

2023 Traceability Webinar Series

DSCSA Solutions Panel: Innovative Systems for Solving Compliance Requirements

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Exceptions and this information may not represent what is compliant. Other than recommending EPCIS for interoperable data exchange, FDA has not accepted or endorsed any particular solution for exceptions handling.

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Speakers



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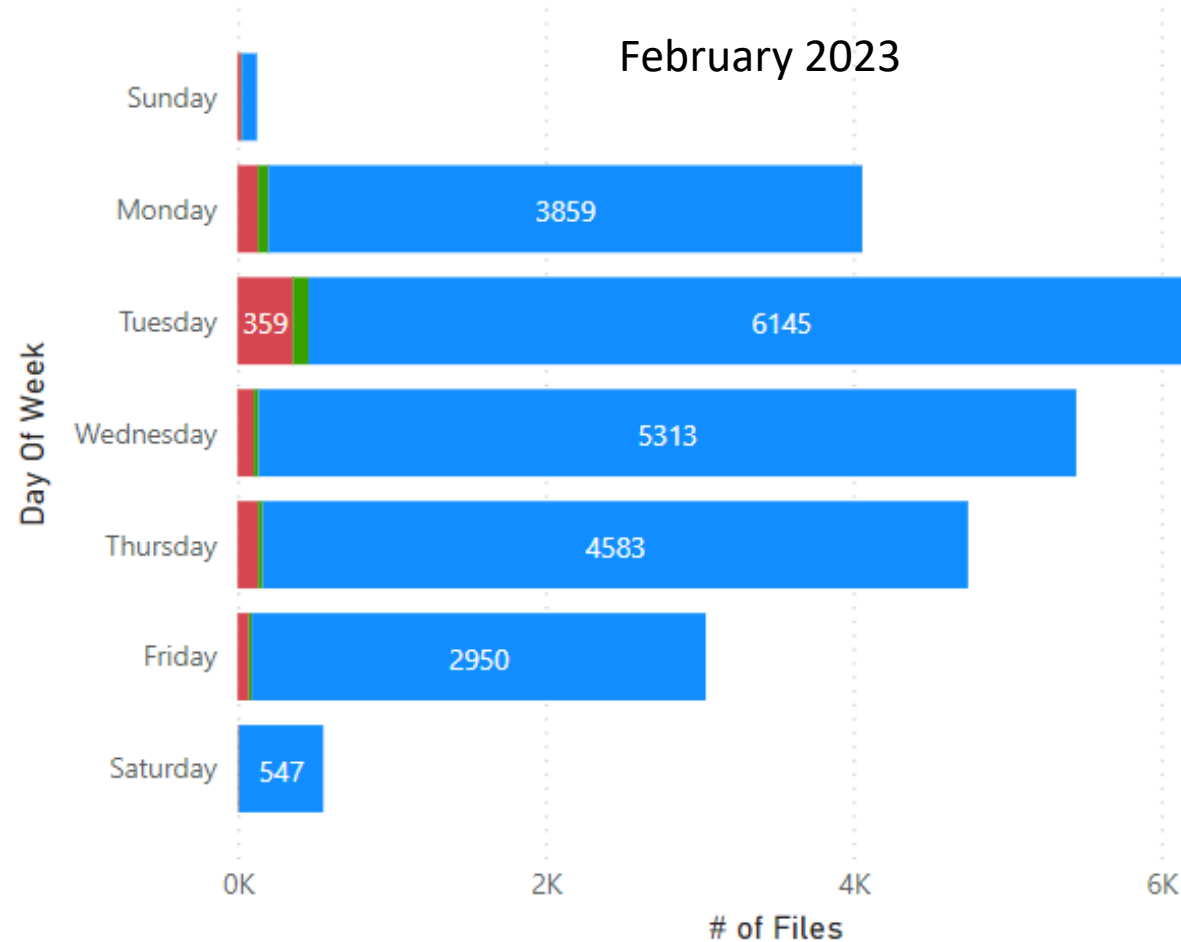
DSCSA Interoperability

