

2016 HPE Software Innovator Awards

Abhi Bansal, Abbott Laboratories

Honorable Mention

Protect Your Digital Enterprise

Enable Workplace Productivity

Software

- HPE Applications Lifecycle Management
- HPE Quality Center
- HPE eSignature

Services

- HPE Software Services

A global leader in medical diagnostics instrumentation systems uses HPE ALM to ensure its instruments meet its stringent quality standards

High-level overview

Using HPE Applications Lifecycle Management and HPE Quality Center Software, Abbott Laboratories realized the following benefits:

- Manages Quality Assurance (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 test results are properly authenticated
- Supports 2-4 major instrument development projects per year, and 10-12 incremental projects
- Now managing hardware verification to support a robust, end-to-end view into its instrument QA processes; potentially requiring an increase to the HPE ALM user base from 200 to around 400 users

HPE ALM integrates with the HPE eSignature solution to provide the following benefit:

- Eliminates the need for Abbott 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 HPE ALM upgrade cycle

Company

Abbott Laboratories, a \$20B health care company based in Lake Bluff, Illinois, has 73,000 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. These 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, and assess other health indicators.

Contact

Abhi Bansal is Manager, System Development at Abbott Laboratories.

Business goals

As a medical device manufacturer, Abbott Laboratories faces distinct—and uniquely demanding—quality 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 also maintain

scrupulous records on all aspects of its development, manufacturing, quality assurance and supply chain processes to comply with 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 HPE ALM, which the QA team uses to manage test cases, create and run tests and track defects. Once 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.

HPE Software products implemented

- HPE Applications Lifecycle Management
- HPE Quality Center
- HPE eSignature

HPE Software Services

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 HPE ALM with third-party digital signature software. However, this approach added unpredictability and overhead to Abbott's IT processes. Abbott lost one digital signature application when the developer got acquired by another

vendor. Abbott tried a plug-in solution next and it tended to create issues whenever HPE released an HPE ALM upgrade. On multiple occasions, the plug-in caused pieces of the HPE 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 HPE ALM upgrade cycle.

Then HPE Software Services developed and released HPE eSignature, a digital signature solution that is fully integrated with HPE ALM. The HPE 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, HPE-developed solution, HPE eSignature relieves Abbott of the overhead and unpredictability associated with managing a third-party plug-in.

Additional benefits

Abbott has begun using HPE ALM to manage hardware verification, in addition to the software 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 HPE ALM to manage testing and results reporting of its in-house applications.



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