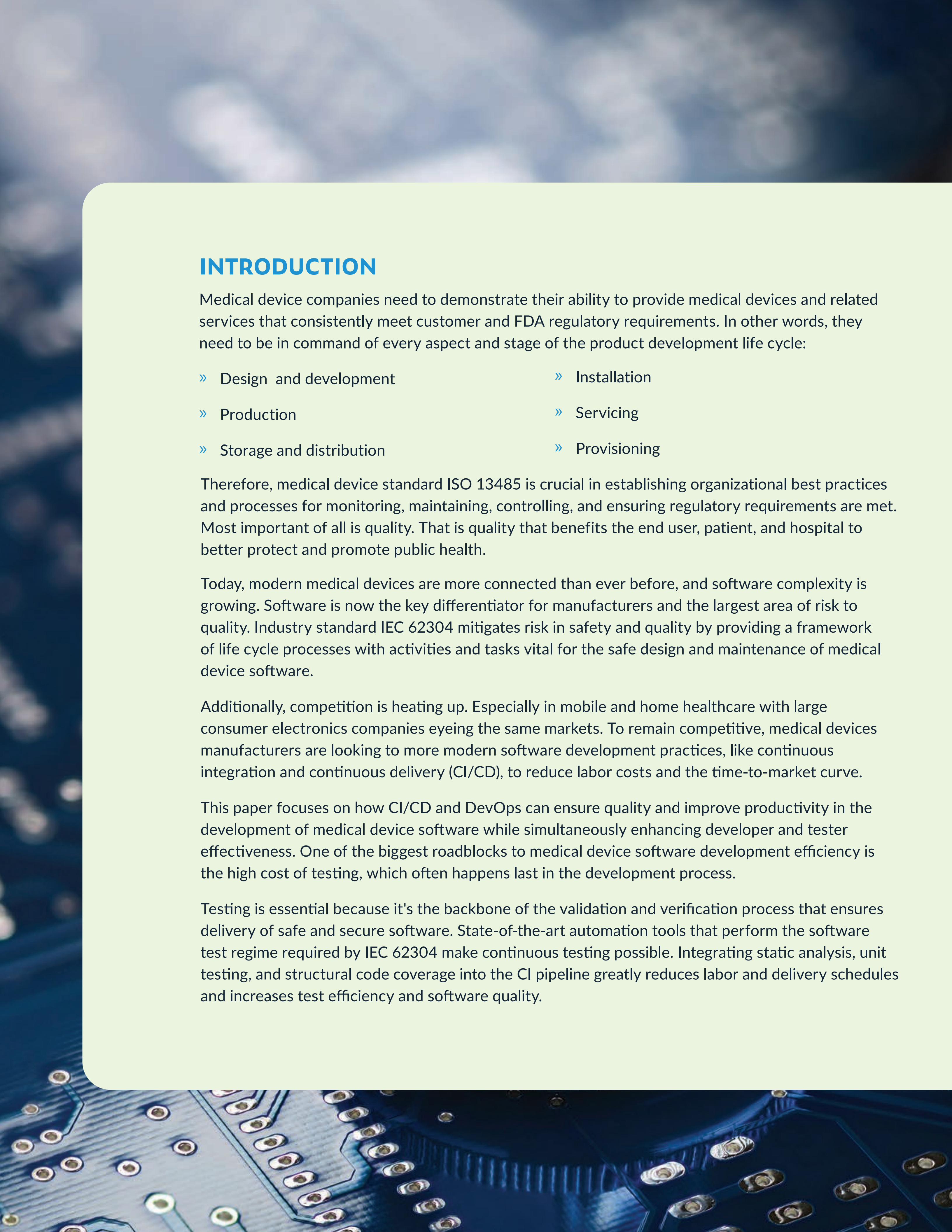
PARASOFT

WHITEPAPER

Guide to CI/CD for Medical Device Software DevOps



INTRODUCTION

Medical device companies need to demonstrate their ability to provide medical devices and related services that consistently meet customer and FDA regulatory requirements. In other words, they need to be in command of every aspect and stage of the product development life cycle:

- Design and development
- Production
- Storage and distribution
- Installation
- Servicing
- Provisioning

Therefore, medical device standard ISO 13485 is crucial in establishing organizational best practices and processes for monitoring, maintaining, controlling, and ensuring regulatory requirements are met. Most important of all is quality. That is quality that benefits the end user, patient, and hospital to better protect and promote public health.

