



# 2014

HDMA EDUCATION  
TRACEABILITY WEBINAR SERIES:  
LEVERAGING EDI AND ASN FOR DSCSA

Tuesday, June 17 • 1:00 PM–2:00 PM (ET)

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## Welcome

### Perry Fri



Executive Vice President

Industry Relations, Membership and  
Education

HDMA

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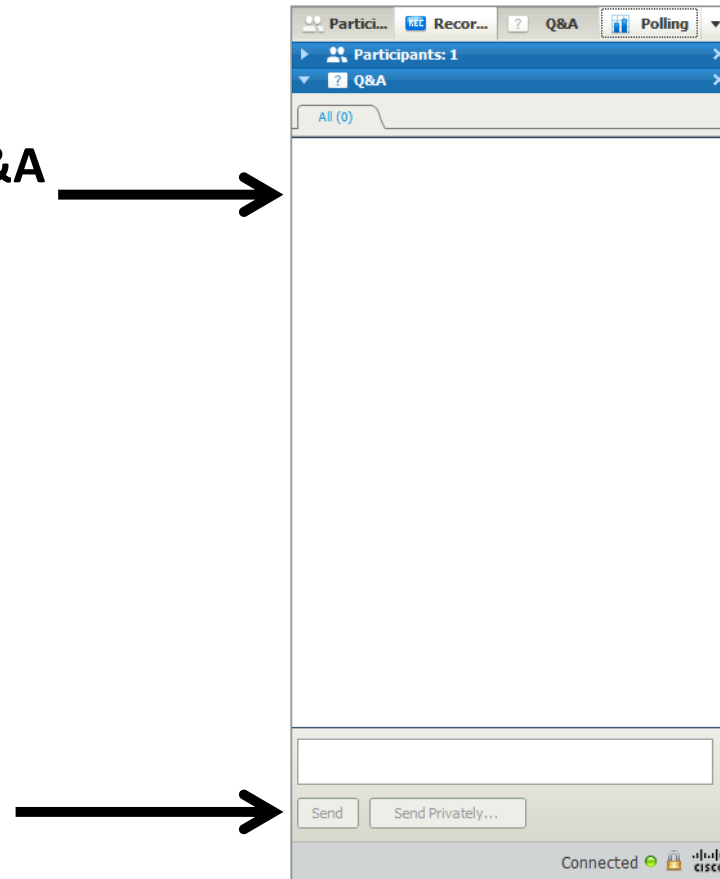
# Before we get started...

- Today's webinar is being recorded.
- All participant lines are muted.
- Presentation and audio-replay will be made available by Friday 6/20.

# Q&A: Submit Your Questions

**1** Type your question into the **Q&A** box located on the **right-hand** side of your screen.

**2** Click the **SEND** button to submit your question.



# Today's Agenda:

1. HDMA Activities Supporting DSCSA
2. EDI Guideline Update ASN 856
3. Industry Observations
4. Implementation Strategies
5. Q&A

# Presenters



**Perry Fri**, Executive Vice President,  
Industry Relations, Membership and  
Education, HDMA



**Marjorie DePuy**, Senior Director,  
Industry Relations, HDMA



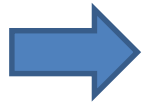
**Atif Chaughtai**, Director of Healthcare  
Solutions, Axway



**Tim Hogan**, Global Healthcare Solution  
Lead, Axway



# Supporting DSCSA



- 1. HDMA Activities Overview**
- 2. EDI Guidelines Review ASN 856**
- 3. Industry Observations**
- 4. Implementation Strategies**
- 5. Q&A**

NOVEMBER 2013  
 Congress enacts the  
 Drug Quality and Security Act



SUPPLY CHAIN MILESTONES

JANUARY 1, 2015  
 Manufacturers send and  
 distributors receive  
 TH/TI/TS + begin direct  
 purchase pedigree

JULY 1, 2015  
 Dispensers receive  
 TH/TI/TS

Federal licensure  
 standards for  
 distributors raised

Manufacturers  
 serialize product  
 (4 YEARS)

Repackagers  
 serialize  
 (5 YEARS)

Distributor  
 lot level traceability  
 (6 YEARS)

Pharmacy  
 lot level traceability  
 (7 YEARS)

Unit-level  
 traceability  
 (10 YEARS)

