VRS as a Service

LSPediA
Life Sciences Solutions

VRS as a Service (VaaS)

Enjoying the benefit of VRS without a VRS. VaaS offering is a light footprint approach to VRS. Manufacturers can pass the EPCIS data to LSPediA to gain instant verification capability.

Upon receiving the EPCIS file, all serialized data is immediately available for downstream verifications This process is illustrated in the flow chart below:

The primary advantage offered by this service is the ability for manufacturers to support the efforts of both their wholesaler customers and themselves towards meeting FDA verification requirements in an easy, affordable, and hands-free manner via Eversana's provision of VRS as a service.

The FDA Verification Requirement for Manufacturers

The Drug Supply Chain Security Act (DSCSA), enacted on November 27, 2013 aims to help combat the threat of pharmaceutical diversion by enhancing the traceability of prescription pharmaceutical products in the U.S. One important milestone in the progress towards the 2023 deadline for full product traceability was hit on November 27, 2018 for manufacturers, and again in 2019 for wholesale distributors. The FDA's enforcement efforts regarding regulation of manufacturers are centered around two key ideas: serial verification and the potential investigation of serialized packages.

Requirement	Description	Enforcement
582 (b)(4)(A)	Manufacturer Requirement for Verification of Suspect Product	11/27/2018
582 (b)(4)(B)	Manufacturer Requirement for Verification of Illegitimate Product	11/27/2018
582 (b)(4)(C)	Manufacturer Requirement for Requests for Verification	11/27/2018
582 (b)(4)(D)	Manufacturer Requirement for Verification of Saleable Returned Product	11/27/2018
582 (b)(4)(E)	Manufacturer Requirement for Verification Electronic Database	11/27/2018

In recently published compliance policy, the FDA called manufacturers to action regarding their "verification obligations pursuant to section 582(b)(4)(C) of the FD&C Act upon receiving a request for verification from a wholesale distributor." Manufacturers need to focus quickly to address the five mandates that have already been enacted in force.

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Wholesaler Requirements

Historically, most manufacturers have considered the product verification process as a purely wholesaler-focused requirement, thereby realizing too late their own compliance liability and risk to product viability. As a result, many wholesalers who have already been driving towards compliance readiness are now demanding specific DSCSA system connections for:

- EPCIS data exchange
- Serial verification via a VRS Network
- Investigation of negative product verifications within 24 hours

As wholesalers begin activating their live VRS and EPCIS systems, manufacturers must meet them halfway to ensure supply chain continuity and prevent business disruptions.

Why LSPediA

LSPediA is a pioneer in the VRS space. OneScan meets every benchmark in functionality and exceeds sub-second response time by a wide margin. It is also the only VRS solution that has been selected by the U.S. FDA for the FDA DSCSA Pilot Program.

VaaS frees customers from the difficulty and frustration of system implementation. In this engagement, LSPediA addresses 100% of implementation efforts, allowing customers to enjoy the benefits of:

1. Turnkey FDA verification compliance for manufacturers
2. Meeting wholesaler customers' requirements

VaaS delivers significant value, surpassing any other solution on the market.

About LSPediA

LSPediA provides SaaS solutions to the pharmaceutical industry. Manufacturers, wholesale distributors, dispensers, and healthcare providers partner with LSPediA to make, move, track, verify, and protect the drug products in their care for patient safety.

LSPediA is different because our solution potential is limitless. Built with user efficiency, automation, and data security at their core, our solutions are transforming compliance and supply chain efforts. LSPediA's OneScan, RxChain, and Investigator technologies enable error-free and keyboard-free capabilities for ASN, EPCIS, VRS, issue tracking, and interoperability.

For more information about our capabilities, call +1 (248) 973-2008, email info@lspedia.com, or visit our website at www.lspedia.com.