Today, modern medical devices are more connected than ever before, and software complexity is growing. Software is now the key differentiator for manufacturers and the largest area of risk to quality. Industry standard IEC 62304 mitigates risk in safety and quality by providing a framework of life cycle processes with activities and tasks vital for the safe design and maintenance of medical device software.

Additionally, competition is heating up. Especially in mobile and home healthcare with large consumer electronics companies eyeing the same markets. To remain competitive, medical devices manufacturers are looking to more modern software development practices, like continuous integration and continuous delivery (CI/CD), to reduce labor costs and the time-to-market curve.

This paper focuses on how CI/CD and DevOps can ensure quality and improve productivity in the development of medical device software while simultaneously enhancing developer and tester effectiveness. One of the biggest roadblocks to medical device software development efficiency is the high cost of testing, which often happens last in the development process.

Testing is essential because it's the backbone of the validation and verification process that ensures delivery of safe and secure software. State-of-the-art automation tools that perform the software test regime required by IEC 62304 make continuous testing possible. Integrating static analysis, unit testing, and structural code coverage into the CI pipeline greatly reduces labor and delivery schedules and increases test efficiency and software quality.

AUTOMATION IN CI/CD

Without automation of the build process and, by extension, processes connected to creating deployment, artifacts and build verification would be tedious and time consuming—the antithesis of continuous.

Continuous integration relies on a single source repository and automated software build tools. It's important that integration issues and broken builds are sorted out immediately. Following that, the most critical step is to build a deployable product and test the integrated product.

This is the point where most CI/CD and iterative approaches grind to a halt. Testing takes time and effort. It's difficult to decide what to test.

Manual testing can exacerbate this problem. Test automation is important, but more is needed than just running tests. Further discussion of this follows in the paper.

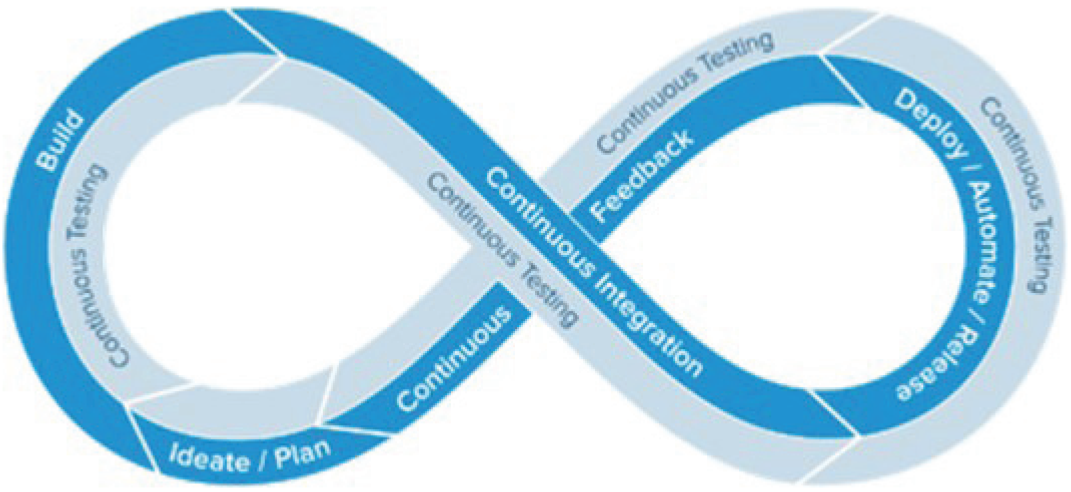


Figure 1: Continuous integration as part of a continuous development cycle.

CI/CD FOR EMBEDDED SYSTEMS

CI/CD continues to increase in popularity within medical device software development organizations. However, projects are often constrained in ways that application development is not.

