U.S. FOOD & DRUG ADMINISTRATION

REI Systems' Long-standing FDA Partnership

Since 2018, we have provided an array of services to the Federal Drug and Food Administration (FDA) to help its mission to ensure products, from medicines to food, are safe, correctly labeled, and that their risks are clearly communicated to the public.

Our roughly 170 full-time experts support close to 30 projects. These range from modernizing systems that document violations by domestic and international entities to creating platforms for coordinating foreign inspections. We've significantly improved mission critical functions through innovative technologies and services, benefitting health of millions of Americans.

We've significantly improved mission critical functions through innovative technologies and services, positively impacting millions in public health.

Looking into the future, we are honored and privileged to help pave the way for a unified OneFDA geared towards improving health for all. We are eager to apply our Mindful Modernization® approach, which not only concentrates on the technological aspect of an enterprise modernization but also encompasses the crucial elements of people and processes.

REI Systems has already implemented aspects of Mindful Modernization within the FDA's Office of Regulatory Affairs component. We have seen much success due to the agency's passion to digitally transform for improved mission delivery. Earlier this year, the new FDA ALIS cloud-native system was honored with the FedHealthIT Disruptive Award for its significant impact on delivering product testing results faster. Additionally, the FDA SERIO mobile application was awarded the AFCEA InnovateIT Award for its contribution to propelling foreign field inspections forward.

Explore our success stories below to understand how our Mindful Modernization approach and innovative solutions have been improving public health outcomes. These examples highlight our steadfast commitment to supporting the FDA in ensuring consumer safety.

Partner Success Stories

AUTOMATED LABORATORY INFORMATION SYSTEM (ALIS)

The Office of Regulatory Affairs' (ORA) labs protect consumers from substandard products. Historically, ORA analysts compiled lab analyses into extensive paper reports, later uploaded to ORA's Compliance Management System and shared with other FDA databases.

ORA plans to build ALIS into a one-stop shop for all sample-related programs.

Recognizing the need for modernization, ORA collaborated with REI to create the cloud-based Automated Laboratory Information System (ALIS). ALIS digitalizes and automates lab data, enabling faster and more streamlined workflows.

ALIS was developed on the AWS cloud in eight months using human-centered design, agile and DevOps, a microservices architecture, and technology like AWS X-Ray that collects data about ALIS service requests to gain insight into issues and opportunities for optimization.

This new system reduces errors and speeds up testing, allowing ORA analysts to work much faster and conduct more testing with fewer errors. One ALIS user said: "The ability to generate work packages in a click of a button is great. Before, it took hours before to do this manually."

With ALIS, ORA now has a versatile tool that could eventually integrate artificial intelligence and predictive analytics. ORA plans to build ALIS into a one-stop shop for all sample-related programs. Impressively, ALIS helps get testing results information to FDA decision-makers 55% faster than was previously possible – enabling a much more rapid response when Americans' health and even lives are at risk.

AUTOMATED INVESTIGATIVE MANAGEMENT SYSTEM (AIMS)

FDA's Office of Criminal Investigations (OCI) investigates illegal actions linked to FDA-regulated products. OCI agents uncover crimes, collect evidence, and pursue legal actions. They use the Automated Investigative Management System (AIMS) to record their findings, manage investigations and analyze trends.

However the old Oracle-based system was inefficient, difficult to use, and could not be adapted to include several new and important functions.

We bolstered security, ensured accessibility, and improved system speed and reliability.

REI was tapped to develop a modern, user-friendly system. Using the low-code Appianplatform, Agile development, DevSecOps, containerization, and cloud technology compliant with FedRAMP standards, we bolstered security, ensured accessibility, and improved system efficiency and reliability. The low-code approach meant we were able to deliver the solution in record time.

Incorporating automated software testing allowed for greater innovation and quicker improvements to functionality. We transitioned data from the old systems to AIMS in phases, ensuring the current system ran seamlessly and setting the stage for an uninterrupted shift to the new platform.

Slated for a late 2024 launch, the revamped system promises improved usability. Quick data access is key for forecasting health risks tied to FDA-regulated products. This upgrade will elevate decision-making, streamline data management, refresh processes, offer improved reporting, and cut down on paper consumption. Based on early signs, we anticipate that the improved useability and quick-to adapt functionality will nearly double the number of users to more than 1,100, and that the system will help the FDA to be much more effective in supporting assertive action against "bad-actors" who produce regulated food, drugs or other FDA-regulated products.