- Master Data
- EPCIS Data Exchange
- Exceptions Management

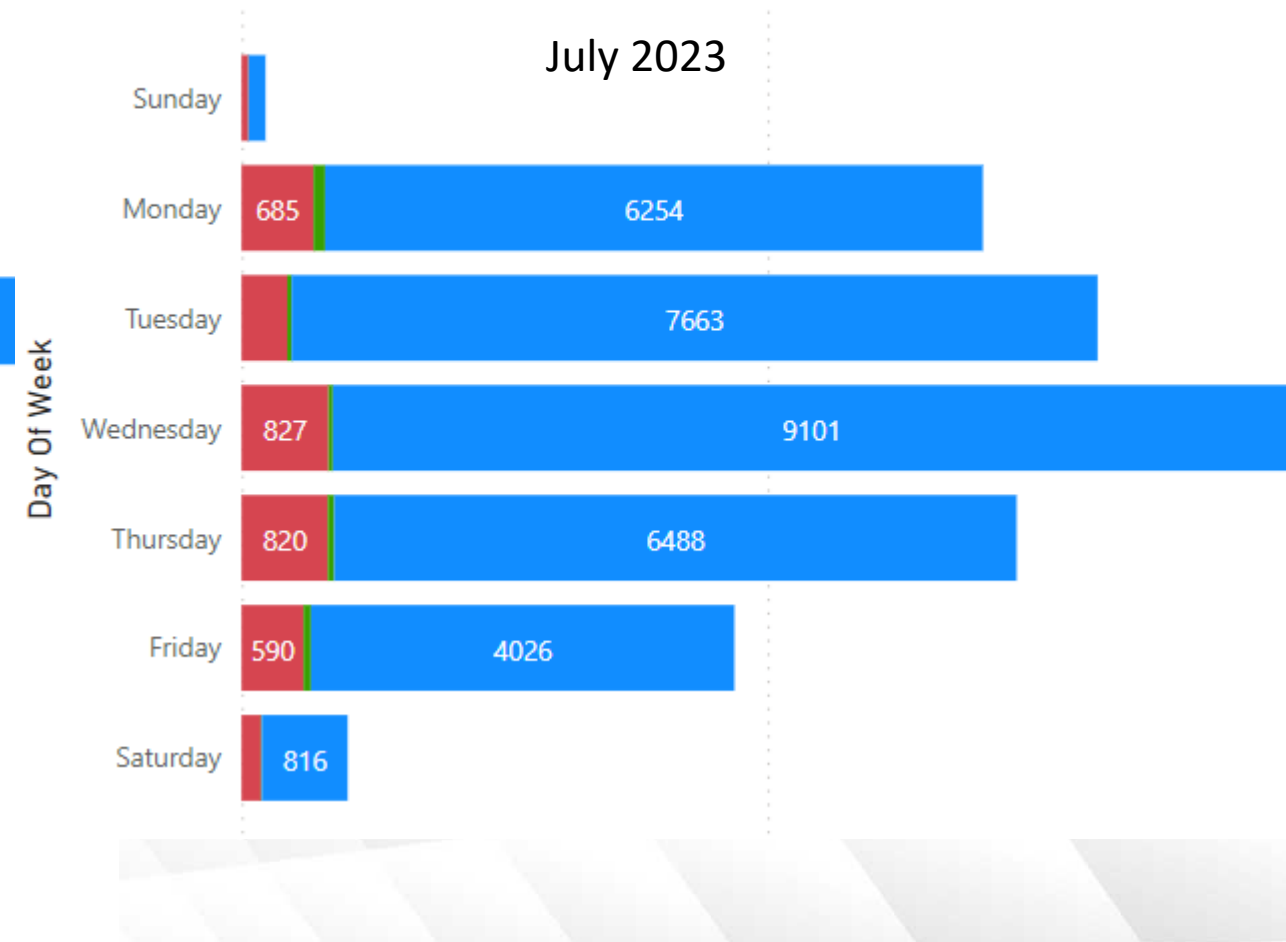
Interoperability at a glance

LSPedia Inbound EPCIS Files

File Status ● Poor ● Good ● Excellent



File Status ● Poor ● Good ● Excellent



Interoperability at a glance

LSPedia Inbound EPCIS Exceptions

February 2023

498.00

Resolution Time Median (Hours)

