



Case
Study

Safeguarding the Supply Chain of FDA-Regulated Products Using Cloud-Native Technologies

CHALLENGE:

The Food and Drug Administration (FDA) is a U.S. Department of Health and Human Services (HHS) agency that regulates clinical investigations of products under its jurisdiction, such as drugs, biological products, and medical devices. The U.S. Food and Drug Administration's Office of Regulatory Affairs (ORA) is the lead office for all agency field activities. ORA inspects regulated products and manufacturers, conducts sample analyses of regulated products, and reviews imported products offered for entry into the U.S. As the lead office for all FDA field activities, ORA professionals work in a range of program areas and locations, with 227 offices and 13 laboratories throughout the United States.



ORA's laboratories play a major role in protecting consumers from unsafe, ineffective, and mislabeled products. They provide a scientific base to support ORA enforcement and regulatory activity. The laboratories test thousands of product samples annually. The majority of the sample and regulatory analysis data are manually compiled into a cumbersome paper-based PDF report. The reports are then uploaded to a Compliance Management System (CMS) and shared between two other larger FDA databases. The first is the

Field Accomplishments & Compliance Tracking System (FACTS), a comprehensive, agency-wide, mission-critical information system that provides automated support for the daily activities conducted by ORA, and the second is the Office of Regulatory Affairs Reporting, Analysis, and Decision Support System (ORADSS), a warehouse database for multiple ORA program records and data sharing throughout FDA.

ORA was ready to start on its journey to the cloud and incorporate automation for the collection, processing, sharing, and compliance of analysis data to modernize field office operations and information sharing across the agency. ORA looked to help the Microbiology Analyst Program first by piloting a program to create a cloud-native Automated Laboratory Information System (ALIS).

SOLUTION:

REI System used its [Mindful Modernization® approach](#) of analyzing the problem holistically and then combining business expertise, best-of-bread technologies, and hyper-efficient processes to develop ALIS. We collaborated with end users and stakeholders throughout the project and took the time to understand our client's problem and implemented user design, educational sessions, frequent communications, and continuous user acceptance testing which vastly accelerated ALIS adoption and increased the productivity of the Microbiology Analyst Program.



Our solution included cloud native development, human-centered design, agile and DevOps processes, microservices architecture, and emerging technologies.

Cloud Native Application

Many of ORA's processes are unique, so REI Systems partnered with ORA to develop a completely new and custom cloud-native, web-based application on FDA's AWS GovCloud platform.

Human-Centered Design

Before any code was written, REI's Customer Experience (CX) team conducted product research via multiple interviews with what would be the systems' end users and stakeholders to document the product user requirements. The team created user personas, user stories, and storyboards to help the UX designers create the specifications for an easy-to-use and intuitive application. REI was able to design and build a scientific lab application without an REI lab subject matter expert due to its front-end examination and research of ORA's business needs and processes.

Agile and DevOps Delivery Framework

Once the CX roadmap was produced, REI applied its Agile Delivery Framework to incrementally build the business functionality of the application. A DevOps pipeline was stood up to leverage automation and continuous integration and continuous deployment (CI/CD) of capabilities.



A Jenkins DevOps pipeline was configured to build and automate blue-green deployments to AWS. The blue-green deployments created two separate and identical environments to increase application availability and reduce deployment risk. The team could do deployment any time of the day, and the end users won't notice any outage.

Microservice Architecture

ALIS is a microservice-based application with a dedicated database. The microservices are deployed in docker containers to an AWS Elastic Container Service (ECS) cluster, a logical grouping of tasks or services. ECS, a serverless architecture, was used to leverage Lambda functions to seamlessly integrate our application with another third-party system. ECS also enables cloud-native capabilities like auto-scaling, managed storage, maintenance overhead, and Infrastructure as Code, with minimal code changes.

Emerging AI Technology

The REI team implemented emerging AI technology into ALIS via AWS X-Ray. AWS X-Ray collects data about requests that ALIS application serves and provides tools to view, filter, and gain insights into that data to identify issues and opportunities for optimization. More emerging AI technology is being evaluated now for future enhancements.

IMPACT:



REI helped stand up ALIS, a completely new cloud native application in under eight months. ALIS is helping ORA with increased mission agility, flexibility, and reduced cost. Because ALIS has been so successful, ORA is planning to build it into a one-stop shop for all sample-related programs.

ALIS is the first full-stack ORA application to be stood up in an AWS GovCloud using ECS and other AWS technologies. The application helps ORA and FDA to proactively identify risks and

quickly respond to public health emergencies to safeguard our national supply chain of FDA-regulated products. ALIS digitized and automated testing analytical packages and automated sample accounting, data analysis, document control, report generation, and other lab operation functions. It also systemized record-keeping, sample tracking, and report activities. E-signatures were added to streamline processes and get reports out the door more rapidly.

ORA analysts can now work much faster and conduct more testing with fewer errors. An ALIS user said, "The ability to generate work packages in a click of a button is great. It took hours before to do this manually."

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