

Axway Verification Router Service (VRS) Solution



SOLUTION BRIEF



The Axway Verification Router Service (VRS) Solution is powered by Axway's market-leading AMPLIFY™ API Management solution and Axway Decision Insight, a recognized leader in real-time analytics and data intelligence solutions, so you can be assured this is a tried and tested solution which is secure, interoperable and easily scalable and will give you full compliance today and for the future.

In accordance with the Drug Supply Chain Security Act (DSCSA), returned serialized product must be verified with the manufacturer before it can be resold by the wholesale distributor in the supply chain. On September 23, 2019, the FDA announced a delay in enforcement of this verification requirement until November 27, 2020 it should be noted that the delay only relates to the requirements that wholesale distributors verify saleable returned products prior to further distribution to comply with the requirements of section 582(c)(4)(D) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This delay in compliance policy does not relieve a manufacturer of its verification obligations pursuant to section 582(b)(4)(C) of the FD&C Act upon receiving a request for verification from a wholesale distributor. The reason for the delay was due to the volume of significant concerns received by the FDA regarding *"industry-wide readiness for implementation"* and *"complexities of building an interoperable, electronic system with the capabilities to timely and efficiently verify the large volume of saleable returned products amid immature technologies."* With Axway VRS Solution we can ensure your readiness today. We do not have the teething problems other vendors have encountered. Our solution is based on mature and proven technology that can handle thousands of transactions a second. Powered by our configurable AMPLIFY API Gateway, we provide out-of-the-box integration capabilities to your existing systems.

To verify product, distributors must determine the manufacturer and "request" them to verify that the product is authentic and still saleable (not subject to a recall). This results in a requirement for a lookup directory of manufacturers where distributors can find contact details for the right manufacturer and a verification routing solution that safely connects the verification requests with the correct manufacturer and handles the appropriate response. At Axway, we have chosen to focus our efforts on delivering the VRS capability

¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/wholesale-distributor-verification-requirement-saleable-returned-drug-product-compliance-policy>

which includes a secure gateway service and our market-leading analytics technology. Our proven technology enables the support of multiple protocols and data formats and provides flexible security and user control policies and much more – all without the need for you to change your existing solutions!