Besides the physical and computational constraints of the target hardware platform, there are constraints in the marketplace. Medical device software has requirements for safety, security, reliability, and extremely long life cycles. Products can remain in the market for decades.

Automation at the build level uses the same techniques. But when code needs to be executed, the host/target barrier becomes significant. Automation that requires code execution needs special support in medical device software development.

Automating testing for medical device software is more challenging due to the complexity of initiating and observing tests on embedded targets, not to mention the limited access to target hardware that software teams have. Software test automation is essential to make medical device testing workable on a continuous basis from the host development system to the target system.

Testing medical device software is particularly time consuming, especially regression tests, which are required after any change. Automation of regression test suites provides significant time and cost savings. In addition, test results and code coverage data collection from the target system are essential for validation and standards compliance.

Traceability between test cases, test results, source code, and requirements must be recorded and maintained so data collection is critical in test execution.

A solution like Parasoft C/C++test comes with an optimized test harness to take minimal additional overhead for the binary footprint and provides it in the form of source code, where it can be customized if platform-specific modifications are required.

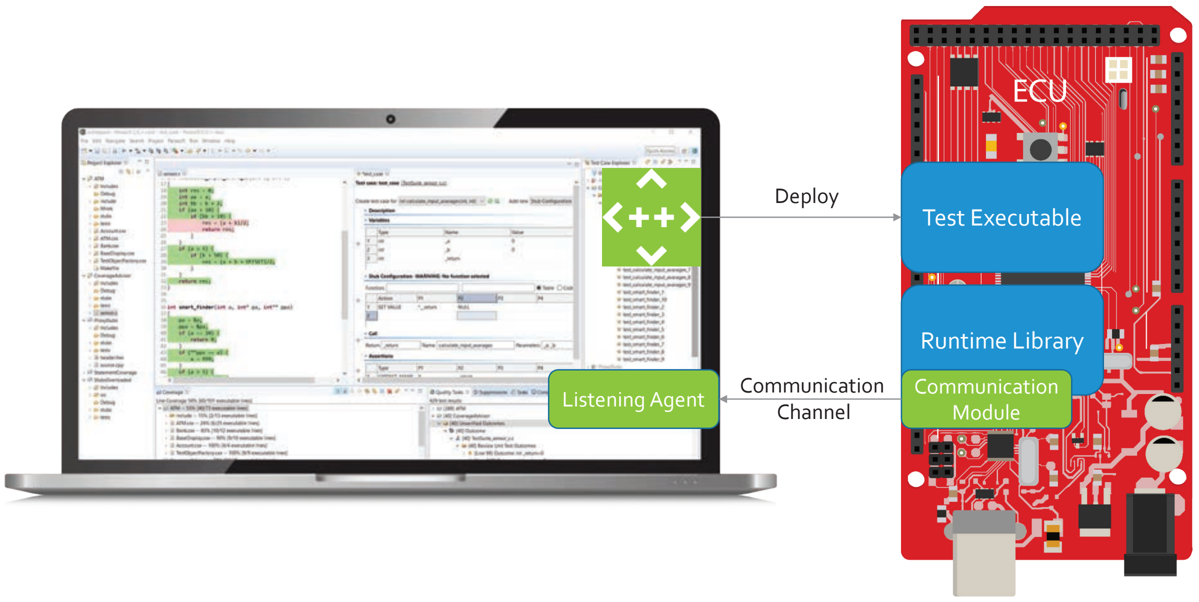


Figure 2:
A high-level view of deploying, executing, and observing tests from host to target.

One huge benefit that the Parasoft C/C++test solution offers is dedicated integrations with embedded compilers, debuggers, and industry-standard IDEs that make the process of executing test cases smooth and automated.

Supported compilers include GNU GCC, IAR, ARM, Intel, Keil, Wind River, Green Hills, and many others.

Supported IDE environments include Eclipse, VS Code, Green Hills Multi, Wind River Workbench, IAR EW, ARM MDK, ARM DS-5, TI CCS, Visual Studio, and more. See all of the technical specifications.

The Parasoft solution supports the creation of regression testing baselines as an organized collection of tests and will automatically verify all outcomes. These tests are run automatically on a regular basis to verify whether code modifications change or break the functionality captured in the regression tests. If any changes are introduced, these test cases will fail to alert the team to the problem. During subsequent tests, C++test will report tasks if it detects changes to the behavior captured in the initial test.

