Disclaimer

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Reference herein to any specific commercial products, process, or service by trade name, trademark, manufacturer, or otherwise, does not constitute or imply its endorsement, recommendation, or favoring by the U.S. Food and Drug Administration. The views and opinions of authors should not be misconstrued as advertising products nor for endorsement purposes.
## DSCSA Pilot Project Program

### Participant Results (2)

<table>
<thead>
<tr>
<th>Program Participant/Speaker (All partnering entities are not listed)</th>
<th>Pilot Project</th>
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<td>MediLedger</td>
<td>MediLedger DSCSA Pilot</td>
</tr>
<tr>
<td>Eric Garvin</td>
<td></td>
</tr>
</tbody>
</table>

We will have a Participant Panel Q&A after the above presentations.
Small Dispenser Pilot Study

Understanding the Impact of the Current and Upcoming Track and Trace Federal Requirements on Small Dispensers

Providence Health Technologies
Introduction

Purpose

• What burden if any will small dispensers be taking with the 2013 DQSA Legislations?
• Is the supply chain ready for small dispensers to take on the above-mentioned responsibility?
• What changes/recommendations are required for the above to take place?

Partners

• Providence Health Technologies, Todd Barrett
• Hamacher Resource Group, Dawn Vogelsang
• Advasur, Randy Hoggle

Participants

• Long Term Care Pharmacies (3)
• Specialty Pharmacies (2)
• Hospital Pharmacies (2)
• Independent Retail Pharmacies (10)
Key Objectives

Small Dispensers Compliance
- Assess ability for Small Dispensers to comply with the DSCSA requirements
- Measure awareness of the DSCSA dispenser requirements among four Small Dispenser types
- Assess current state of Small Dispenser readiness for 2020 & 2023 DSCSA requirements
- Calculate associated costs to implement systems

Workflow & Best Practice
- Develop best practices model for Small Dispensers compliance
- Simulate full scale workflow in pharmacies and measure impact

Product Compliance
- Measure percent of products received at each level of serialization compliance
- Evaluate accuracy of scanned data vs ship notices
Key Outcomes

Small Dispensers Compliance

- Small dispenser pharmacies were willing and able to comply with the DSCSA requirements outlined for dispensers.
- There was no significant difference in prior DSCSA knowledge or awareness between the different dispenser types.
- The study helped dispensers gain confidence that compliance could be achieved.
- It is anticipated that our dispensers could spend over $15,000 per annum to properly scan, identify, and verify each serialized product. Extrapolating industry wide for over 67,000 dispensers, the average cost of this endeavor would be over $1 billion annually.

Workflow & Best Practice

- In developing the processes for implementation and execution of data collection for the study, we determined that it was best to standardize “Best Practices” for drug product procurement and inventory maintenance.
- Dispensers agreed to make changes that improved workflow and improved scanning efficiency. However, most pharmacies found that the scanning, and more significantly the prompts to take pictures of non-compliant drugs, created significant barriers within their workflow.
Key Outcomes

Product Compliance

• The non-compliance rate for barcodes when we began the study was reasonably high and, as predicted, improved as the study progressed. As non-serialized inventory within the supply chain was consumed, it was replaced with DSCSA compliant labeling.

• Data received via the electronic advance ship notices (ASNs) were of poor quality with many of the required data elements missing. Some products were even missing National Drug Code (NDC) records. Additionally, there were challenges in discerning whether a ship date should be present and added to the shipment notice upon transmission.

• While most manufacturers and labelers incorporated the assigned legacy NDC numbers into the Global Trade Item Number (GTIN) format, there was no assurance that this was universal, nor reliable.
**Conclusion & Recommendations**

**Continued Education**

- Make available more continuing education programs for pharmacists
- Provide detailed training and resource programs on FDA Guidance and upcoming regulations required for both dispensers and wholesale distributors
- Work with Pharmacy Associations and Trade Groups to provide educational programs describing how FDA Guidance impacts decisions for pharmacy dispensers

**Data Input & Mapping**

- Development of a GTIN to NDC crosswalk data index is imperative
- Alternatives to scanning the incoming prescription product shipments should be evaluated to meet product lot level validation