2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024

FDA MILESTONES

Federal distributor licensure regulations effective

NOVEMBER 27, 2015  
 National standards for wholesaler licensure issued  
 National standards issued for 3PLs  
 Waiver guidance issued for exchange of TI/TH/TS  
 Standards issued for exceptions to product identifier requirements  
 Standards issued for grandfathering product

JANUARY 1, 2015  
 Wholesaler reporting begins  
 Publicly available database of wholesale distributors  
 established by FDA

NOVEMBER 27, 2014  
 Standards published for TI/TH/TS 3PL licensure reporting begins

MAY 26, 2014  
 Guidance on suspect product and terminating notifications

KEY \_\_\_\_\_

TH – Transaction History

TI – Transaction Information

TS – Transaction Statement

# What is TI/TH/TS?

## **Transaction Information (TI):**

Proprietary or established name or names of the product;  
strength and dosage form of the product;  
NDC number of the product;  
container size;  
number of containers;  
lot number;  
date of the transaction;  
date of the shipment, if more than 24 hours after the date of the transaction;  
business name and address of the person from whom and to whom ownership is being transferred.

**Transaction History (TH):** A statement (paper or electronic), including the TI for each prior transaction going back to the manufacturer of the product.

**Transaction Statement (TS):** A statement, in paper or electronic form, that the--  
entity transferring ownership in a transaction 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;  
did not knowingly ship a suspect or illegitimate product;  
had systems and processes in place to comply with verification requirements under the law;  
did not knowingly provide false transaction information; and  
did not knowingly alter the TH

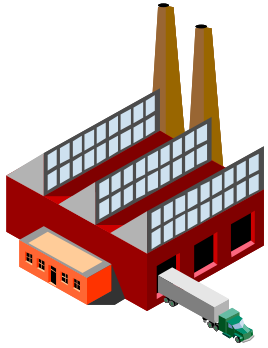
# Transaction Scenarios

## Supply Chain Product Transaction Scenarios:

- HDMA's interpretation of how physical product, product ownership, and data move between trading partners
- Each scenario includes a matrix with elements of TI, TH and TS that must be sent by trading partner identified
- Graphic depiction shows flow of product, data and ownership

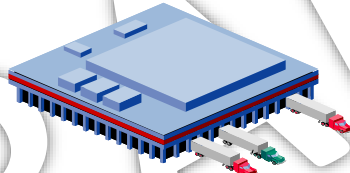
# Direct Purchase to Dispenser

Manufacturer



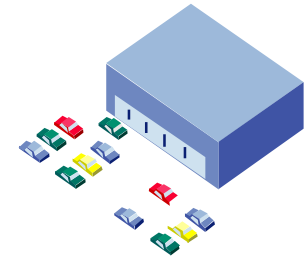
Product, Data,  
Ownership

Distributor  
(Direct Purchaser)



Product, Data,  
Ownership

Dispenser  
(including Practitioner)



# Direct Purchase Model

Transaction Information Sent	Manufacturer	Distributor
Proprietary or Established Name	✓	✓
Strength / Dosage Form	✓	✓
National Drug Code	✓	✓
Container Size	✓	✓
Number of Containers	✓	✓
Lot Number	✓	Not Required
Transaction Date	✓	✓
Date of Shipment	✓ (If >24 hr From Transaction Date)	✓ (If >24 hr From Transaction Date)
Business Name / Address of Seller	✓ Manufacturer	✓ Distributor
Business Name / Address of Buyer	✓ Distributor	✓ Dispenser

Transaction History Sent*	Manufacturer	Distributor
Number of Containers		✓ Represented in Current TI
Lot Number		Not Required
Transaction Date		Not Required
Date of Shipment		Not Required
Business Name / Address of Seller		✓ Manufacturer
Business Name / Address of Buyer		✓ Represented in Current TI

Transaction Statement Sent	Manufacturer	Distributor
✓ = Yes	✓	✓ Must include direct purchase statement

<b>Data Format</b>	Single Document; Electronic Required 11/27/17	Single Document if to Dispenser
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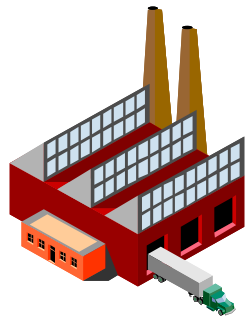
\* Proprietary/established name, strength/dosage form, NDC, and container size are static and appear in TH throughout the transmissions