4M

Sum of All Unresolved Days

1

EPCIS Process Time (Median)

25K

of Files

832

of Poor Files

3.38%

Failure Rate

July 2023

76.55 ↓

Resolution Time Median (Hours)

1M ↓

Sum of All Unresolved Days

2 ↑

EPCIS Process Time (Median)

38K ↑

of Files

3608 ↑

of Poor Files

9.38% ↑

Failure Rate

Master Data Usage

Required for

- Inbound EPCIS/ASN
- Receiving
- Transfer
- Pick
- Pack
- Ship
- Outbound EPCIS/ASN

No required

- VRS

Location Master Data

- Your GLN/sGLN
- Your trading partners' GLN/sGLN

Manufacturer	Wholesaler	Dispenser
Apply for a Company Prefix	Apply for a company Prefix	Apply for a single-gln
https://my.gs1us.org/product/1024/gs1-company-prefix	https://my.gs1us.org/product/1024/gs1-company-prefix	https://my.gs1us.org/product/1366/single-gln
Select "Yes" Labeler Code, if applicable (can use corporate GLN prefix not tied to an NDC labeler code)	Select "No" Labeler Code	
Use a GLN Template	Select "1-10" Items	

GLN	GS1 Company Prefix	GLN Name	Type of Address (Sold From or Ship From)	SGLN	Address	City	State	Zip Code	Name (Point of Contact)	PoC Email	EPCIS Investigator Email	Phone (Optional)
0332822000000	0332822	Sample Pharmaceuticals Inc.	Sold From	0332822.00000.0	12345 Main Street	Pleasantville	NC	23123	John Smith	john.smith@gmail.com	ProductionTeam@gmail.com	813 234-1234