**Product Compliance**

- Encourage suppliers to provide data in an electronic format to dispenser customers
- Work with suppliers and manufacturers to standardize data elements within ASNs (EDI 856 formatted data)
Conclusions & Recommendations

1. Encourage suppliers to provide data in an electronic format to dispenser customers

2. Work with suppliers and manufacturers to standardize data elements within ASNs (EDI 856 formatted data)

3. FDA to instruct wholesale distributors that were unresponsive to requests for data submission comply by providing a way to track data submissions

4. Development of a GTIN to NDC crosswalk data index is imperative

5. Alternatives to scanning the incoming prescription product shipments should be evaluated to meet product lot level validation
DSCSA Verification to Improve Product Traceability Pilot

Participants

• Submitter Chris Chandler, PharmD and William Mosser, VP Franciscan Missionaries of our Lady (FMOL) Health System - Logistics One 12100 Little Cayman Ave Baton Rouge LA 70898
  – FMOLHS 22 Pharmacies located within our 11 hospitals and associated surgical centers, outpatient clinics, infusion centers and retail locations
  – Member of the Healthcare Transformation Group to SHARE best practices, DRIVE standards and TRANSFORM healthcare https://www.healthcaretransformationgroup.com/

• Partners
  – ConsortiEX 3rd party DSCSA Service Provider 1000 N Water St Suite 950 Milwaukee WI 53202
    • Neal Long, CEO
    • Jim Brunner, Software Engineer - EDI Implementation Specialist
  – McKesson Pharma Wholesale Distributor - 6555 State Hwy 161 Irving TX 75039
    • Scott Mooney, VP Operations - Pharmaceutical Solutions and Services
    • David Pugh, B2B Customer Integration - EDI Specialist
DSCSA Verification Pilot to Improve Product Traceability

Goals & Objectives

• Automate delivery and confirmation the Dispenser has valid T3 for each product received from trading partners to the last mile

• Capture and achieve perfect order via electronic data interchange (EDI) and automatic identification and data capture (AIDC) for a touch-less process from trading partners through pharmacy receiving areas
DSCSA Verification Pilot to Improve Product Traceability

Process Studied

• Validation via DSCSA business rules running in the background of established supply chain practices to compare wholesaler T3 (EDI 856) with the bar code scanning data captured by the Dispenser upon receipt of the shipment.

• We (FMOLHS, McKesson, ConsortiEX) acknowledge the FDA’s request for unit-level traceability, however lot and serial numbers are not electronically shared from the Wholesaler to Dispenser at this time.
DSCSA Verification to Improve Product Traceability Pilot

Evaluation Methods

• Success rate of EDI 856 shipment T3 matching EDI 861 product receipt via dispenser bar code scans; can match to EPCIS if sent by suppliers*

• Identification of data, system, or process challenges to automating validation of DSCSA transaction data requirements

• For the full intent of DSCSA to improve the recall process via a secondary objective- in future pilots to carry the traceability to the patient record at administration or dispense or final decommission via return or destruction with a mock recall as proof of concept*

*previously studied by https://www.gs1.org/docs/healthcare/12h05_Traceability_put_into_praxis_MAGER_BONE_DREES_CHANDLER_eng.pdf
DSCSA Verification to Improve Product Traceability Pilot

Timeline and Results to-date

• Pilot Team weekly calls began in April 2019
  – Testing McKesson Connect Handheld Scanner Use, Remapping EDI, Aligning data (UoM), Adding unique identifier to link/match McKesson EDI
    • From Sep 5-16th 2019 we matched all 1017 lines of T3 (EDI 856) from McKesson at one of our Medical Centers with 994 NDC Receipt scan lines (EDI 861) with a 98% match; 2% (23) T3 lines did not have a receiving scan match due to item mismatch or failed scans resulting in manual receiving via McKesson Connect software program.

• Inventory Software Enhancements *(delayed by unforeseeable disruptions in 2020)*
  – Perfect order touchless 3-way match with bar code scanning at receipt (Advance Ship Notice EDI 856 plus PO Ack EDI 855 drop shipments match pharmacy barcode scans creating Order Receipt EDI 861)
  – Push scan of DSCSA Product Identifier, Lot Number, Expiration Date and Serial Number to inventory system and point-of-care cabinets
DSCSA Verification to Improve Product Traceability Pilot

Lessons Learned - FMOLHS

• EDI process flow for perfect order in pharmacy is complex!