SYSTEM FOR ENTRY REVIEW AND IMPORT OPERATION (SERIO)

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.

ORA partnered with REI Systems in building SERIO, which began as a modernization initiative to replace OASIS. 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 shipment 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.

SERIO helped enable a 10% uptick in the number of products examined.

The SERIO mobile application has significantly improved the daily work of investigators, inspectors, and warehouse workers who are 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 records to support decisions as well as regulatory and enforcement actions. 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.

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, without an increase in the number of staff.

FOREIGN INSPECTION PLANNING AND SCHEDULING SYSTEM (FIPSS)

Before inviting REI to develop a better solution, FDA relied on manual methods to organize foreign inspections, leading to inefficiencies and duplicated efforts across various products, from human food and drugs to medical devices, animal food, and cosmetics. These inefficiencies created the potential to miss inspections at high-risk sites, thus endangering consumer safety.

We automated over 90% of the application's testing, elevating the efficiency and security of the software development cycle.

Inspectors often faced costly and complex travel plans. Poor coordination with foreign officials even led to canceled inspections. Additionally, limited collaboration among FDA divisions increased travel costs and decreased the effective capacity of FDA inspectors.

To tackle these problems, REI developed the Foreign Inspection Planning and Scheduling System (FIPSS). Built on cloud-native technologies, it uses open-source .Net and Angular frameworks. With its modular microservices structure rooted in Domain Driven Design (DDD), ORA now can quickly modify business logic for a small part of the system's functionality, without any disruptions to other system segments or applications.

Together with FDA's IT teams, we revamped deployments across FDA Data Centers by automating them, improving the current CI/CD pipeline. We also refined the transfer of artifacts between data centers, eliminating the tedious MoveIT procedure.

FIPSS set a milestone as FDA's first software application to automate deployment from the development phase through testing, pre-production, and production. Additionally, we automated over 90% of the application's testing, elevating the efficiency and security of the software development cycle.

ELECTRONIC INSPECTION (ENSPECT)

FDA's Electronic Inspection (eNSpect) system is a tool for conducting inspections and investigations related to FDA regulated products, such as human and animal food, medical devices, drugs, and tobacco, with the goal of protecting public health.

REI collaborated with FDA's Office of Digital Transformation (ODT), ORA leaders, and front-line personnel to upgrade eNSpect, enabling quicker, more streamlined inspections that better assist compliance with regulations. Now, investigators can conduct inspections using tablets or laptops, even offline.

The revamped eNSpect system offers multiple benefits. It standardizes data gathering, empowering FDA to more accurately foresee health or safety risks. It also speeds up the inspection process, outpacing the older Oracle application. The user-friendly interface is so intuitive that more investigators choose to use it, saving them time on tasks like typing notes. Additionally, the new system is less burdensome for food and drug producers, as it minimizes disruptions during inspections.

This change allows FDA to tackle health challenges and regulations 75% faster.

eNSpect adopted DevSecOps and replaced the old Oracle Policy Automation tool. Now, updates roll out in less than two weeks, a sharp contrast to the former two-month cycle. This change allows FDA to tackle health challenges and regulations 75% faster.

eNSpect also provides a platform for potential future transformation using technologies such as artificial intelligence.

Our partner stories showcase how REI's collaboration with FDA has driven key improvements with the agency. Using technology, we've helped create a flexible, risk-aware approach, collaborating with FDA to adapt to changing circumstances and to learn from the successes and challenges of its experience. In essence, our deep collaboration covers technology upgrades, process enhancements, and engagement across offices and components. Our technological expertise, combined with FDA's commitment to both modern trends and existing strengths, ensures the agency gets cutting-edge solutions that will be flexible enough to meet future needs while remaining compatible with those legacy systems upon which FDA continues to rely.

About REI Systems

REI Systems offers cutting-edge tech solutions that empower missions across federal, state, local, and nonprofit sectors. Our dedicated team thrives on tackling big challenges with far-reaching impacts. We champion "Mindful Modernization®," a unique REI approach that connects our government clients' goals with tangible results by harmonizing people, processes, and technology. This ethos underpins our work in application modernization, grants management, data analytics, and advisory services.

Learn more at REIsystems.com.