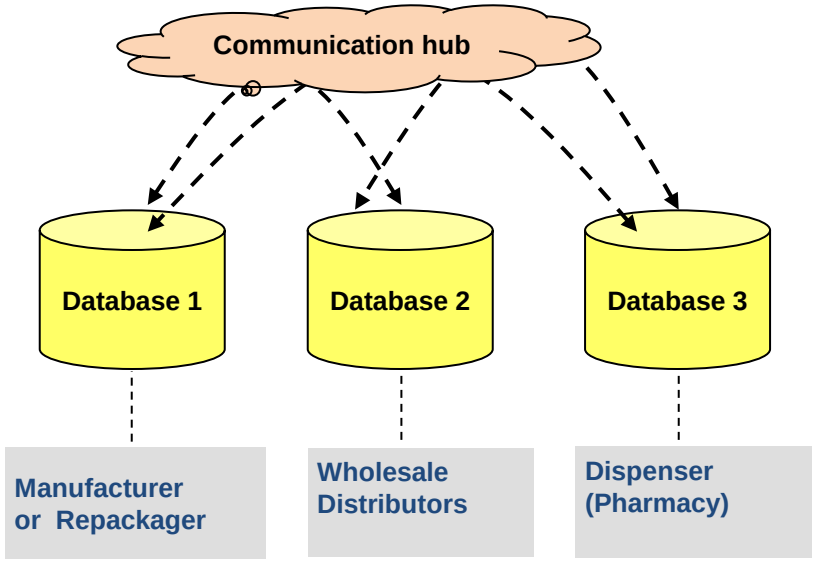
Centralized Model



Description

- Trading partners provide data into a central repository (database)
- Product tracing and verification is performed by querying the central repository

Decentralized (Distributed) Model

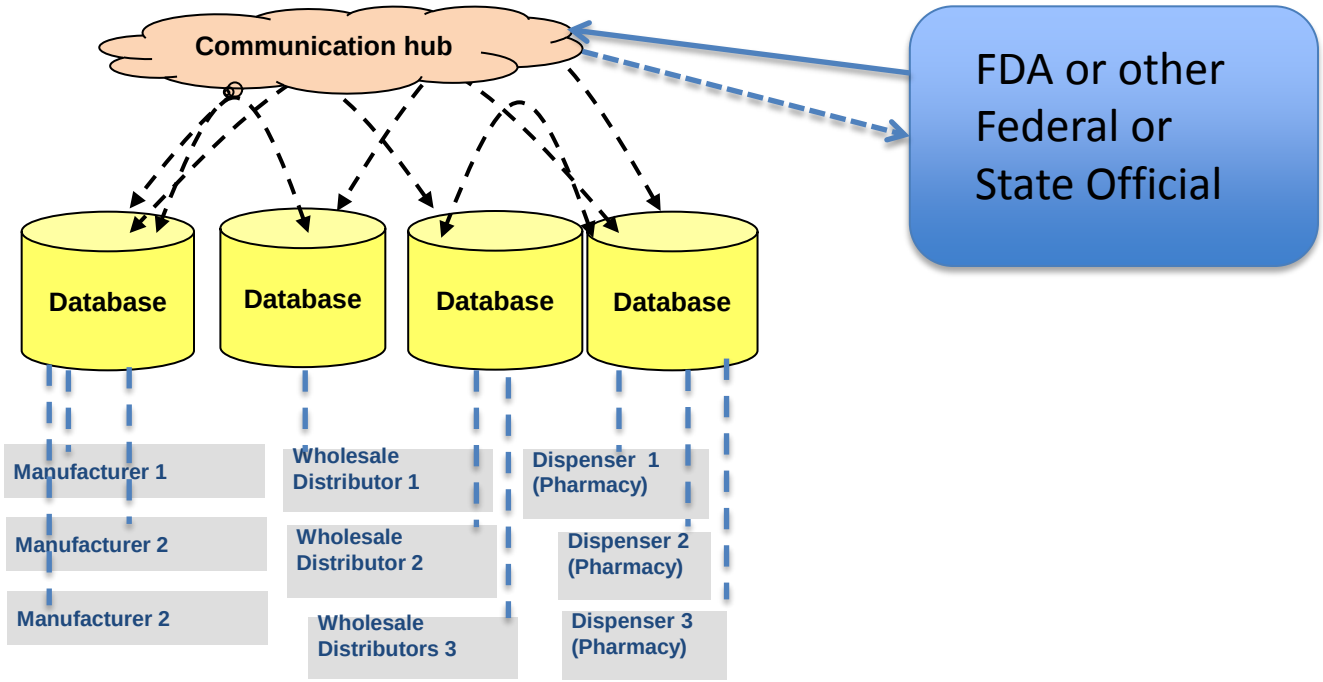


Description

- Trading partners maintain their data in their own local database or a data storage provider's database
- Product tracing and verification is performed by querying the each databases
- A communications hub connects different databases

Data Architecture

Semi - centralized (Distributed) Model (Various)



Description

- Trading partners maintain data into a few centralized databases or data storage provider(s) database(s)
- Product tracing and verification is performed by querying the each databases
- A communications hub connects different databases

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Data Architecture

- Distributed Model
  - We have heard at previous public meetings and through comments that many stakeholders prefer a distributed data architecture model, so we will be focusing on this model at the meeting. Stakeholders should plan to discuss issues related to the use of a distributed data architecture model for an electronic, interoperable system.

Data Architecture

Speakers:

- Peter Sturtevant, GS1 US
- Perry Fri, Healthcare Distribution Alliance (HDA)
- Michelle Davidson, National Council for Prescription Drug Programs (NCPDP)
- Bob Celeste, Center for Supply Chain Studies

Breakout Session
Data Architecture

How can the distributed data architecture model enable interoperability and ensure:

- the ability to exchange and use data for product tracing and verification?
- the ability to manage and maintain data, including master data?
- the ability to request and promptly obtain data to fulfill the request?
- appropriate access to the data?
- privacy, security, and integrity of the data and the system?

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How to submit comments to the docket

- Submit electronic comments to http://www.regulations.gov
- Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- All comments should be identified with the docket number FDA-2017-N-3857.
- Please note that the deadlines for submitting either electronic or written comments are 30 days after the meeting to which the comments relate.
- Stakeholder input essential and valued!