DEVICETALKS TUESDAYS

Leveraging Shift-Left Testing for Enhanced Quality and Compliance

TECH BRIEF

Presenters:
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Jack Wallace, Solutions Engineer II, Qt Group

Moderator: **Tom Salemi,** Editorial Director, DeviceTalks

Qt Group

Overview

In the medical device industry, delivering safe, effective, reliable, and compliant products is mandatory. Companies are constantly searching for innovative ways to meet industry requirements. Shift-left testing, an approach that emphasizes early testing in the development cycle, is one way to achieve this goal. It is a key strategy for enhancing medical device quality, reducing risks, and more easily meeting regulatory requirements.

Qt Group works with its customers worldwide to increase productivity through the entire product development lifecycle—from user interface (UI) design and software development to quality management and deployment. Qt Quality Assurance solutions ensure the quality of cross-platform desktop, mobile, embedded, and web applications—regardless of the platform used. Qt Group's emphasis on and expertise in implementing automated testing empowers companies to save time, lower costs, and enable growth.

Context

The presenters discussed how shift-left testing helps medical device manufacturers reduce time to market while enhancing product safety.

Key Takeaways

Mission-critical software is driving an increasingly complex future for medical device development.

While software has been part of medical devices for decades, the relationship between software and device has evolved significantly over time. Today, software is the device. Beyond the direct interaction between user and device through the UI, medical devices use software to provide additional capabilities such as data collection, remote monitoring, communications, interoperability, and more.

The overall user experience (UX) is increasingly software-developed, software-driven, and software-controlled.

There are two types of software used in the medical device industry: Software in the Medical Device (SiMD) and Software as a Medical Device (SaMD).

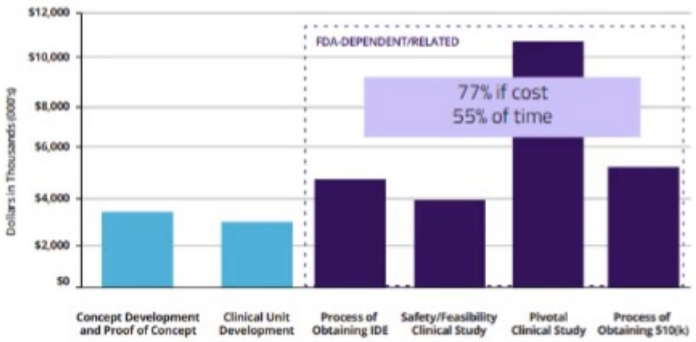
- SiMD means that software is an integrated part of the device itself (e.g., infusion pumps), providing mission-critical functionality. Any issues with the device could result in serious consequences, including death. These devices usually fall into the Class III risk category.
- SaMD, however, describes devices in which a failure could cause a misdiagnosis but will rarely result in grievous harm. Smartwatches, for example, usually fall into this category.

From richer and more complex UIs to higher user expectations around devices' ease of use, platform and hardware proliferation, interaction with larger data sets, the use of artificial intelligence, and more, the growing dependence on software is driving an increasingly complex future for the development and testing of medical devices.

Increased complexity and stricter regulatory requirements drive up development costs.

As software increases the complexity of medical devices, regulatory requirements are becoming stricter, and thus more costly to fulfill. Device development, proof of concept, and implementation of device hardware now account for less than half the total time and cost of bringing a medical device from concept to clearance. A 2020 study found that, on average, more than three-quarters of the cost of bringing a device with FDA 510(k) clearance to market was spent on satisfying security and/or functional safety regulations.

Figure 1: Average total expenditures by stage for 510(k) product



2 "FDA Impact of U.S. Medical Technology Innovation – A Survey of Over 200 Medical Technology Companies" Josh Makower, MD, Aobed Meer, Lyn Denend

Conducting tests during the design and development phases, as well as post-deployment, of devices supports software quality assurance (SQA) and provides critical evidence that is needed to meet regulatory and security requirements. Tests can vary between products and manufacturers and might include unit testing, static analysis, architectural verification, functional testing, code coverage analysis, integration testing, security testing, performance testing, stress testing during design and development, and installation and usage testing after deployment.

In traditional devices with less software, manual testing was a feasible approach to validation. However, in today's more complex environment, regardless of which tests are used, most testing efforts conducted on medical devices involve a significant amount of effort.

This is due in large part to *software erosion*, which is introduced over time as the code base grows. Software erosion might include bad or dead code, clones, metric violations, style violations, and cycles, among others.

Erosion raises complexity, which in turn causes an exponential increase in cost and effort per feature, bringing operations to a limit of maintainability and expandability—even with additional resources. Too much erosion will speed Tmax (the maximum time in which a device can be confidently developed and sold into the market).