# Drop Shipment – Model 1 – Manufacturer to Dispenser

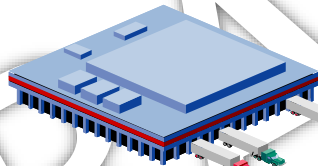
Manufacturer

Distributor

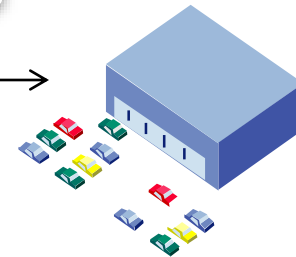
Dispenser  
(including Practitioner)



Ownership



Ownership



Product, Data

# Drop Shipment – Model 1 – Manufacturer to Dispenser

Transaction Information Sent	Manufacturer	Dispenser
Proprietary or Established Name	✓	
Strength / Dosage Form	✓	
National Drug Code	✓	
Container Size	✓	
Number of Containers	✓	
Lot Number	✓	
Transaction Date	✓	
Date of Shipment	✓ (If >24 hr From Transaction Date)	
Business Name / Address of Seller	✓ Manufacturer	
Business Name / Address of Buyer	✓ Dispenser and Distributor	

Transaction History Sent*	Manufacturer	Dispenser
Number of Containers		
Lot Number		
Transaction Date		
Date of Shipment		
Business Name / Address of Seller		
Business Name / Address of Buyer		

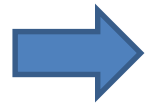
Transaction Statement Sent	Manufacturer	Dispenser
✓ = Yes	✓	

<b>Data Format</b>	Single Document; Electronic Required 11/27/17	
--------------------	---	--

\* Proprietary/established name, strength/dosage form, NDC, and container size are static and appear in TH throughout the transmissions



# Supporting DSCSA



1. **HDMA Activities Overview**
2. **EDI Guideline Update ASN 856**
3. **Industry Observations**
4. **Implementation Strategies**
5. **Q&A**

# HDMA EDI Guideline Update (04-2014)



## 856 Ship Notice/ Manifest (ASN) Changes

- Logistical purpose of transaction customized to include ownership transfer information
- Shipment level address information added for buyer and seller
- Shipment level compliance statement added
- Item level address information added to convey transaction history information

# HDMA EDI Guideline Update 2.0 (expected 07-2014)



## 856 Ship Notice/ Manifest (ASN) Changes

- Clarify Ship from/to and Sold by/to codes and usage notes
- Shipment level compliance statement edits
- Inclusion of direct purchase statement if needed

# Product Tracing – Phase I

## Transaction information (TI) – includes

- Name of the product (Item-level PID segment in 856 ASN)
- Strength and dosage form (Item-level PID segment)
- NDC (Item-level LIN segment)
- Container size (Item-level PID segment)
- Number of containers (Item-level SN1 segment)
- Lot number (Item-level LIN segment)
- Transaction date (invoice date)/shipment date\* (Shipment-level DTM segment)
- Name and address of the seller (Shipment-level N1 segment)
- Name and address of the purchaser (Shipment-level N1 segment)

**Transaction history (TH)** - paper or electronic statement that includes the transaction information for each prior transaction back to the manufacturer.  
(Which pieces of TI same as above segments, depending on scenario)

**Transaction statement (TS)** - A statement, in paper or electronic form, that the entity transferring ownership in a transaction is authorized as required under DSCSA; etc. (Shipment-level YNQ segment)

\* Needed if shipment date is more than 24 hours after date of the transaction

# HDMA EDI Guideline Update (04-2014)

## 856

### Ship Notice/Manifest




POS	ID	NAME	REQ	USE/REPEAT	USAGE
010	ST	Transaction Set Header	M	1	
020	BSN	Beginning Segment for Ship Notice	M	1	
010	HL	<b>Shipment Level</b>	M	200000	
010	HL	Hierarchical Level	M	1	
110	TD1	Carrier Details (Quantity and Weight)	O	20	
120	TD5	Carrier Details (Routing Sequence/Transit Time)	O	12	
130	TD3	Carrier Details (Equipment)	O	12	
150	REF	Reference Identification	O	>1	
200	DTM	Shipped Date	O	10	
200	DTM	Delivery Date	O	10	
220	N1	<b>N1-N3-N4-REF</b>	O	200	
220	N1	Name	M	1	
240	N3	Address Information	O	2	
250	N4	Geographic Location	O	1	
260	REF	Reference Identification	O	12	
220	N1	<b>N1-N3-N4-REF-PER</b>	O	200	
220	N1	Name	M	1	
240	N3	Address Information	O	2	
250	N4	Geographic Location	O	1	
260	REF	Reference Identification	O	12	
270	PER	Administrative Communications Contact	O	3	
335	YNQ	Yes/No Question	O	10	
010	HL	<b>Order Level</b>	M	200000	