The parity of capabilities of remote target execution with host-based testing means that medical device software teams can reap the same benefits of automation as any other type of application development.

CONTAINERIZED DEVELOPMENT PLATFORM AT EVERY DEVELOPER'S DESKTOP

Containerized deployments of development tools are becoming the bread and butter of medical device development teams. Even though containers were initially developed to solve problems with the deployment of microservices and web-based applications, they recently gained popularity among development teams. Especially big teams that use containers to manage complex toolchains.

When it comes to managing complex development environments, specifically in safety-critical software development, teams usually struggle with the following challenges.

- Synchronizing upgrades for the entire team to a new version of a tool like a compiler, build toolchain, and so on.
- Dynamically reacting to a new security patch for the library or software development kit (SDK), and the like.
- Assuring consistency of the toolchain for all team members and the automated infrastructure (CI/CD).
- Ability to version the development environment and restoring it to service the older version of the product that was certified with the specific toolchain.
- Supporting the audit of tool chain requirements.
- Onboarding and setting up new developers.

All these problems are easy to solve with containers.

USING A COMMAND-LINE BASED TOOL WITH A CONTAINERIZED COMPILATION TOOLCHAIN

It's easy to configure the command-line based tool, Parasoft C/C++test Professional, to work with a compilation toolchain and the execution environment deployed in containers. For example, the Parasoft tools can be deployed with a single compressed archive to dramatically simplify and accelerate container initialization. The tool supports deployments that are based on Linux and Docker containers.

Containerized deployments of development tools are becoming the bread and butter of embedded development teams. Even though containers were initially developed to solve problems with the deployment of microservices and web-based applications, they have gained popularity among embedded teams—especially big teams that use containers to manage complex toolchains.

As a command-line based tool, Parasoft C/C++test standard is very fitting for in-container deployments. It can be packaged with the compiler and build system into one container image, used for CI/CD, and deployed to developers' desktops for the local command-line scans.

The tool accesses the containerized compiler (GNU GCC) and the runtime environments.
In this specific setup, there are two separate Docker containers:

- One for the compiler and build tools
- Another for the execution environment, such as a stripped down version of embedded Linux

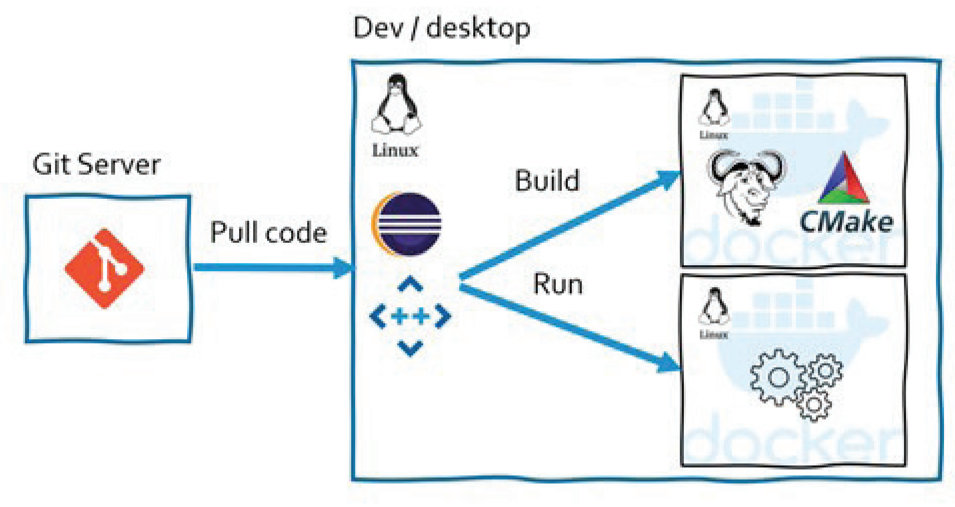


Figure 3:
An example deployment of the command-line based tool with Docker build and run containers

The diagram shows Jenkins using containerized C/C++test to run static analysis. In this specific setup, the tool, the compilation toolchain, and the build tools are deployed in the container shown in the top right corner of the diagram.

