

Abbott Laboratories

Abbott Laboratories overcomes time-consuming application-upgrade issues by replacing its third-party digital signature software with an integrated Micro Focus® eSignature solution.



Overview

Abbott Laboratories, a \$20bn healthcare company based in Lake Bluff, Illinois, creates breakthrough products in diagnostics, medical devices, nutrition, and branded generic pharmaceuticals. The company has 94,000 employees and operates in more than 150 countries worldwide. Its portfolio of medical devices includes in-vitro diagnostics and point-of-care systems used to perform immunoassays and blood screening. The company's medical test and diagnostic instrument systems are used worldwide by hospitals, laboratories, blood banks, and physician offices to diagnose and monitor diseases such as HIV, hepatitis, cancer, heart failure, and metabolic disorders.

Challenge

As a medical device manufacturer, Abbott Laboratories faces distinct—and uniquely demanding—quality-assurance (QA) challenges. Clinicians rely on Abbott's diagnostics systems to help them understand and treat patients' medical conditions. Fast, accurate test results help clinicians quickly and correctly assess patients' medical status, which can significantly impact patient prognosis. Like all medical device manufacturers, Abbott must maintain scrupulous records on all aspects of its development, manufacturing, QA, and supply chain

processes to comply with U.S. Food and Drug Administration (FDA) and other regulations.

For these reasons, Abbott's instrument manufacturing organization has established stringent QA standards to govern all aspects of its hardware, software, and assay testing processes. Abbott leverages several integrated management systems to support its governance model. It manages requirements in IBM Rational DOORS. When it is ready to run a test, Abbott exports the requirements to Micro Focus Application Lifecycle Management (ALM), which the QA team uses to manage test cases, create and run tests, and track defects. When tests are complete, defect verification results are transmitted automatically to Serena Business Manager, which serves as Abbott's system of record and allows the QA team to track test results.

Within the medical device industry, one of the most critical QA requirements is to ensure that authorized individuals have authenticated all test results.

In the past, Abbott satisfied this requirement by supplementing ALM with third-party digital-signature software. However, this approach added unpredictability and overhead to Abbott's IT processes. Abbott lost one digital



At a Glance

- **Industry**
Healthcare and Medical
- **Location**
Chicago, IL
- **Challenge**
Meet stringent quality standards while reducing the overhead and complexity introduced by a third-party digital signature solution.
- **Products and Services**
Application Lifecycle Management
eSignature
Quality Center
- **Results**
 - + Manages QA and regulatory compliance processes
 - + Supports up to 4 major instrument development projects and 12 incremental projects per year
 - + Manages hardware verification to support a robust, end-to-end view of instrument QA processes
 - + Eliminates the need to manage and support digital-signature plug-in software

The eSignature solution allows Abbott to meet FDA requirements related to demonstrating that its testing records are authenticated and protected. And because it is an integrated solution, eSignature relieves Abbott of the overhead and unpredictability associated with managing a third-party plug-in.

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signature application when the developer got acquired by another vendor. It tried a plug-in solution next and the solution tended to create issues whenever there was an ALM upgrade. On multiple occasions, the plug-in caused pieces of the ALM interface to malfunction. In addition, installing, debugging, and validating the plug-in typically took 3-4 months to complete, and added complexity to each ALM upgrade cycle.

Then came the release of Micro Focus eSignature, a digital signature solution that is fully integrated with ALM. The eSignature solution allows Abbott to meet FDA requirements related to demonstrating that its testing records are authenticated and protected. And because it is an integrated solution, eSignature relieves Abbott of the overhead and unpredictability associated with managing a third-party plug-in.

Solution

Abbott Laboratories upgraded its digital signature solution to eSignature, which integrated with its existing ALM and Micro Focus Quality Center deployments to overcome the challenges that its former third-party solution presented.

Results

Using ALM and Quality Center, Abbott Laboratories now:

- Manages QA processes for its diagnostic instrument manufacturing organization—

including creating, running, and managing instrument software test cases, and tracking defects and test results

- Manages regulatory compliance processes while maintaining digital signatures as required by the FDA to ensure that test results are properly authenticated
- Supports 2-4 major instrument development projects per year, in addition to 10-12 incremental projects
- Manages hardware verification to support a robust, end-to-end view into its instrument QA processes, which potentially requires an increase to the ALM user base from 200 to around 400 users

ALM integrates with the eSignature solution to eliminate Abbott's need to manage and support third-party digital signature plug-in software, which formerly required Abbott to allocate IT resources for 3-4 months to install, debug, and validate the plug-in software for each ALM upgrade cycle.

In addition to software verification, Abbott has begun using ALM to manage hardware verification using the solution's native testing tools. This gives Abbott a more comprehensive, end-to-end view into its diagnostic instrument QA processes. In the future, Abbott also plans to use ALM to manage testing and results reporting of its in-house applications.