# HDMA EDI Guideline Update (04-2014)



010	HL	<b>Item Level</b>	M	200000
010	HL	Hierarchical Level	M	1
020	LIN	Item Identification	O	1
030	SN1	Item Detail (Shipment)	O	1
070	PID	Product/Item Description	O	200
150	REF	Reference Identification	O	>1
150	REF	Reference Identification	O	>1
200	DTM	Lot Expiration Date	O	10
220	N1	<b>N1-N3-N4-REF</b>	O	200
220	N1	Name	M	1
240	N3	Address Information	O	2
250	N4	Geographic Location	O	1
260	REF	Reference Identification	O	12
010	CTT	Transaction Totals	O	1
020	SE	Transaction Set Trailer	M	1

# Agenda – Supporting DSCSA

1. HDMA Activities Overview
2. EDI Guideline Update ASN 856
-  3. Industry Observations
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# Industry Input to FDA

- **Public workshop was held on May 8<sup>th</sup> and 9<sup>th</sup>**
  - To obtain input from workshop participants on how trading partners can best comply with the requirements of DSCSA by January 1, 2015
  - Breakout sessions to discuss various options to comply with DSCSA
- **Clarification of terms**
  - **Drug Pedigree Messaging Standard (DPMS):** defines an XML data format designed specifically to satisfy pedigree requirements.
  - **EPCIS - Electronic Product Code Information Services (EPCIS):** defines a data-sharing interface about the movement and status of objects in the supply chain.
  - **Advance Ship Notice (ASN):** is an Electronic Data Interchange (EDI) transaction used to provide the receiving company with advance data on shipments.



# FDA Workshop Outcome


- The most frequently identified tools to exchange information were Electronic Data Interchange (EDI)/Advance Ship Notice (ASN), packing slips, web portals, Electronic Product Code Information Services (EPCIS), invoices, and email
- Paper is still often used to exchange information through the supply chain, and would need to be available as an option to meet the 2015 deadlines

<http://www.fda.gov/downloads/Drugs/NewsEvents/UCM399693.pdf>

# Observations

- **Participants still confused about the purpose of EDI vs. EPCIS**
- **Participants wanting to use e-mail as means of communicating but expose themselves to audit of corporate emails**
- **Participants scanning of packing slips**
- **Confusion with the elements that makeup TI, TH, TS.**
- **Exception process not defined which requires modification of TH. For instance, received damaged shipment**

# Agenda – Supporting DSCSA

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# Interoperability on January 1<sup>st</sup>, 2015

## Paper / Portal

- Minimal impact to existing systems and processes
- Likely occur by modifying packing slip or providing a customer portal

## Document Pedigree Messaging Standard (DPMS)

- Purpose built EPCGlobal standard to meet state pedigree laws
- Mature supply chain use-cases
- Paper-to-electronic
- A number of supply-chain participants own DPMS systems to meet state level pedigree laws

## HDMA ASN

- HDMA response to DSCSA
- Released Q2 2014
- Modified version of ANSI X12 ASN 856
- Expect revision to be released soon

## GS1 EPCIS 1.1/CBV

- GS1 response to lot traceability
- Released Q2 2014
- Outlines lot-level traceability using EPCIS transactions
- GS1 US Implementation Guide will align standard with DSCSA
- GS1 US Implementation Guide v1.1 is in final stages

## FDA Interoperability Guidance

- Released no later than November 27<sup>th</sup>, 2014
- Held public workshops in May
- Current RFI docket open for public comment until June 9<sup>th</sup>, 2014
- Not expected to endorse a single interoperability format

### Key Considerations:

- Trading partner's infrastructure capabilities
- Paper will exist in supply-chain on January 1<sup>st</sup>, 2015
- Integration to existing portals / website

### Key Considerations:

- Maturity of supply-chain use-cases
- Will your trading partners accept DPMS?