Traditional manual testing no longer scales. Automated testing is critical to maintaining sustainability in a demanding regulatory landscape.

A shift-left approach to SQA can significantly reduce the cost of medical device development.

In traditional SQA processes, development teams usually conduct QA testing towards the latter half of the development process, with most testing occurring post-development and build.

However, in most software lifecycles, the bulk of issues are introduced during the design and coding phases, making it more costly and difficult to remedy problems found during the more traditional late-stage testing phase.

Figure 2: Before (l) and after (r) minimizing software erosion

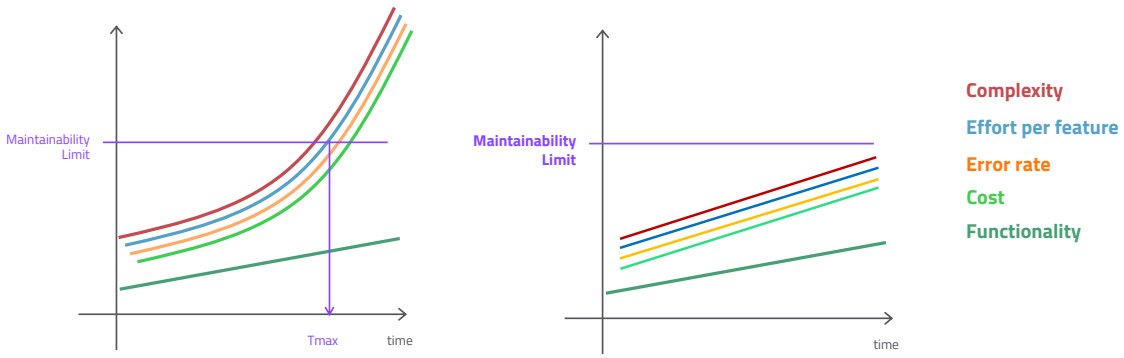
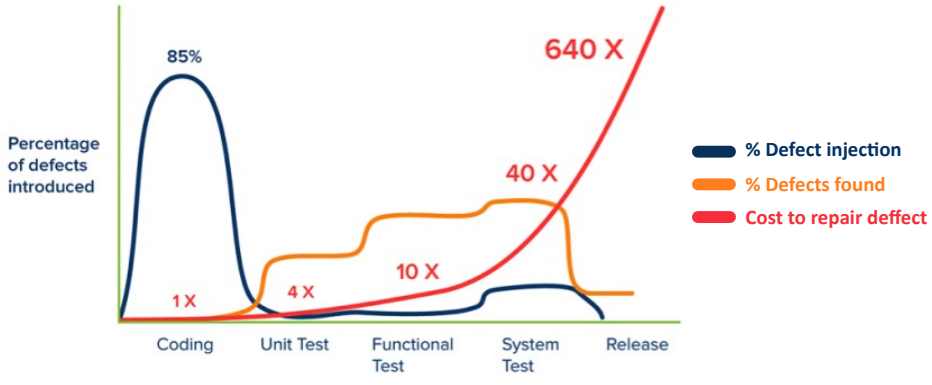


Figure 3: Delaying testing until after development and build exponentially increases costs



Jones, Capers. *Applied Software Measurement: Global Analysis of Productivity and Quality.*

Shift-left emphasizes early issue detection and remediation, as well as incorporation of automated testing into the development process. Instead of starting after development and build, shift-left incorporates more of its testing and validation efforts during the planning, design and development, and build phases.

Specifically for medical devices, the timeline usually moves from product conception to planning and design, followed by development. Once a working prototype is complete, documentation is prepared and submitted to the relevant regulatory body.

In medical device development cycles, it is best to implement testing during the planning stage. When the software development tools are selected, so too should the testing tools and processes be chosen. This will not only streamline the efficiency of the development process but will also establish a history of testing that can be used to demonstrate to regulatory bodies the validation and remediation processes for the device, as most regulatory bodies require this information.

> "If you have gotten to the document preparation step, and you haven't really started your testing, this is quite a bit too late. . . What we want and what we encourage is integrating testing from the very beginning."
>
> Jack Wallace, Solutions Engineer II, Qt Group

Automated testing streamlines regulatory submission.