• Use of McKesson Connect mobile handhelds
  – Main use is currently for accounts payable processes, look to Next Gen upgrade
  – 861 Order Receipt exceptions require a process for manual T3 matching

• EDI connections for drop shipment and direct supplier T3
  – Suppliers are still not 100% electronic, sending paper and/or directed to portals
  – Drop shipments have a different invoice number and require another field to match or SNI
  – Lack of a standard listing of products exempted from providing DSCSA T3
DSCSA Verification to Improve Product Traceability Pilot

Lessons Learned – ConsortiEX and McKesson

• Manual Intervention
  — Matching required customization to EDI transactions which needs to be maintained and replicated if expanded to other trading partners
  — Products or cases when the barcode scanner is not used for receiving (drop shipments and non-McKesson orders)
  — The process occurs after product receipt and accepted into inventory versus catching suspect/missing T3s prior to receipt
  — The linear scanners do not capture Lot/Expiration to automatically add to the T3 record for search ability; future enhancements with Next Gen McKesson Connect to begin in Fall 2020.

• Future Opportunity - unforeseen circumstances delayed Phase 2 to develop a comprehensive solution:
  — Incorporate 855 Order data to proactively identify drop shipments
  — Handle all received shipments, non-EDI records and new trading partners
  — Capture Lot # and Expiration date directly from 2D barcodes on delivered drugs
  — Check for T3 at receiving and prevent inventory without valid T3
Questions?
Additional Reference Slides
# FDA Pilot Project - DSCSA Verification to Improve Product Traceability

## Phase 1

<table>
<thead>
<tr>
<th>Pharmacy Buyer</th>
<th>Distributor ERP (McKesson)</th>
<th>Distributor EDI (McKesson)</th>
<th>DSCSA Solution Provider (ConsortiEX)</th>
<th>FMOLHS Pharmacy Receiving</th>
<th>FMOLHS DSCSA Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily pharmacy order placed via Wholesale Distributor’s website</td>
<td>- Generate PO Ack to Distribution Center (DC) for product fulfillment</td>
<td>- Send PO Ack 855</td>
<td>Upload <strong>ASN 856</strong> for DSCSA T3 retention on web portal; direct &amp; drop shipment suppliers do not all send EDI; upload paper T3</td>
<td>- Scan tote label</td>
<td>- Pilot 3-way match</td>
</tr>
<tr>
<td><em>&lt;10% of orders placed directly with Manufacturers was out of scope for pilot</em></td>
<td>- Generate Invoice &amp; Advance Ship Notice (ASN)</td>
<td>- Send <strong>ASN 856</strong> mapped for DSCSA Transaction Data (T3) excluding drop shipments &amp; Invoice 810</td>
<td><em>Requires manual receipt in portal by Pharmacy receiver; who verifies T3 follows business rules including grandfathering?</em></td>
<td>- Scan NDC bar codes</td>
<td>- Order: PO Ack 855 fills drop ship gap noting pending T3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Cradle McKesson handheld generate Receiving Acceptance 861 &amp; Invoice AP520csv to Accounting</td>
<td>- Ship: ASN 856 for DSCSA T3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Receipt: Acceptance 861 from handheld scans <em>missing if manual entry</em></td>
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AmerisourceBergen & Xavier Health
2023 End-to-End Interoperability Pilot
End-to-End Interoperability Pilot

2023 Regulatory Focus

- Manufacturers, re-packagers and wholesale drug distributors shall **include product identifier** in the Transaction Information.

- Trading partners shall exchange, or share, required transactional information in a secure, **interoperable**, electronic system.

- Trading partners **shall not accept ownership of a product** unless the previous owner provides transaction information, and the transaction statement for the product.