### Key Considerations:

- Trading partner preferences
- Migration path from lot traceability to item level serialization
- Data storage

### Key Considerations:

- Single platform for lot and item level traceability.
- Aggregation / Inference support
- Integration to business processes

### Key Considerations:

- Supply-chain can not wait for guidance to start implementation
- Reply to public comment

# Key Questions - January 1<sup>st</sup>, 2015

How can I verify the correct data is available to ship / receive?

How do I create, store, retrieve, and append transaction records?

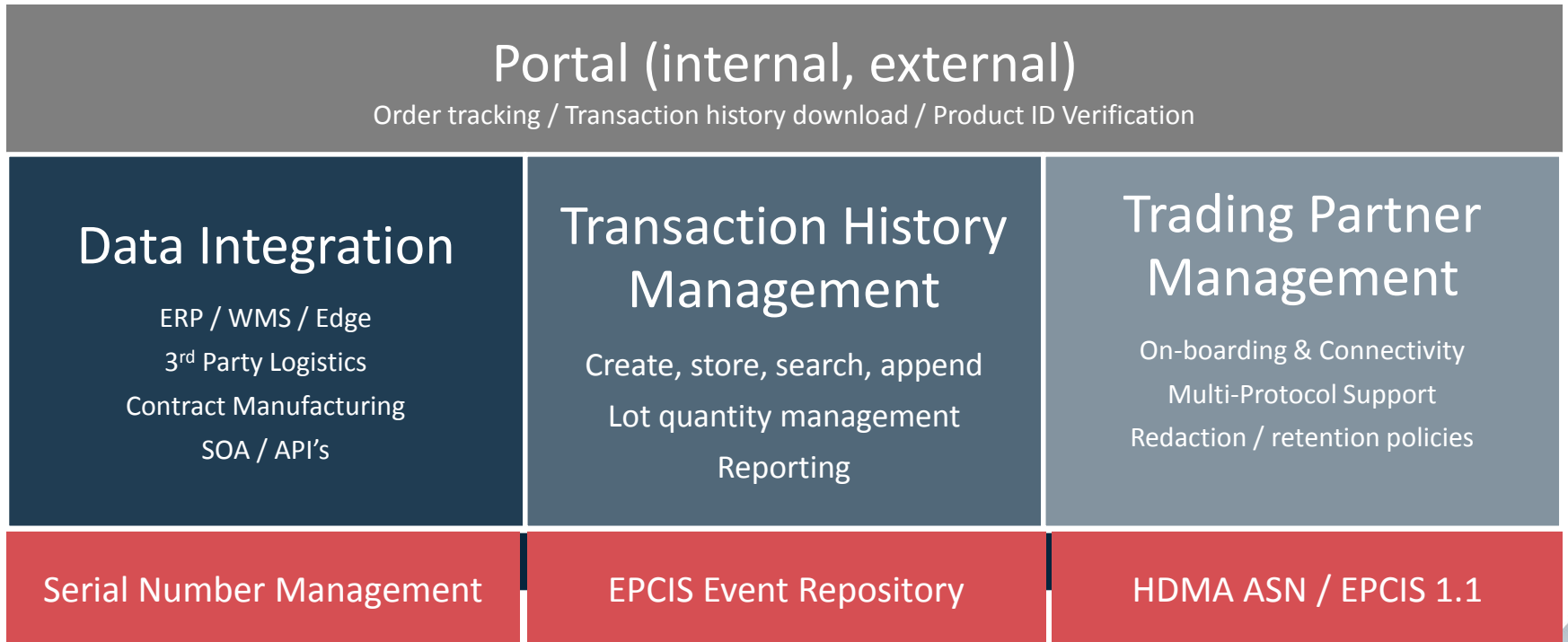
How do I correlate outbound lots with their transaction histories?

How can I prevent shipping more than received for a specific lot?

How do I provide support for non-EDI capable trading partners?

How will customer service representatives handle exceptions?