The container below it in the bottom right, provides the execution environment, which may be required to execute runtime tests, like unit tests or automated system level tests. If you on want to implement static analysis, then the setup will most likely include only one type of container with the compilation toolchain and Parasoft C/C++test.

BENEFITS OF CI/CD

The biggest benefit of CI/CD is reducing project risk. In the past, too many projects relied on "big bang" software integration efforts where software teams attempted to integrate their software too close to the end of product development. These teams encountered huge issues with integration and were often under massive crunch schedules to get the project finished. Testing was pushed even further to the end of the project where it became a large effort that caused frustration and delays.

By using continuous integration, software teams always have a full build of the product ready for testing, delivery, and release. Rather than throw things together in one big bang, the team goes through smaller integration steps, continuously, to find compliance issues early and reduce the risk from late cycle integration.

Here are more benefits to continuous integration. Think of this list as incremental and contributing to reduced risk and better quality.

» **Integration testing is early and often,** which means bugs are exposed earlier where they can be fixed easier and more cheaply.

» **Regression testing starts earlier** so that new features can be tested to see how they impact existing code. New tests are added to the regression test suite after each iteration.

» **Incremental improvements** of the product in terms of adding and testing new features and removing bugs. It's easier to build in quality and security in an incremental fashion.

» **Enables continuous testing and delivery,** which are equal parts of the continuous development process. Continuous integration alone isn't effective without continuous testing and continuous delivery.

CI/CD NEEDS CONTINUOUS TESTING

Continuous integration is just part of a continuous development process that needs testing and delivery to reap the benefits of the approach.

Continuous testing provides an automated, unobtrusive way to obtain immediate feedback on a software release candidate. Continuous testing isn't simply more test automation. The purpose is to build quality and security into the product as part of a continuous integration/release/delivery process. Here are some of the included activities.

- **Static analysis for early detection of bugs and security vulnerabilities.** Early detection, usually at the developer's desktop, prevents bugs from wasting unit testing time and entering the software build.
- **Coding standard enforcement** helps conform to required industry standards, like MISRA C/C++ or SEI CERT C, and prevents whole classes of defects and poor coding practices from entering the build to become larger issues later on.
- **Automated test execution** is needed as soon as the application is built. The required tests that need to verify units also include nonfunctional, load, security, and performance testing. These tests are executed directly from the CI orchestration system. The results from these tests get pulled back into the same build and gathered. Code coverage information (statement, branch, and MC/DC) is cross referenced by unit, file, test, and build number.
- **Requirements traceability** correlates code, tests, and other assets with business requirements. This provides an objective assessment of the requirements that are working as expected, which ones require validation, and the ones at risk.
- **Test impact analysis** provides direction to the team on where testing efforts need to go. From a risk perspective, changed code impacts more than the software itself, it impacts relevant tests and assets. As teams make code changes, questions arise:
  - Do we need new tests or modify existing ones?
  - What are the impacts on dependencies?

  Automation helps teams focus only on the tests that are impacted.
- **Test data management** significantly increases the effectiveness of a continuous testing strategy. Good test data and test data management practices increase coverage and drive more accurate results. However, developing or accessing test data can be a considerable challenge in terms of time, effort, and compliance.
- **Data generation** underpins continuous testing. You can continuously generate data appropriate for the type of scenario you're trying to execute instead of trying to rely on production data sources and hoping that all the right data is in the right place. Combining data generation with simulation will allow you to inject the right data in the right place at the right time.

SHIFT LEFT WITH CI/CD

The drive to shift-left quality, safety, and security in the software development life cycle (SDLC) comes from the desire to find and fix bugs and security vulnerabilities as early as possible. Issues are much easier, cheaper, and less risky to fix earlier, not later. Common sense, but the software industry is full of examples where critical defects caused catastrophic results.

