

QA Automation for Testing Medical Device Software

Benefits, Myths and Requirements

Automation can dramatically increase product quality, leading to lower field service, product support and liability cost. It can speed up overall development cycles and provide a very tangible ROI (return on investment). It can provide types of testing that simply can't be performed by people. Based upon your requirements, QA automation may have a dramatic effect on your costs.

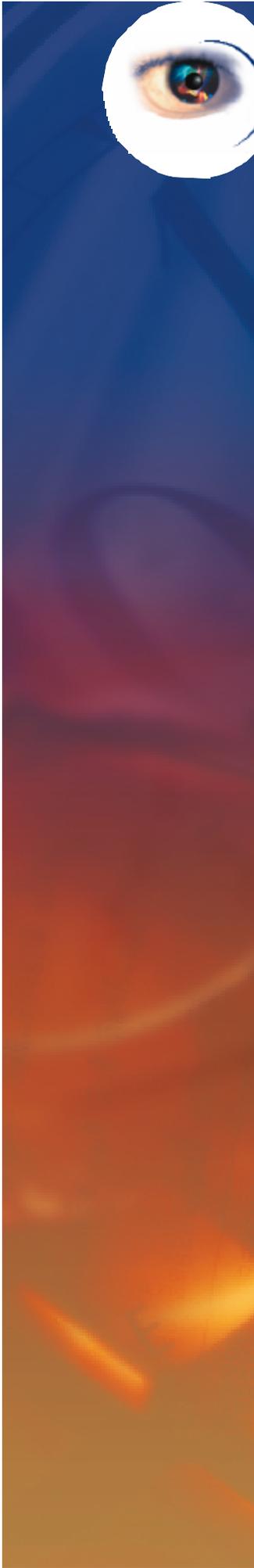
When fully implemented, dozens of machines can be running automated tests all night, providing many more hours of testing than ever before possible. The benefits of QA automation are very substantial.

The purpose of this paper is to provide the reader with practical guidelines on selecting the correct tools for an FDA controlled software project, understanding the costs associated with QA automation and maximizing the ROI on QA test automation tools.

The management of documentation in an FDA controlled software project is paramount to success. The manual tests form the basis for any tool used in test automation. The FDA wants proof that you have met the requirements stated in your design documentation. In other words, every test must be traceable back to a specific requirement. In order to do that an automated test tool must be capable of generating that documentation. Look for the following capabilities in an automated test tool.

- **Revision Control**
A good QA tool should have this built in.
- **Document Tracking**
The revision or approval history of documents should be available to the entire team as well as management.
- **Analysis and Reporting**
This type of feature is helpful for both the project team and management to have visibility into the status of the project.
- **Electronic Sign-offs**
The FDA allows for electronic signature of documents as long as all relevant information is recorded, such as date and time stamp, person and a description of the meaning or reason for sign-off. This is not a requirement, just a "nice to have" feature. Manual signature is of course required if electronic is not provided.

In addition to these requirements, you need to ensure the system will comply with your company's Quality System. If purchasing procedures or vendor qualifications are required,



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you'll have to follow them. Validation procedures will also have to be performed when you acquire the system. That may include tool validation as well as installation validations.

After considering the traceability and documentation requirements of the FDA regulations, there are some other practical considerations in terms of tool selection. One of those considerations is always cost. The true cost of a QA automation tool consists of four elements.

- Licensing cost of tools
- The cost of learning the tool
- The cost of implementing test scripts
- The cost of maintaining test scripts

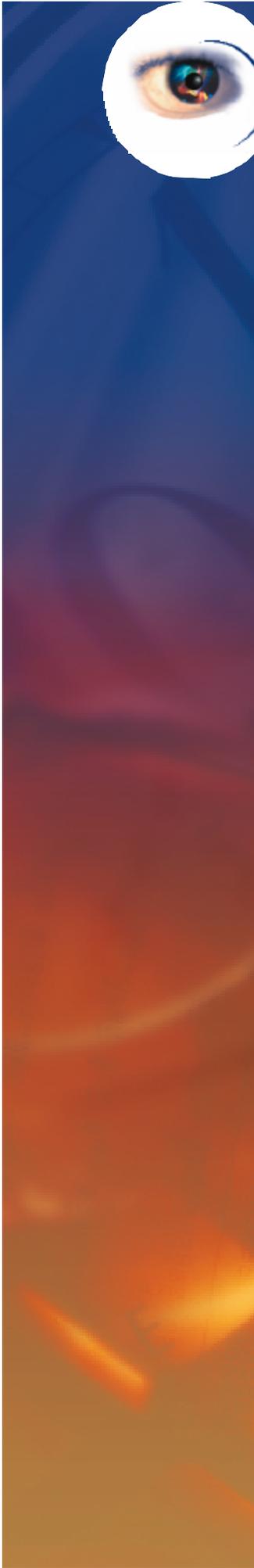
In addition to the license cost of an automation tool, you also need to take into account the extra machines required for long term testing. If a test, or a series of tests, is scheduled to run consistently for periods of 15 to 20 hours at a time, you will need to factor in the cost of additional machines dedicated to testing. If turnaround time is important, you may want to have several machines running tests in parallel using data sets or scripts that result in different run times.