# Functional Solution Architecture



# Phased Approach To DSCSA

## Assessment

- Assess current serialization project
- Develop strategy with end-state in mind
- Harmonize on GS1 standards
- Evaluate current infrastructure
- Evaluate partner capabilities
- Identify non-regulatory opportunities

## Phase 1 –

### Lot Level Tracing

- Implement enterprise platform which supports serialized and non-serialized tracking
- Locate required attributes in backend and partner systems
- Build-out required interfaces to ERP, WMS, and partner systems
- End-to-end testing with trading partners

## Phase 2 -

### Serialization

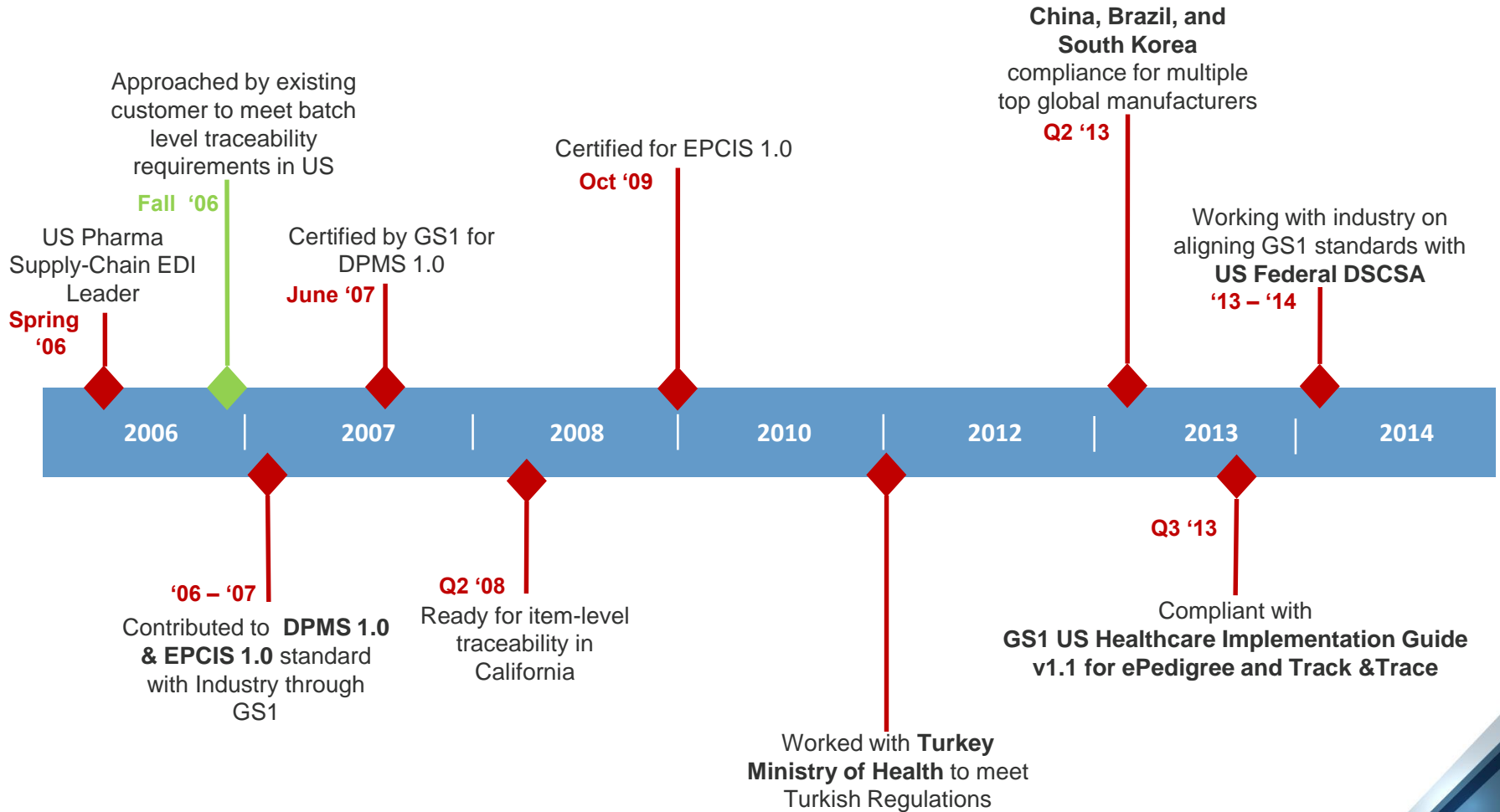
- Learn from early pilots with trading partners
- Develop enterprise serial number management strategy
- Rollout and testing of manufacturing lines / CMO's
- Rollout and testing of distribution center edge systems / 3PL's