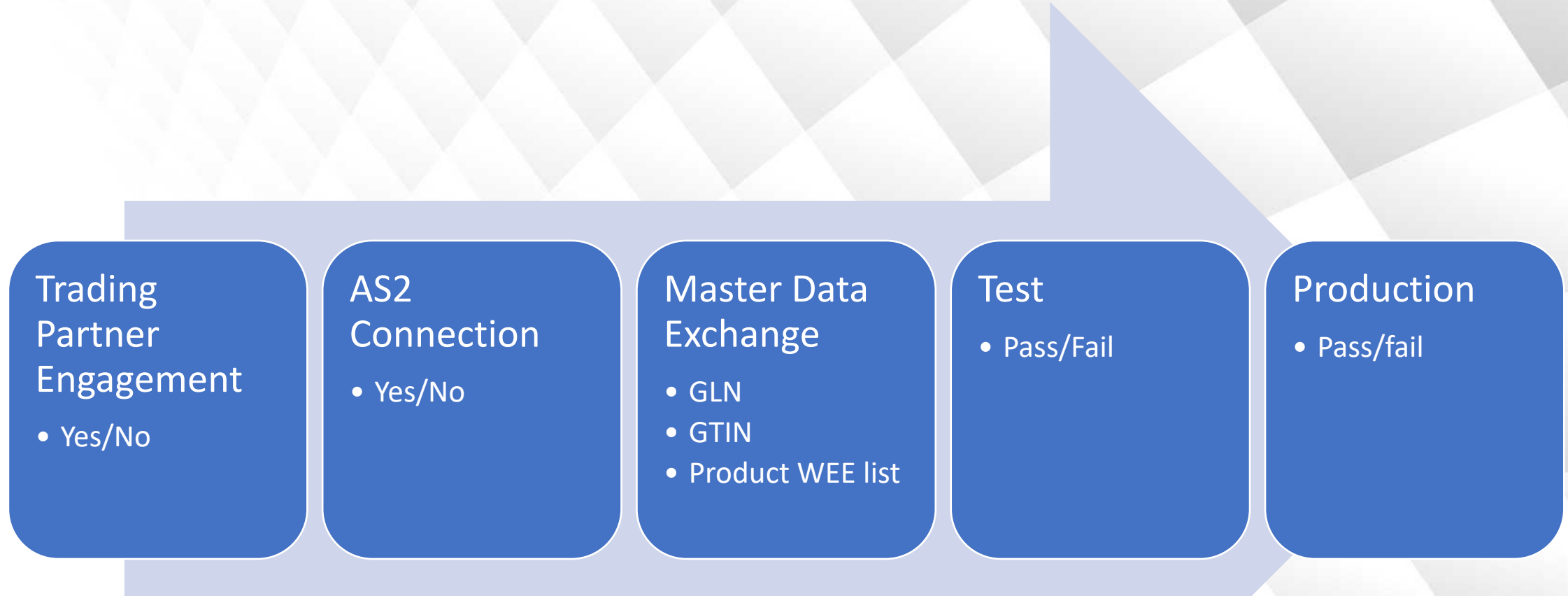
Product Master Data

- Global Trade Item Number (GTIN)
- Proprietary or established name or names of the product (Name)
- Strength and dosage form of the product (Strength)
- National Drug Code number of the product;
- Container size;

Use a GTIN Template

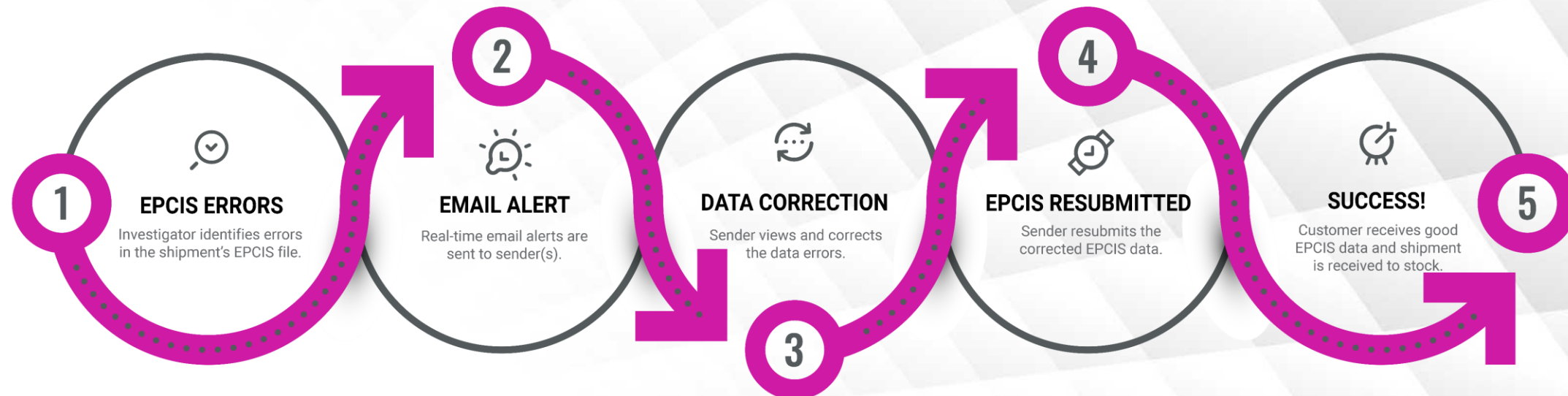
GTIN	Company Prefix	Indicator	Saleable UoM (Each, Bundle, Case, Etc)	QTY (Lowest Unit of Sale)	NDC Code (11- digit)	Drug Name / Description	Packaging Type	Dosage Form	Strength	Strength Unit Of Measure	End Point	Email (Point of Contact)	UPC
00399999401043	0399999	0	EACH	1	99999040104	Ibuprofen 300 MG 10CT	BOTTLE	TABLET	300	MG	vrs.lspedia.com	support@lspedia.com	#####
20399999401047	0399999	2	BUNDLE	6	99999040104	Ibuprofen 300 MG 10CT	BOTTLE	TABLET	300	MG	vrs.lspedia.com	support@lspedia.com	#####
30399999401044	0399999	3	CASE	72	99999040104	Ibuprofen 300 MG 10CT	BOTTLE	TABLET	300	MG	vrs.lspedia.com	support@lspedia.com	#####