---

**Use of GS1 Standards for Encoding Product Identifier on the product and in the transaction statement.**

**Implementation of GS1 EPCIS 1.2 standards for the exchange of Transaction Information and Statement**

**Evaluation of processes and system changes to ensure Transaction Information received.**
End-to-End Interoperability Pilot

Industry Participants

Manufacturers:
- Amag
- Apotex
- Amgen
- Eli Lilly
- EMD Serono
- Genentech
- J&J
- Mylan
- Pfizer

Distributors / 3PL:
- AmerisourceBergen
- ICS 3PL

Dispensers:
- The Chris Hospital
- Walgreens
End-to-End Interoperability Pilot

Scope of the Pilot

- Send serialized products to AmerisourceBergen.
- Transmit serialized GS1 EPCIS 1.2 files along with, or prior to, shipment of product (TI, TS exchange).

- Receive serialized products and GS1 EPCIS 1.2 files; confirm receipt of TI, TS.
- Scan & aggregate at outbound shipments.
- Build customer capabilities for DSCSA: Send GS1 EPCIS 1.2, enhance customer portal, update customer handhelds, etc.

- Receive serialized products and GS1 EPCIS 1.2 data (TI, TS) into customer solution.
- Receive serialized products & data (TI, TS) using ABC solutions.
- Implementation processes to confirm receipt of TI, TS.

~400 Products

~120 Products
End-to-End Interoperability Pilot

Tested two different dispenser processes and technologies

- **The Christ Hospital**
  - Audited 100% of all items received
  - Utilized ABC’s portal and DSCSA system to run a full TI report

- **Walgreens**
  - Sampled/Audited items via scanning Totes and/or individual items
  - Utilized third party (rfXcel) application for receiving EPCIS and auditing
End-to-End Interoperability Pilot

What were the results?

- **TI & TS (Via GS1 EPCIS)**
  - ~400 Products

- **TI & TS (Via GS1 EPCIS)**
  - ~120 Products

**Results**:

- **>18,000 Serialized Cases Shipped**
- **406 Inbound Scans**
  - 174 EA, 232 CS
  - 3 “Missing” TI*
- **736 Outbound Scans**
  - All EA
  - 239 TI Exists **
- **558 EPCIS Files Exchanged**
  - 99.8% Processed Successfully
- **232 EPCIS Files Exchanged**
  - 86% Processed Successfully
- **43 Scans**
  - 33 EA, 10 Totes
  - 6 “Missing” TI***

---

* Product arrived before data
** Product in inventory prior to pilot execution
*** 1 manually entered serial number type, 5 with mis-match expiration date.
End-to-End Interoperability Pilot

Closing Thoughts

- GS1 EPCIS 1.2 meets need for interoperable TI Exchange
  - The industry needs more robust master data sharing; and
  - The industry must test performance and capabilities on 2023 scale
- Dispensers can continue technologies that exist today
  -Wholesaler portals and tools; or
  -3rd party integrated solutions
- Barcode and data issues will stop products!
- There’s still an incremental 2023 need??
  -Promptly facilitate gathering the information
Where knowledge, reach and partnership shape healthcare delivery.
UCLA-LedgerDomain: DSCSA Solution Through Blockchain Technology

Drug Tracking, Tracing, and Verification at the Last Mile of the Pharmaceutical Supply Chain with BRUINchain

Submitter: Han-Lian William Chien, PharmD, MBA
Chief Pharmacy Officer: Josenor “Jess” DeJesus, PharmD, MBA, FACHE
Senior Supervising Dispenser: Jennifer Colon, PharmD
Prescriber: Prof. Perry B. Shieh, MD, PhD
Ronald Reagan UCLA Medical Center

Partner & Presenter: Ben Taylor, CEO, LedgerDomain

Thanking Biogen serialization team led by Bjoern Rosner, PhD as well as Imran Shakur

FDA DSCSA Pilot Project Program and Enhanced Drug Distribution Security
Public Meeting, December 2020
UCLA Health

✧ 5 facilities, >200 clinics, 600,000 unique patients yearly
✧ 300+ pharmacy staffers support three hospital pharmacies, an infusion pharmacy, two research pharmacies & five retail/specialty pharmacies
✧ UCLA partnered with LedgerDomain to build WORKING APP to apply DSCSA requirements to a large hospital pharmacy: the most complex LAST MILE

