LSPediA

Investigator for Exceptions Management

Investigator is the go-to exceptions management solution for the FDA's Enhanced Supply Chain Security requirement, a 2023 mandate under the Drug Supply Chain Security Act (DSCSA). It manages the errors and failures that arise from new DSCSA transactions including EPCIS and VRS. Without Investigator, supply chain exceptions that are not resolved in a timely manner present severe compliance and business risks:

- Compliance gaps – FDA's Enhanced Security requirement
- Issues and errors in the supply chain – EPCIS and VRS exceptions
- Overwhelming workload – error detection and resolution are complex and resource intensive

FDA DSCSA Enhanced Supply Chain Security

The DSCSA requires product tracing information at the package level for every trade and product verification at package level for every saleable returned drug product in 2023. The EPCIS 1.2 standard has been widely adopted by the pharmaceutical industry for product tracing information and Verification Router Service (VRS) for product verification for DSCSA implementation. To stay current and compliant, a pharmaceutical company needs the technology stack of EPCIS, VRS, and Investigator.

Why Investigator?

As pharma companies begin to add EPCIS and VRS into their daily operations, data errors are inevitable.

- The average EPCIS error rate is 36% in the Production system. [1]
- The average VRS failure rate is 44% in the Production system. [2]

Under these two categories, there are a great many different scenarios that each require different procedures, corrections, and sometimes even different personnel to manage.

By 2023, buyers will be prohibited from accepting shipments with any EPCIS errors. If EPCIS exceptions go unaddressed today, they are sure to wreak havoc on the 2023 supply chain with shipment delays, quarantines, and returns.

How does Investigator manage EPCIS exceptions?

Investigator for EPCIS is built with hundreds of GS1 data rules and complex business algorithms. It detects EPCIS errors in seconds and sends real-time alerts to the sender. The sender then follows a live hyperlink in the alert to view the errors and start their resolution process. The result is a successful EPCIS data file exchange that keeps your product moving through the supply chain.

"LSPediA brought in a methodology, a foundation so that we can built upon what we had; also, to seek solutions we may or may not thought of on our own. We have come a very long way since we engaged LSPediA in our DSCSA journey."
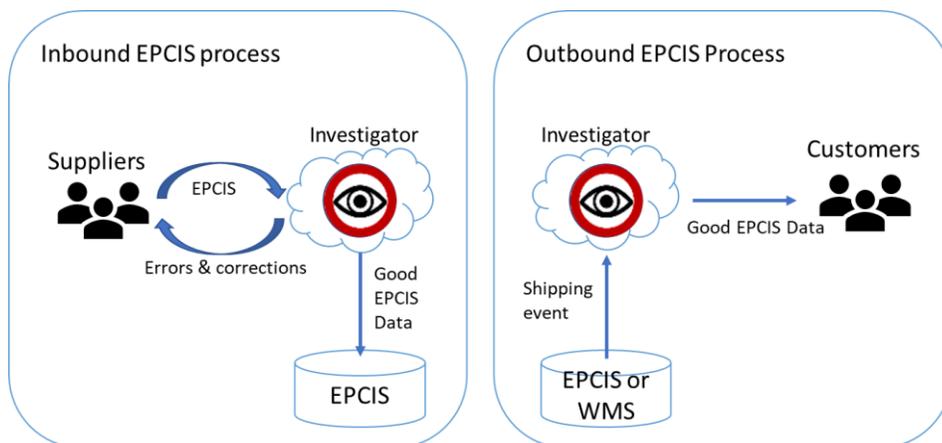
- *Joseph Barna*
CFO
Kowa Pharmaceuticals

"We feel the pain when EPCIS files are late or error out. Shipments get set aside and pile up at receiving. With our volume, it's impossible for us to check and catch errors manually. This needs to be addressed with automation and, Investigator is, in my mind, the best product out there to help with exceptions management."

- *Jeff Falardeau*
Manager, Pharmaceutical Information Technology
Cardinal Health

Shipment has EPCIS errors → Real time email alert to sender → Sender view & correct errors → Sender submits good EPCIS → Shipment received to stock

---

[1] Based on 7,720 EPCIS files processed from 20 manufacturers to 5 wholesalers in 2021
[2] Based on 57,867 verifications from 103 requestors to 49 manufacturer responders in 2021

System Architecture

Investigator can be utilized for inbound EPCIS data governance. It performs error discovery and facilitates error correction with suppliers. It delivers good data to your EPCIS system to strengthen your data quality and integrity. Similarly, for the outbound process, Investigator receives shipment events from EPCIS or WMS, generates an accurate EPCIS 1.2 data file, and sends it to downstream customers.

Who should use Investigator?

All manufacturers, wholesale distributors, 3PLs, and dispensers should use Investigator to address supply chain exceptions. Agnostic to EPCIS, VRS, ERP, and Dispensing systems, Investigator enhances your current technological repertoire by adding the exceptions management capability to your toolbox.

Benefits

The ability to meet FDA's regulatory requirement is paramount for all pharmaceutical businesses. The most successful pharma companies are committed to FDA compliance, customer service, and operational efficiency. They use Investigator for the following benefits:

- Meeting FDA's Enhanced Security requirement
- Resolving EPCIS and VRS exceptions rapidly
- Eliminating overwhelming exceptions workloads

Investigator is the perfect tool to mitigate compliance risks and solve difficult supply chain challenges.

Additional information

To learn more, visit https://www.lspedia.com/investigator/. For information about EPCIS and VRS solutions, visit https://www.lspedia.com/onescan/. For sales, please call (248)458-4367 or email sales@lspedia.com.

"Investigator is efficient, effective, and accurate. It's accurate because the system communicates the data. There are no typos, no human intervention, no human has to type anything with their eyes getting crossed as they count the zeros in the serial numbers. Investigator is really a great system for exceptions management."

-   Kelly Lacy
Product Owner
Manufacturer Operations
AmerisourceBergen

"There are challenges out there and one of the challenges is our CMOs. We reply on our CMOs and most of them are abroad. LSPediA has been instrumental in managing CMOs and getting the EPCIS data. My CEO and I placed our trust into LSPediA. I am just happy that LSPediA is in our corner because I don't have time to check EPCIS for errors. We are a small company. I wear a lot of hats.
LSPediA took a lot of burden away from us which gives me more time to generate revenue."

-   Jay Madden
Director National Accounts
ACI Healthcare