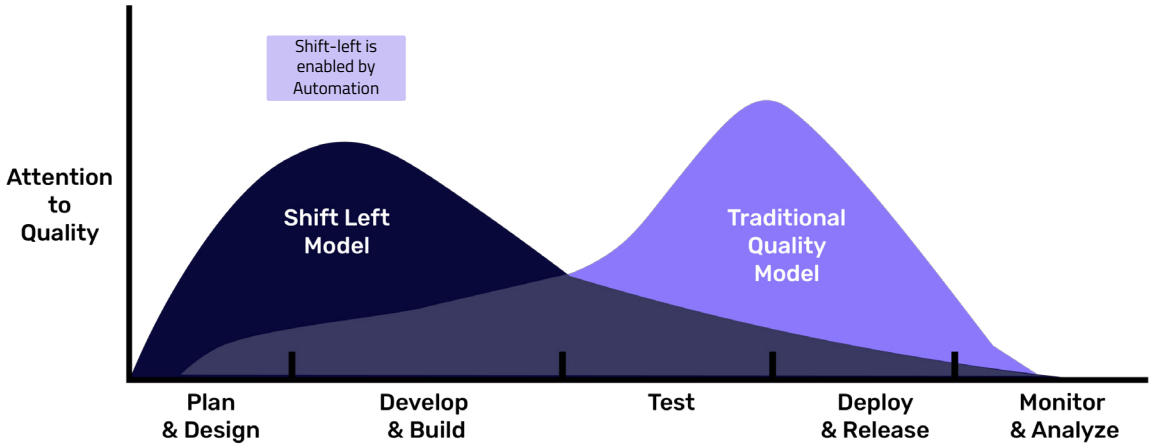
Quality assurance testing is necessary to ensure that SiMD and SaMD is going to be safe and effective, and complies with required medical device standards. There are several medical device standards set by the respective regulatory body of a given country or region.

Device manufacturers should be aware of which regulatory requirements apply to their given devices and markets; however, many regulatory bodies share common or similar requirements, such as a thorough description of software testing used, the history of software versions that were tested and documented as part of verification and validation, and unresolved software anomalies.

Automated testing as a key part of a shift-left strategy not only speeds and streamlines device development; it also helps with generating and organizing the necessary documents for submission to a regulatory body.

Using an automated testing tool in test-driven development will provide a built-in history of all bug fixes and burn down rates, a summary of regression tests, and more. And because automated test platforms store detailed testing information, additional specific data can be extracted depending on the need for a standard or submission.

Figure 4: Shift-left in SQA

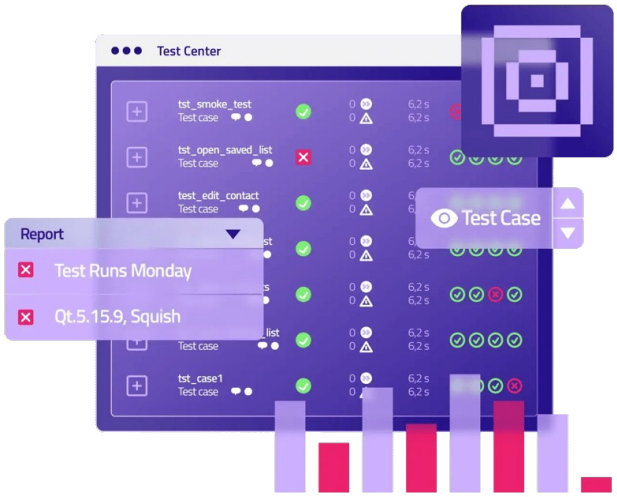


Source: https://techigai.io/5-reasons-why-shift-left-testing-can-lead-to-faster-better-releases/

> "Automation is the big new requirement . . . from the development point of view, to be able to create these devices and meet the regulatory requirements."
>
> Jan Aarsaether, Senior Business Development Lead, QA, Qt Group

Adding an automated test platform tool to the build pipeline enables unit and integration tests to run on every commit, ensuring that bugs are found and resolved quickly. Full test suites can be run according to less frequent custom schedules.

Figure 5: Automated testing streamlines the regulatory submission process



Additional Information

- **Qt Group.** To learn more, visit qt.io/quality-assurance

Biographies

Jan Aarsaether

Senior Business Development Lead, QA, Qt Group

Jan Aarsaether is an experienced Sales and Business Development professional with a strong technical background and a deep understanding of the software development and testing industry. With over 20 years of experience in the field, his expertise includes cross-platform software development, GUI automation, code coverage, and other testing tools.

Tom Salemi

Editorial Director, DeviceTalks

DeviceTalks Editorial Director Tom Salemi has been writing and talking about the medtech industry for over two decades. Prior to joining WTWH Media, Tom organized conferences, wrote feature articles and broke news for industry-leading business-to-business publications. Tom lives north of his native Boston with his wife, two sons, and Daisy the Dog.

Jack Wallace

Solutions Engineer II, Qt Group

Jack Wallace has been a sales engineer focused on the medical device space for the last 3 years. Before changing his career to focus on the medical field, he worked as a software engineer in the automotive industry at several tier 1 suppliers. Jack is passionate about helping his customers create beautiful GUIs for their products, and to ensure that they are of the highest quality.

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