Please take a moment to thank UCLA’s COVID responders

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LedgerDomain Solution Partner

Built KitChain for Clinical Supply
Blockchain Working Group

FDA Naloxone Challenge
fda.gov/NewsEvents/PublicHealthFocus/ucm533711.htm

THE NALOXONE APP
COMPETITION

The TEAM
Hattie Chung (Lead)
Rodrigo Ipince
Emily Zhao
Sinha Banerjee
Grace C. Young

Sponsor: Ben Taylor (LedgerDomain LLC)
Submission by TeamMIT

UCLA Health

Hyperledger Fabric
Member, Hyperledger Project
Last Mile DSCSA Objectives

- Robust DSCSA checks & verification
- Flag double-counts & surface suspect transactions
- Exception handling; escalate to 3911
- Real-time inventory & quarantine at refrigerator level
- Real-time availability & verification notifications
BRUIINchain Pilot

- Scanning 2D barcodes, not “paper-pushing” (>8% error)
- Tracks changes in drug custody with guaranteed auditability and security
- Expiration flagging & suspect product quarantining
- Manufacturer verification & real-time notifications

Real data; real caregivers; life-saving medication; in real-time
Foundations for Interoperability

- DATA SCIENCE: GS1-compliant salable units
- IDENTITY: Capture entities, members & locations
- SOURCE: Relational & blockchain interoperability
- HISTORY: Audit-readiness through immutable time-stamps
- LEDGER: Real-time persistent data to query quickly & reliably

*If counterfeit duplicate scanned, must be flagged in real-time*
Last Mile DSCSA Role-based Happy Path

P2P blockchain supplemented with department & location info
Privacy & role-based privileges preserved
Last Mile DSCSA “Sad Paths”

Auditable “Sad Path” Escalates to Generation of 3911
Content, Scalability & XATP

COMPLETE DRUG CONTENT
- >100,000 drugs; >200,000 packages
- Expiration extensions & recalls
- Building block for flagging & 3911s

TRANSACTIONS ON SINGLE SERVER
- ~5Bn Rx/year = ~87 saleable units/sec
- 2024 US Target ~250 per second

Final hurdle: fading “human-in-the-loop”
Last Mile Learnings & Perspectives

LEARNINGS
- App barcode scanning 100% on iPhone
- Expiration, verification & inspection targets achieved
- Interoperating with upstream manufacturer database
- Refrigerator-level inventory tracking & soft quarantine
- Quarantine stickers & trays
- 3911 reports can be generated automatically
- >17¢/unit cost borne by dispenser (not including safety stock)

DISPENSER PERSPECTIVES
- Barcode size, quality & placement
- Quick verifications reduce safety stock
- Crisp guidance(s) for white bagging, 3911s, inspection
- Reward compliance “bottle bill”?
Resources

Peer-reviewed study in BHTY
doi.org/10.30953/bhty.v3.134

Hyperledger case study
https://www.hyperledger.org/learn/publications/ledgerdomain-case-study

XATP Pilot
xatp.io

Acknowledgements

Special thanks to UCLA Health under the leadership of CEO Johnese Spisso, including Marlon Barrios, Veronica Burwick (PharmD), Cheng Cai (PharmD), & Jacquelin Parker; and Victor Dods (PhD), Leo Alekseyev (PhD) & Ben Nichols of LedgerDomain. Grateful for Biogen’s support, from Imran Shakur and Serialization Lead Bjoern Rosner (PhD), including Steve Van Nuffel, Derry Manley, Lindy Blom & Donncha Phelan. Thanks also to Leigh Verbois (PhD), Connie Jung (PhD) & Dan Bellingham, all of FDA; Bob Celeste; and Desmond Hunt (PhD)
Pharma Enabled Blockchain Platform
FDA Pilot Overview
December 2020
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San Francisco, CA 94105
eric@chronicled.com
773-858-4998
FDA Pilot Overview
MediLedger FDA Pilot Report - Published February, 2020

Cross-industry effort to evaluate blockchain as a solution to DSCSA 2023 track and trace requirements

Manufacturers
- Pfizer
- AMGEN
- Genentech
- Novartis
- Gilead
- Hikma
- Dermira
- Lilly
- GSK
- Sanofi