The costs of learning the tool and implementing test scripts is highly dependent on the technical experience level of your QA engineering staff. If you're fortunate enough to have highly experienced QA engineers who have a strong automation background and are very experienced with writing test scripts, then your costs will be relatively low and you can select a relatively sophisticated tool.

If you don't employ such individuals, you either might consider buying the automation tools that support a very simple "record and playback" mode and allowing your manual QA engineers enough time to learn the more advanced features. You could also consider hiring one or more highly experienced QA automation engineers. However, this will raise your total cost substantially.

Alternatively, you could bring in a highly experienced consulting firm to help you set up the tools correctly, design a test environment and architecture, train your staff on their use and document a QA process that is consistent with your existing development methodology. The advantage of this approach is that while it still increases costs, it can be viewed as a one-time cost and results in a turn-key automation system that has residual value not only in executing tests but in expanding to meet your changing technical needs.

Regardless of your staff skill sets, designing an architecture, building reusable support scripts, defining which tasks to automate, implementing effective test scripts and verifying them to make sure they work will take a significant amount of time. This time will be measured in months, not weeks.



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This cost should not be underestimated. A prudent approach is to automate a small, well defined set of tasks while also defining processes and procedures for developing and maintaining test scripts. From early test scripts, the team should be able to identify key areas for reusability. Organizational changes will need to be made as well with manual QA engineers coordinating their efforts with the engineers assigned to developing automated test scripts and strategy.

Maintaining the test scripts should be integrated into a document or source code management (SCM) system. In your system it should be clear which protocols are manually executed versus which are automated.

QA Tool Evaluation

Acquiring a set of QA automation tools for an FDA controlled software environment should follow a well defined process. To the extent possible, all users who will be using the new tools or will be impacted by their introduction should be involved in a well defined evaluation process.

As with the selection of any sophisticated software tool, requirements analysis should be documented, vendor sales people should be asked not only if their software meets the requirements, but also to explain how their solution meets the requirement. The latter is a more important data point.

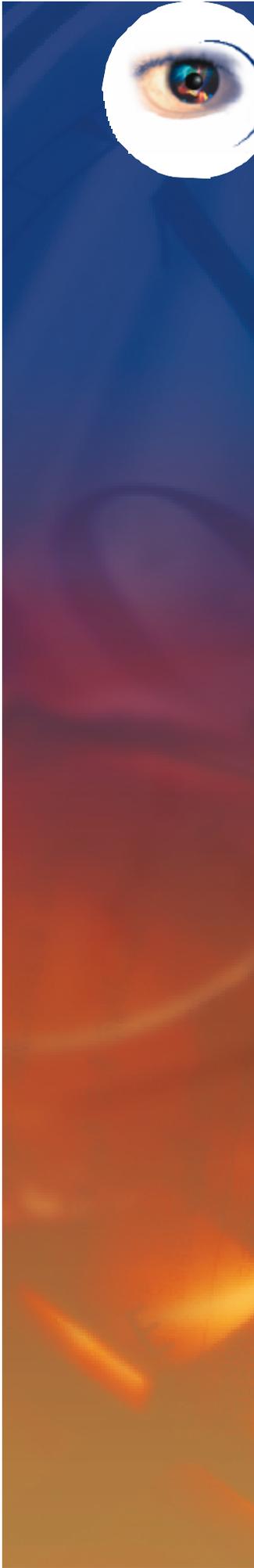
Once a final set of requirements is compiled, the field of vendors should be narrowed to 3 vendors whose products meet all the requirements and should be invited for a thorough product demo.