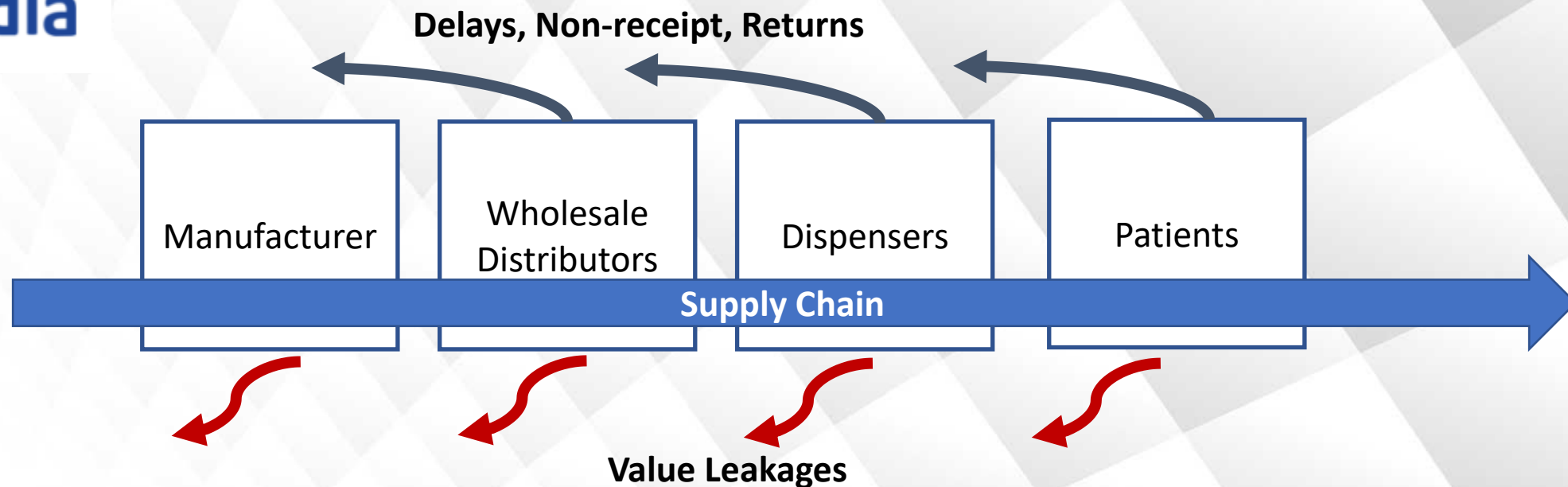
Trading Partner Onboarding Process



Exceptions Management Process

- Enhanced Supply Chain Security requirement
 - Identify exceptions
 - Notify trading partners
 - Resolve exceptions (3 days)





Problems

- Failed EPCIS data exchange leads to supply chain interruptions.
- Unresolved exceptions causing delays or non-receipt of products.
- Shipments associated with unresolved exceptions are returned to senders, leading to inefficiencies and waste.