Wholesalers
- McKesson
- AmerisourceBergen
- Cardinal Health
- Maxor
- Walmart
- Walgreens

Dispensers
- CHRONICLED
- GS1 US
- FedEx
- INMAR Intelligence
- Center for Supply Chain Studies

Others
# Pilot Conclusions

<table>
<thead>
<tr>
<th>Chain of custody and provenance can be assured</th>
<th>Additional supply chain benefits for participants</th>
<th>Strong adoption required</th>
<th>Interoperability standards are required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Business rules for each transaction can be enforced by blockchain smart contracts in real time, while keeping each company’s data 100% private</td>
<td>Trust established by a blockchain network can be leveraged to flag suspicious product and automate exception handling.</td>
<td>Long-term success will require strong participation and adoption from all segments of the supply chain. (manufacturers, wholesalers, dispensers, service providers, etc…)</td>
<td>Without appropriate standards, it is unlikely that disparate track and trace systems can be interoperable.</td>
</tr>
</tbody>
</table>
MediLedger
How it could work
MediLedger Basics

- Are these raw materials from the correct supplier?
- Is this product authentic?
- Was my supplier’s rebate correct?

Trusted, real-time industry-wide network to automate the way trading partners do business together.
The MediLedger Network

A secure, decentralized, peer-to-peer messaging network and blockchain network become the backbone for solutions between trading partners

Maintain total control over your private data

Proof for every update published to blockchain
DSCSA 2023: How it could work

1. GTINs managed on current systems

2. Commissioned sGTIN records published on blockchain

3. Ship product and send electronic record of transaction

4. Posts record of input transaction on blockchain

Manufacturer

Distributor

Dispenser

The MediLedger Node

Blockchain Network

- Authenticates registered trading partners as the product origin
- Validates unique product identifiers
- Allows for payment automation and rapid dispute resolution

Blockchain Interface

Peer-to-Peer Interface

Complete control over private data behind internal firewall
Appendix
FDA Pilot Report
Table of Contents
FDA Pilot Request: Drug Supply Chain Security Act, 2023
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Acronyms
Pilot Description and Report Overview
Executive summary
Working Group Approach
Guiding Principles
High Level System Requirements
Technology Solution
Solution Overview
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Standards
Exception Handling
Suspect or Stolen Product Scenarios
System Adoption
Authorized Trading Partners
Vision for Use of Blockchain
Solution Overview
Guidelines for Governance
Blockchain Interoperability
Summary/Next Steps

https://www.mediledger.com/fda-pilot-project
MediLedger FDA Pilot Report - Highlights

- Used MediLedger prototype
- Collected information via testing of this prototype and simulation of business processes
- Used staged data for testing and simulated transactions
- Explored weaknesses in the supply chain and the simulation of “bad actors”

https://www.mediledger.com/fda-pilot-project
Enable participation by all authorized trading partners

Ensure 100% privacy of data

Process 2000+ transactions/second

Manage aggregation/deaggregation and exception handling scenarios

eliminate potential for vendor lock-in
The overall vision of our work was to create a system that could confidentially track the change of ownership of prescription medicines without requiring trading partners to reveal data to each other or require a centralized system to hold the information.
MediLedger FDA Pilot Report - Highlights

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Solution Overview
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Blockchain Interoperability
Summary/Next Steps

- **Private messaging** between Clients to exchange confidential messages between Trading Partners by leveraging EPCIS technology and standards.
- **Blockchain** as a shared, immutable ledger to register the proof of the authenticity of transactions and execute smart contracts.
- **zk-SNARKs** to further enhance privacy
Next Steps
FDA Pilot Next Steps

PDG
Looking to industry direction on business requirements and expectations for interoperability

MediLedger Supply Chain Working Group
Topics will be discussed as they come up on Supply Chain Working Group

Industry dictates timing
Solution timing will depend on industry timing
Thank you!

For more info: eric@chronicled.com
# DSCSA Pilot Project Program

## Participant Results (2)

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**Participant Panel Q&A**
- Please type in your question for the panel into the chat box.
- FDA will select and direct questions to the panel.