

Case Study



FDA ORA Streamlining Workflows: How SERIO is Transforming Field Work



BACKGROUND:

The Food and Drug Administration (FDA) is charged with making sure food, drugs, medical devices, cosmetics, and other products are safe and effective. One of the many offices within this regulatory body is the Office of Regulatory Affairs (ORA), consisting of, among other offices, the Office of Import Operations (OIO) which keeps a watchful eye on imported products and ensures they comply with regulations.

However, the exponential rise in imported products globally, driven by advancements in production and distribution, created a complex environment for OIO to navigate.

Amid the ever-evolving landscape of imported products, the Operational & Administrative System for Import Support (OASIS) plays a vital role in supporting the Import Operations business and ensuring a safe and compliant product environment. This system processes and determines the admissibility of FDA-regulated products entering the U.S. and its territories.

However, because it was built on legacy technology, OASIS has struggled to keep pace with the increasing demand and is in dire need of modernization.





SOLUTION:

ORA partnered with REI Systems to continue building the System for Entry Review and Import Operation (SERIO), which began as a modernization initiative. The main goal is to boost ORA field staff efficiency with advanced technology, reliable automation (where feasible), and easy integration, reducing the need to constantly expand the workforce.

Alongside the scalable and user-friendly web application, SERIO has a mobile app solution designed for installation on multiple types of devices such as tablets and smart phones.

FDA field staff at various international mail facilities across the country use the application to collect a portion of data electronically with technologies like Optical Character Recognition (OCR) and barcode scanning, even offline. When connected, the data is securely sent to the application servers.

Using Angular technology, SERIO provides a modern, scalable web and mobile app with a single team of developers. The design is beneficial to FDA, as it needs less technical expertise and has lower maintenance costs, making the application scalable, reliable, and secure.



SERIO has three components:

- SERIO Web uses Angular and a responsive design for a dynamic web interface for investigative, compliance, and international mail facility functions.
- iOS SERIO Mobility is a native iOS app built using NativeScript and Angular to provide essential functions for field operations. It can be used offline when there is no network connection, which is a significant time-saving feature for FDA Field Staff who used to take notes on paper.
- SERIO uses an Application Programming Interface (API) framework enabling seamless integration and communication with other Imports systems thereby introducing efficiencies (time-savings as well as providing a better user experience).

IMPACT:

The SERIO mobile application has significantly improved the daily work of investigators, inspectors, and warehouse workers constantly on the move. Instead of dealing with manual data entry and paper notes, they can now collect data instantly, leading to fewer mistakes and better-quality notes. Tasks can be completed more efficiently, with the ability to capture photos and record sample information and inspectional observations directly on the mobile device leading to more accurate and complete data.

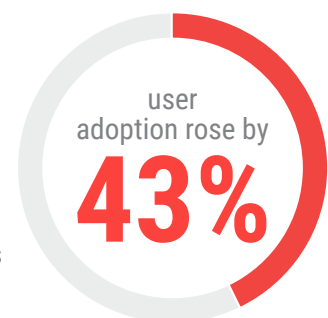


The SERIO application improves security and saves time and resources. Integration with other ORA systems streamlines processes, allowing users to access essential information with one click and avoiding multiple logins. The Single Sign-On (SSO) implementation for SERIO mobile increased user adoption, making the app more accessible and convenient for all users.

SERIO's technology simplifies the development process, resulting in faster deployments and increased productivity for developers. These benefits lead to overall cost savings for FDA.

In measurable terms, SERIO's implementation greatly improved ORA Investigations Branch field officers' performance. By integrating SERIO with other ORA systems, user adoption rose by an impressive 43%. Moreover, SERIO helped enable a 10% uptick in the number of products examined and a 9% average rise in compliance actions taken.

Finally, SERIO's enabling of quicker and more efficient import investigations means that the burden on the import trade community is reduced – helping lower costs and prices and increase the speed at which food and drugs can reach consumers. Happily, this occurs at the same time as consumer safety is better protected because the use of mobile devices offline eliminates the need to transcribe information recorded manually and allows FDA inspectors to focus better on risk and quality of manufacture as they perform inspections.



BEFORE AND AFTER SERIO:

ID	Description	Before SERIO	After SERIO	Business Benefit
1	Modern User Interface	Legacy technology, Oracle forms-based Windows application.	Angular-based single-page application, adaptive design for desktop and mobile device users.	Modern look and feel, overall improvement in user experience and application performance, reduced maintenance costs.
2	SERIO-Mobile: Unique App for FDA, allowing FDA officers to Complete Work Without Internet	This capability was not available prior to SERIO.	FDA inspectors can use iPads in the field to do their work, log the results, and then sync the data back to the SERIO database when they return to the office and have a connection.	Field inspectors can finish their work without having to manually document it, even without the internet. This reduces the need for data entry and helps prevent mistakes.
3	Certificate-based Single Sign On (SSO) Capability	Certificate-based authentication was not available.	Enables authentication through a PIV card for web users and SSO technology using certificates and tokens for mobile users.	Provides benefits such as strong security and saves time and money by eliminating the need for PIV exemptions and extra hardware costs (card readers).
4	Seamless Integration with Other Imports Applications	Partially implemented, hard to maintain	Works seamlessly with other FDA systems using standardized and reusable frameworks that are easier to maintain and grow.	Richer integration capability from multiple layers (UI, service, and data level integrations) allow users to manage the entire compliance process using multiple systems without having to log in multiple times.
5	Optical Character Recognition	This capability was not available prior to SERIO.	Integrates with Google's AI/ML APIs, allowing users to use the camera on their mobile device or uploaded images to read shipping labels.	Enhanced user experience, reduced manual data entry resulting in improved operational efficiency and fewer human errors.
6	Integration with USPS	Future implementation. This capability was not available prior to SERIO.	This will enable ORA users to scan barcodes and automatically retrieve parcel information from USPS as well as provide parcel admissibility information back to USPS.	The integration is expected to enhance user experience, reduce manual data entry, and lead to better efficiency.

In conclusion, innovative products like SERIO are vital for fulfilling FDA's mission in ways outdated legacy systems can't. Modern applications such as SERIO not only streamline processes but also deliver an improved user experience, making them indispensable tools in enhancing efficiency and ensuring the safety of the public.



The SERIO project team won the 2023 AFCEA InnovateIT Award for the IT Modernization Innovation of the Year.

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