Key issues to consider when looking at QA automation tools are;

Are they scalable? This is a critical issue. Talk to their other customers and find out if the tool can scale to large, complex production environments. Large can mean both lengthy scripts with lots of functions as well as parallel and remote execution.

If you support multiple development environments, does the tool support each environment equally well? Does the tool support your underlying technology. If the tool can't directly interrogate or actuate necessary controls, it's not going to be of much value.

How easy or time consuming is it to set up a test. Insist that the vendor use your application and data and watch how long it takes to set up various tests. Now imagine having to do this hundreds of times internally. Watch for problems the vendor runs into. They should be experts with the tool and if they can't immediately solve an issue, its going to take your team even longer.



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Carefully review test reports. Look for the ability to customize the report, interoperability with existing in-house systems and electronic signature capability. You may need to create your own reporting mechanism. Time to implement this should be included in your evaluation. Electronic signatures are a “nice to have” feature and should not impact your decision making.

Be especially thorough with new, small companies. While they may have the latest, greatest, easiest to use technology, their products may, ironically, still have significant bugs in them simply because their product is not sufficiently mature. At the same time, mature products have known limitations. These along with the inevitable defects may make a high-priced “industry leading” tool unsuitable for you.

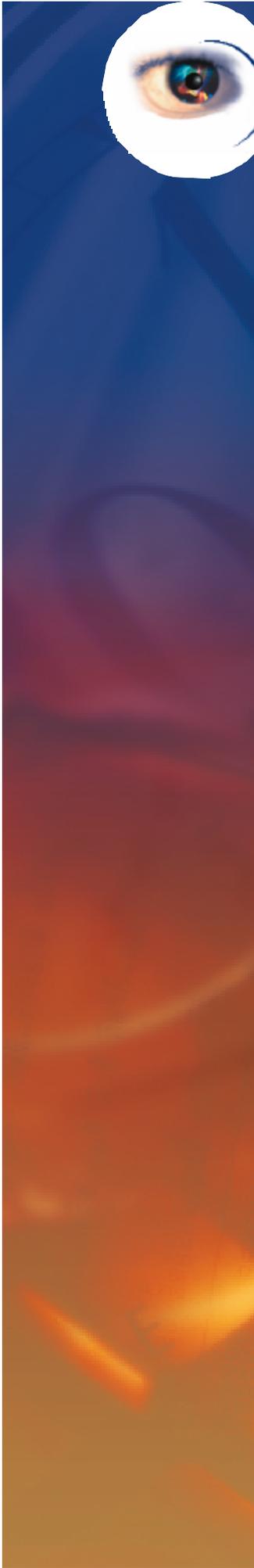
Lastly, and most importantly, approach the acquisition of QA automation tools or systems with exactly the same scrutiny, thoroughness and corporate due diligence that you would use when purchasing a sophisticated development tool. Too many companies make poor decisions, and suffer disastrous outcomes, because acquiring QA automation tools is not subjected to the same standards of corporate and technical purchasing rigor as software development tools or the evaluation team simply doesn't have the experience necessary to make a good comparison.

Maximizing ROI from QA Automation Tools

The real business and technical benefits that accrue to the organization, the measurable ROI, as the result of a successful implementation of test automation is in the amount of testing, the type of testing and a reduction in repeated regression testing that be accomplished by the same number of people. The ROI argument is that by employing automated tools, you bring the hourly cost of test down significantly, since many more hours of testing are being utilized, even accounting for the extra work of designing and running the tests.

Over the course of a year, automated testing can add thousands of additional test hours, thereby bringing down the total hourly cost of QA. Driving down the total hourly cost of the QA department, while substantially increasing software quality, which drives down other costs, is an argument that most CFO's will embrace. The other costs that can be added to the ROI are decreased support, field service and liability costs.

When the QA department goes home, automated tests can be initiated that will run a range of automated tests overnight. Better yet, in an automated build environment, automated testing can automatically be triggered to test each build immediately as it becomes available. This again doesn't reduce head count but can liberate your QA engineers to focus on more



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valuable and meaningful testing. In addition, some tests such as regression testing, can be automated and a higher degree of efficiency can be achieved.