Risks

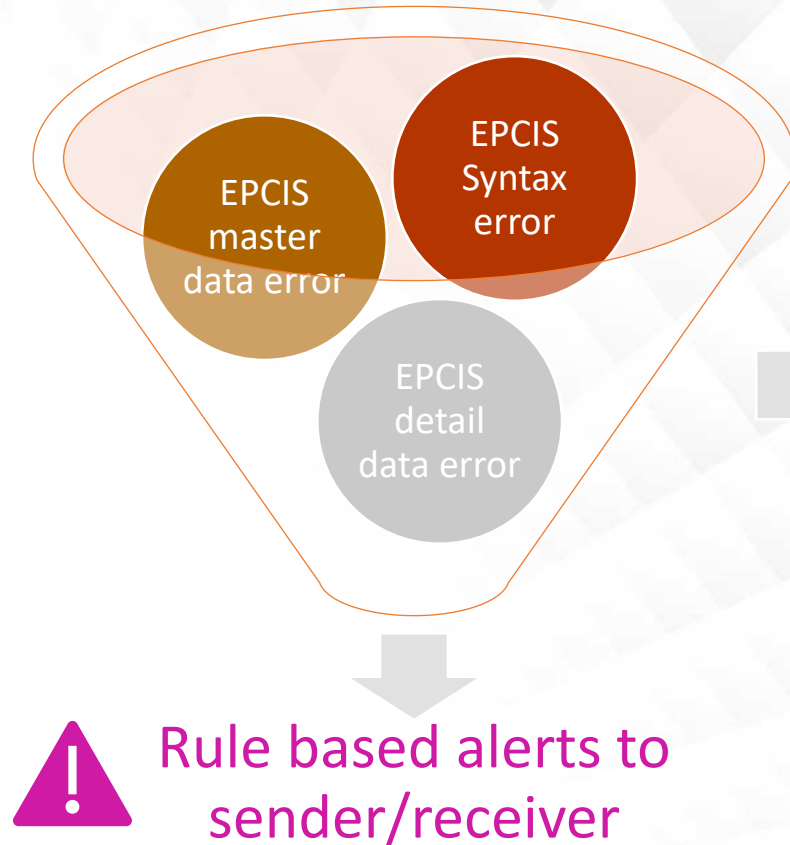
- Increased workload for both sender and receiver
- Creating inventory shortage, back order, and risk of lost business
- delays in revenue recognition, lost revenue, and increased reverse logistics

LSPedia Exceptions Pilot Takeaways

- LSPedia Exceptions Pilot from Jan. 2023 to May 2023
- Best time to catch exceptions is in the EPCIS data file itself
- Send best time is at receiving
- After receiving, Rx/Data mismatch becomes difficult to sort out

Common Exceptions

Validate EPCIS



- Syntax Errors
 - Malformed XML, whitespaces
- Semantical errors
 - Chronology issues (timestamp)
- Older versions
 - EPCIS 1.0, EPCIS 1.1
- Missing master data
 - GTINs, GLNs
- Missing key business data
 - PO
 - Aggregation events
- Late files, duplicate files...

Call To Action

1. Webinar: 2x Industry Connections & Exchange

Date: Tuesdays
Time: 1:30pm ET
Duration: 1 hour

2. Cardinal Health Investigator Onboarding for EPCIS Data Exchange On Demand

3. AmerisourceBergen Open Office
Monthly
kelly.lacy@amerisourcebergen.com

4. DSCSA General Training
[LSPedia DSCSA Training | GoToStage.com](https://www.lspedia.com/dscsa-training)

Exceptions: Life Cycle of an Exception



EPCIS Exchange

Serialized Data for Products



Exception Detected

① File Processing, ② At Receipt, ③ At Ship



Exception Investigated

① Email, ② Phone, ③ Portal



Exception Corrected

① Resend, ② Correction, ③ Return

Exceptions: Quarantine & Returns



Exceptions: An Immediate Need

*If you Design for the Extremes you
will Design for the Middle*

Scan
SELECTED



One of the Largest
Non-Profit Healthcare Provider
~**300 Pharmacies**



Scan
ALL



One of the Largest
Retail Pharmacies
~**9000 Pharmacies**

Exceptions: Pilot/POC



EPCIS Exchange
Serialized Data for Products



Exception Detected
① File Processing, ② At Receipt, ③ At Ship



NABP
National Association of
Boards of Pharmacy



Exception Investigated
① Email, ② Phone, ③ Portal



Exception Corrected
① Resend, ② Correction, ③ Return

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