



Investigator Enhances Issue Tracking

1 DO YOU KNOW?

- a) Federal law DSCSA requires Rx verification and failed Rx verification identified, quarantined, investigated, and reported per DSCSA section 586(c)(2)(A)-(E).
- b) Investigator enables issue tracking and establishes higher supply chain security standard under DSCSA.
- c) Wholesale distributors require all manufacturers to have **Investigator starting April 2020**.

2 IF YOU SOLD RX PRODUCTS, THIS IMPACTS YOU!

- a) Wholesalers email the notification of the failed verification to manufacturers. The notification requires a direct response from the manufacturer using Investigator.
- b) All manufacturers have potential verification failures¹. The law requires manufacturers to respond to the failed verifications in 24 hours.
- c) Wholesalers disposition packages accordingly corresponding to manufacturer's response

¹ Rx fails verification for various reasons including non-GS1-standard barcoding, barcoding errors, label print quality, lack of system, system downtime, system time out, missing EPCIS data, miss-matching EPCIS data, and more.

Investigator manages all failed VRS verifications. It informs and enables manufacturers so they can research the verification failure and respond accordingly with the automated workflow.

3 ANY OF THESE CAN BE USED TO ENHANCE ISSUE TRACKING

- a) Investigator Enterprise Account
- b) Investigator Notification Account

Investigator is an interactive system that enables wholesalers and manufacturers to work together in resolving verification issues. VRS, EPCIS, QMS, ERP, and other systems are not an Investigator system. However, they can be integrated to Investigator² for an efficient and secure platform for serial data integrity.

4 WHO CAN GET INVESTIGATOR?

All manufacturers are eligible for getting Investigator.

- a) Manufacturers with any VRS system
- b) Manufacturers without a VRS system
- c) Manufacturers with any EPCIS system
- d) Manufacturers without an EPCIS system

OneScan Investigator is VRS agnostic, EPCIS agnostic, and ERP agnostic. It is available to all manufacturers. Click [here](#) to get Investigator.

5 ENTERPRISE ACCOUNT V. NOTIFICATION ACCOUNT

Enterprise account is a full license Investigator system. Notification account is a limited license system sponsored by your wholesale distributor customers requiring the manufacturers to respond to notifications.

Product Features	Enterprise Account	Notification Account
Test sandbox environment	Y	
Computer system validation with IQ, OQ, PQ	Y	
Notification of failed verifications	Y	Y
Respond to failed verifications	Y	Y
Attach records, files, pictures, screens to response	Y	Y
Respond within the notification email	Y	Y
View all notifications	Y	
Receive notification from all wholesale customers	Y	
View notification history	Y	
View response history	Y	
View investigations and history	Y	

² Please note that only Enterprise account offers integration to VRS, EPCIS, QMS, or ERP systems.

Request pictures and records from wholesalers	Y
Audit trail	Y
Initiate 3911	Y
Follow up 3911	Y
Track consultation with FDA	Y
Terminate 3911	Y
Role-based user security	Y
User management	Y

6 REGULATORY REFERENCE

Enterprise account provides full turnkey DSCSA compliance meeting all five verification requirements for manufacturers.

Manufacturer Requirement for Verification	Enterprise Account	Notification Account
582 (b)(4)(A) - Verification of Suspect Product	Y	
582 (b)(4)(B)- Verification of Illegitimate Product	Y	
582 (b)(4)(C) –Requests for Verification	Y	Y
582 (b)(4)(D)- Verification of Saleable Returned Product	Y	Y
582 (b)(4)(E) - Verification Electronic Database	Y	

Enterprise account provides full turnkey DSCSA compliance meeting all four verification requirements for wholesale distributors. Notification Account is used by manufacturers only.

Wholesale Distributor Requirement for Verification	Enterprise Account
582 (c)(4)(A) - Verification of Suspect Product	Y
582 (c)(4)(B) - Verification of Illegitimate Product	Y
582 (c)(4)(C) - Verification Electronic Database	Y
582 (c)(4)(D)- Verification of Saleable Returned Product	Y

7 PRICING

Only authorized trading partners are allowed access to Investigator. LSPediA registers every user under the governance guideline published by Healthcare Distribution Alliance. An annual registration fee applies to each registered user. A registration fee waiver is available to eligible manufacturers³.

	Enterprise Account	Notification Account
Annual registration fees per named user	\$182	\$182
Annual subscription fees	Request Quote	Free

³ The registration fee waiver program is sponsored by top US wholesale distributors. Eligible manufacturers can request the registration fee waiver after you have completed registration process. If you are eligibility, your initial registration fee will be refunded.

8 ACTION ITEMS

Complete your registration today. It's available at no cost for eligible manufacturers.

- [Register for New Enterprise Account](#)
- [Register for New Notification Account](#)

9 NEED HELP?



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