## Phase 3 -

### Unit-Level Tracing

- Enable support for aggregation and inference
- Integration to warehouse edge systems and processes
- Advanced exception handling

# Axway Traceability History





# How does Axway help meet DSCSA Requirements?

## Product Tracing (Lot)

- Axway has 40+ in-production customers using lot level traceability
- GS1 certified, supports all EPC Global use-cases
- Supports paper-to-electronic and electronic-to-paper
- Supports paper, DPMS, ASN, and EPCIS

## Product Tracing (Unit)

- EPCIS certified event repository
- GS1 US Healthcare implementation Guide 1.0 compliant
- Mature, 3<sup>rd</sup> generation product
- Inference and aggregation support

## Serialization

- Centrally manage the generation and allocation of serial numbers in range or randomized formats
- Secure portal allowing CMO's to manually download serial numbers
- Full GS1 identifier support (SGTIN, SSCC)
- Provides web services API serial number request service

## Verification

- Out-of-the-box product verification service portal
- Provides secure, instant verification of products
- Easy integration into existing websites
- Mobile-enabled verification of transaction histories

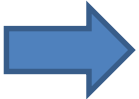
## Request for Information

- Respond within milliseconds to FDA requests for information
- Auditing of external inquiries for information
- Alerting and reporting of verification inquiries



# Agenda – Supporting DSCSA

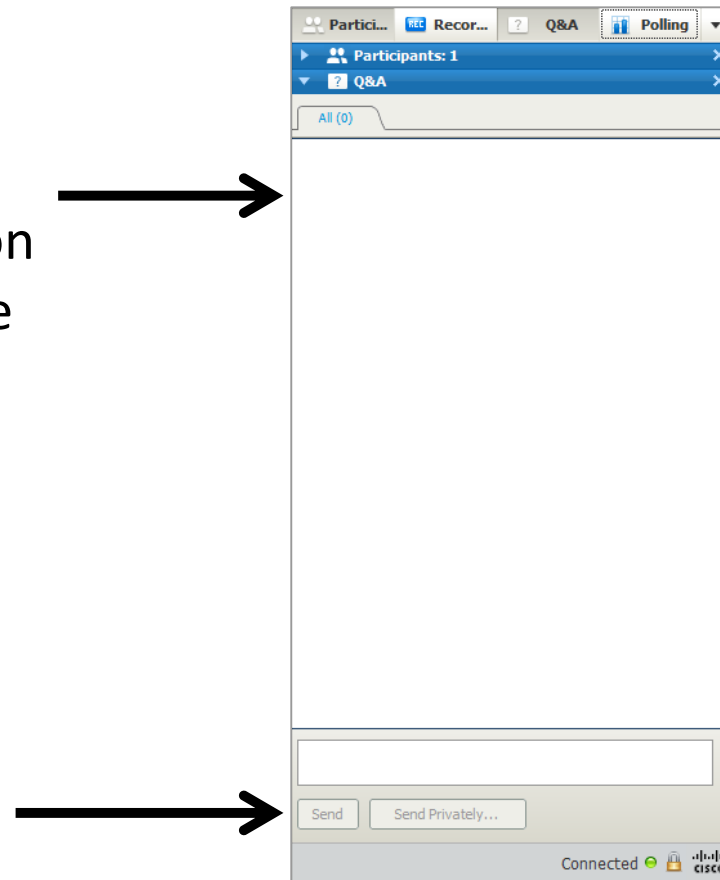
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# Q&A: Submit Your Questions

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**2** Click the **SEND** button to submit your question.



## Save the Dates . . .

- **Traceability Webinar Series: Identification of Suspect and Illegitimate Product – *Date TBA***
- **Traceability Seminar**
  - November 10-12, 2014 | Arlington, Virginia

<http://hdmanet.org/meetings/upcoming.asp>

# Additional Resources

## HDMA Resources

- Issue Overview:  
[http://www.healthcaredistribution.org/ir\\_issues/pedigree.asp](http://www.healthcaredistribution.org/ir_issues/pedigree.asp)
- Traceability Fact Sheet  
[http://hdmanet.org/press\\_room/pdf/HDMA-ToolKit-traceability.pdf](http://hdmanet.org/press_room/pdf/HDMA-ToolKit-traceability.pdf)

## FDA Resources

- DSCSA Website  
<http://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/drugsupplychainsecurityact/ucm382022.htm>

# Contact Information



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