Key advantages of the Axway VRS Solution

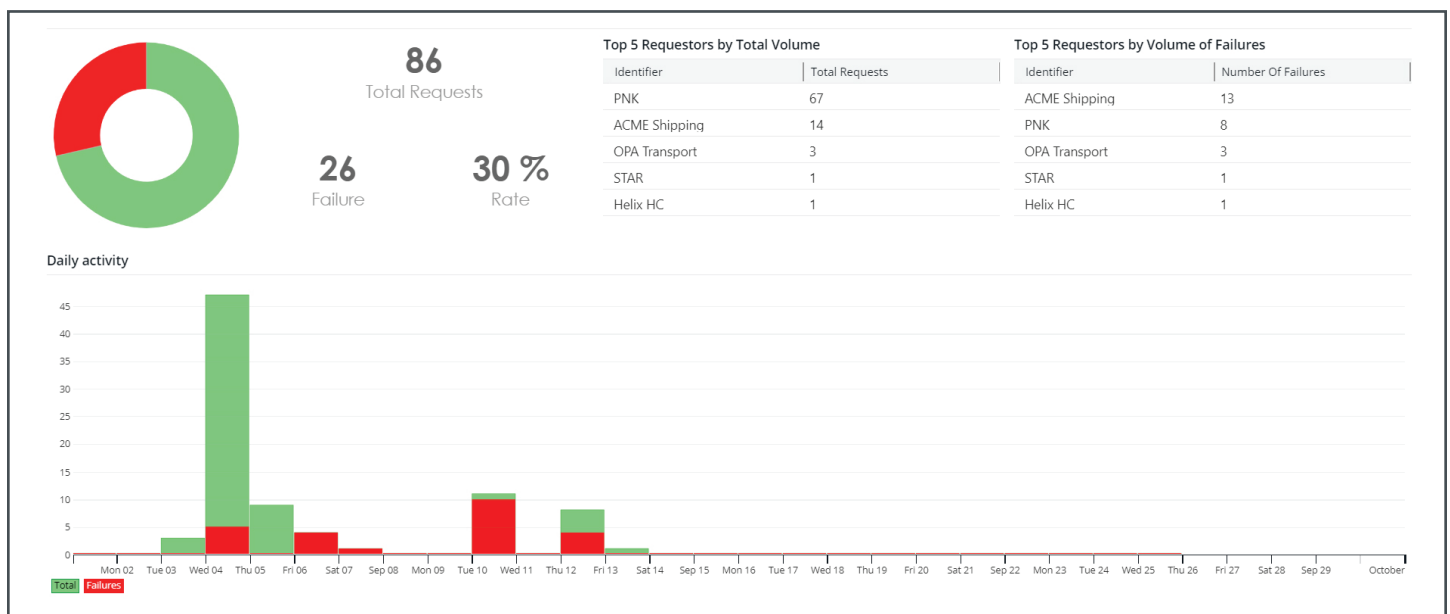
Interoperable

The Axway VRS Solution is interoperable with Axway Track & Trace or any serialization solution regardless of whether it is in the cloud or on-premises. Our open-API based VRS Solution will work with any solution providers following the GS1 VRS guidelines. With our in-built protocol and data format transformation capability we support the transformation of requests into the required format and type needed by the manufacturer.

We provide responses to verification requests at scale and from all VRS directory services and requestors. We can integrate with any Lookup Directory including blockchain or proprietary solutions and offer product update services as part of our support service package. We can configure integrations with minimal effort and no hardcoding, allowing you to keep your current solutions as they are and able to take advantage of this service immediately. With configuration templates and security and compliance policies delivered out of the box, your set-up time and cost are minimized. And as your demand changes, we can too with our auto-scaling cloud service.

Operational intelligence

User-friendly dashboards powered by Axway Decision Insight provide operational intelligence and transparency. Full reporting on Requestors and Verification Responses by type and volume. Standard dashboards include business insights such as the top Requestors by total count and those with the highest total number of negative verifications. Automatic alerts with email notifications can be implemented as required.





Security

We have taken advantage of Axway AMPLIFY API Management and provide extensive security policy management and scalability as standard. Our flexible security policies will protect your backend repository and services from security attacks and threats and can also support quality of service with quota, throttling and Requestor controls. Full logging and reporting are provided out of the box. As in all our solutions, the security policies are flexible, and we can work with you to optimize the policies for your business and security needs. Axway's strength in managing certificates, secure connections and APIs in pharmaceutical distribution is unsurpassed.

Regulatory compliance today and for the future

The Axway VRS solution is highly configurable and therefore we can immediately react to any changes in regulations, GS1 standards or in our Customer's requirements. Unlike other vendors, Axway VRS Solution is powered by proven market leading technology solutions so you can rest assured this is not a "first release" or "immature technology" offering.

Manufacturer considerations

To date, manufacturers have carried the financial and regulatory burden of compliance with DSCSA and as downstream partners begin to understand the master data management, the integration and the scale of the repository, we expect additional needs to emerge. The technology powering Axway VRS Solution provides a strong foundation and enables us to assure our customers that we can meet all future security and functional requirements that may be encountered, as well as scalability requirements if peak time issues arise and/or as volume increases with adoption.

Additionally, our solution can be configured to meet emerging international verification requirements providing our customers additional confidence in their ability to meet future compliance regulations. The Axway VRS Solution and our experienced service teams are here to support your business for the long term.

Axway VRS Solution offers advanced security, interoperability, flexibility, and operational intelligence, enabling any serialization repository to safely receive and respond to verification requests.



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