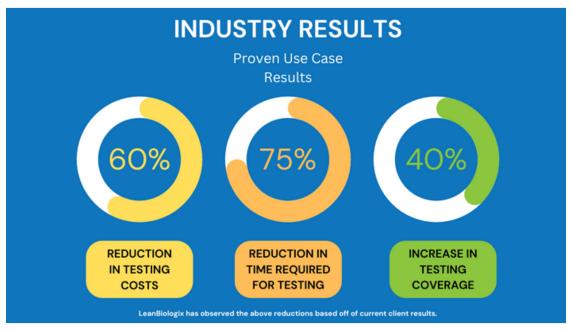
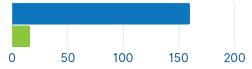
Automating the computer system validation process

Large (650M+) Medical Device Manufacturer Case Study



Results - Large (650M+) Medical Device Manufacturer

Effort Hours (yearly)



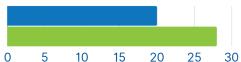
Annually there are 8-10 software patches which require risk-based regression testing. Each change takes about 40 hours including risk assessment, testing, document review and approvals.

Annual Cost (USD)



Initially the annual costs were \$40000, after automated implementation annual cost was reduced to \$16000.

Test Requirement Coverage



Test coverage went from 20 requirements run every month to 28 requirement tests run daily.

To illustrate the impact of automated testing, let's examine the following case study:

Large (650M+) Medical Device Manufacturer

- Background: Manufacturer faced challenges in validating routine monthly equipment management software updates, which was subject to regulatory requirements.
- Challenge: Manual regression testing was laborintensive and lacked full coverage due to personnel availability.
- Solution: They adopted an automated testing approach with Selenium
- Outcome: Regression testing time was cut by 90%, and test coverage increased by 40%. The automation framework ensured that all regulatory requirements were met consistently.