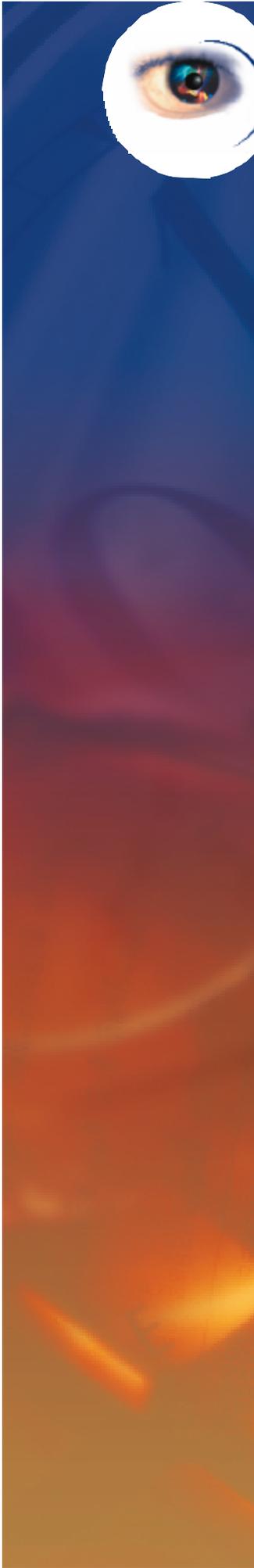
It is true that certain types of tests, such as finding memory leaks are better suited to automated testing. Memory leaks tend to manifest themselves over time in an application. A function might allocate a tiny amount of memory and fail to release it. It might have to be run thousands of times to have a noticeable effect. Performing that much testing is not feasible to do manually. Other examples include applications that consume escalating amounts of CPU, disk or table space as transactions and data volume grows or as the number of users increase. Clearly simulated users are easier to come by than additional testing staff.

Thorough manual testing of input fields has always been a challenge. Manual testers can test for many boundary conditions, but automated tests can test for hundreds of variations on every field 24 hours a day and can be “data driven.” For example, with data driven testing, you can have thousands of records of demographic information stored in a database and used to create new records in your application.

There is sometimes a misperception that by employing test automation, an organization will need fewer people in the QA department. Based on Full Spectrum Software’s experience in implementing a very high degree of test automation in our own test labs and in working with clients who are introducing test automation, we have observed that there are organizational and process changes that need to be executed. QA engineer’s roles and responsibilities change along with processes, tools and procedures, but the business driver for implementing automated testing is, in its broadest sense, to increase software quality, not to reduce headcount. A high degree of human judgment is always required in QA. Even interpreting the results of an automated test requires human judgment.

Based on the results of an automated test, the manual QA engineers will have to work with the test automation engineers to develop new scripts to cover new cases, or test different areas of the code. Defining new test scripts and refining existing test scripts is an ongoing, iterative process.

A review of the results might also indicate that certain areas of the code need extensive exploratory manual testing. Exploratory manual testing cannot be automated. It requires highly experienced manual testing based on the manual QA engineer’s knowledge of the code. They make decisions regarding what areas of the code to explore and test based on the behavior they are seeing or the results of a test. Those decisions lead to other decisions to track the source of a bug. Automation can extend and refine the capabilities of a QA team and give them new diagnostic tools, but it can never replace human judgment and experience. If anything, the manual QA engineers will be busier than ever.



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Conclusion

Selecting the right QA automation tool involves getting all stakeholders involved in the decision, QA, development, management, even manufacturing and production. It also involves developing a rigorous technical and business process to guarantee that the correct tool is selected. Selecting the wrong tool is a guarantee for failure, generally of epic proportion.

Implementing an automation tool is time consuming at the outset. Having the right people, or allowing time and resources to train the right people is critical. New processes and procedures need to be developed in order to be effective. Proper planning and setting realistic expectations is also critical.

The adoption of automation tools should be seen as an effort in improving quality first. An improvement in quality has a direct financial benefit in reduced debugging time, faster release cycles and improved end-user experience. In the medical industry this can also mean more easily defended verification and reduced likelihood of recall.

Summary

We hope you found some tips or techniques that will be beneficial to your organization. Full Spectrum Software will be hosting a series of webinars to explore each of these topics in greater detail in the near future. If you would like to be notified of upcoming webinars, please send an email to ClientServices@FullSpectrumSoftware.com

Full Spectrum Software is a 14 year old consulting firm specializing in the development of embedded and applications software for medical devices. The company has helped their clients deliver over 100 commercial products and systems to market. Andrew Dallas, the firm's CTO, is widely considered one of the leading authorities on best practices in FDA controlled software projects. Andrew has published extensively in major trade and technical publications.

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