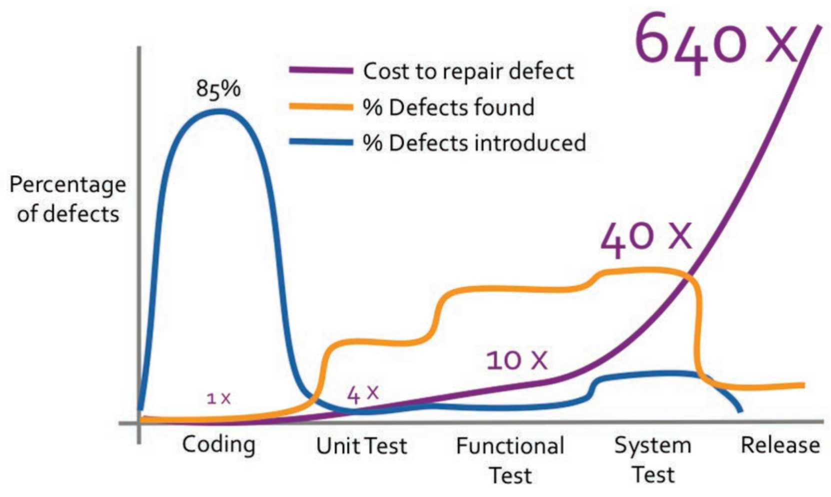


Figure 4:
Finding and fixing security vulnerabilities early is cheaper and less risky.

The essential requirements to shift-left center around the need to incorporate quality into any and all applications at the very beginning. Quality and security can't be added on. They must be built in. Here are some recommendations to shift left in the CI/CD pipeline that help create the necessary platform for continuous testing.

- Improve test automation.
- Increase code coverage.
- Automate bidirectional traceability.
- Monitor commits made into the software repository.

IMPROVE TEST AUTOMATION TO OPTIMIZE CI/CD

It should be clear at this point that test automation is a key aspect of achieving quality and security in a CI/CD pipeline. In turn, it becomes clear that test automation needs to be a focus for improvement and optimization. The largest struggle teams face is what to test. Since full system testing with each new candidate release is too time consuming and expensive, teams inevitably compromise testing by picking parts of the test suite to execute.

Focusing testing on exactly what is needed to increase code coverage and determine which regression tests are needed after each code change is critical to speed up testing, enable continuous testing, and accelerate the pipeline.

INCREASE CODE COVERAGE

In general, code coverage is a measurement of how much of the production code is executed while your automated tests are running. By running a suite of tests and looking at code coverage data, there is a general sense of how much of the application is being tested.

There are multiple kinds of code coverage. For medical device software, you may need to measure and record code coverage like statement, branch, and MC/DC (modified condition/decision coverage). Code coverage may also be required for the strictest requirements, such as building FDA Class C devices, object code verification, or assembly language.

Structural Code Coverage

Collecting and analyzing code coverage metrics is an important aspect of safety-critical medical device software development. Code coverage measures the completion of test cases and executed tests. It provides evidence that validation is complete, at least as specified by the software design.

It also demonstrates the absence of unintended behavior. Code that isn't covered by any test is a liability since its behavior and functionality are unknown. The amount and extent of code coverage depends on the safety integrity level. The higher the integrity level, the higher the rigor used. And, inevitably, the higher the number and complexity of test cases. Below are examples of types of recommended code coverage.

» **Statement coverage** requires that each program statement be executed at least once. Branch and MC/DC coverage encompasses statement coverage.

» **Branch coverage** ensures that each possible decision branch (if-then-else constructs) is executed.

» **Modified condition/decision coverage (MC/DC)** requires the most complete code coverage to ensure test cases execute each decision branch and all the possible combinations of inputs that affect the outcome of decision logic. For complex logic, the number of test cases can explode so the modified condition restrictions are used to limit test cases to those that result in stand alone logical expressions changing. See this tutorial from NASA.

Advanced unit test automation tools like Parasoft C/++test provide all of these code coverage metrics and more. C/C++test automates this data collection on host and target testing and accumulates test coverage history over time. This code coverage history can span unit, integration and system testing to ensure coverage is complete and traceable at all levels of testing.

Code Coverage With Automated Unit Test Case Creation

The creation of productive unit tests has always been a challenge. Functional safety standards compliance demands high-quality software, which drives a need for test suites that affect and produce high code coverage statistics.

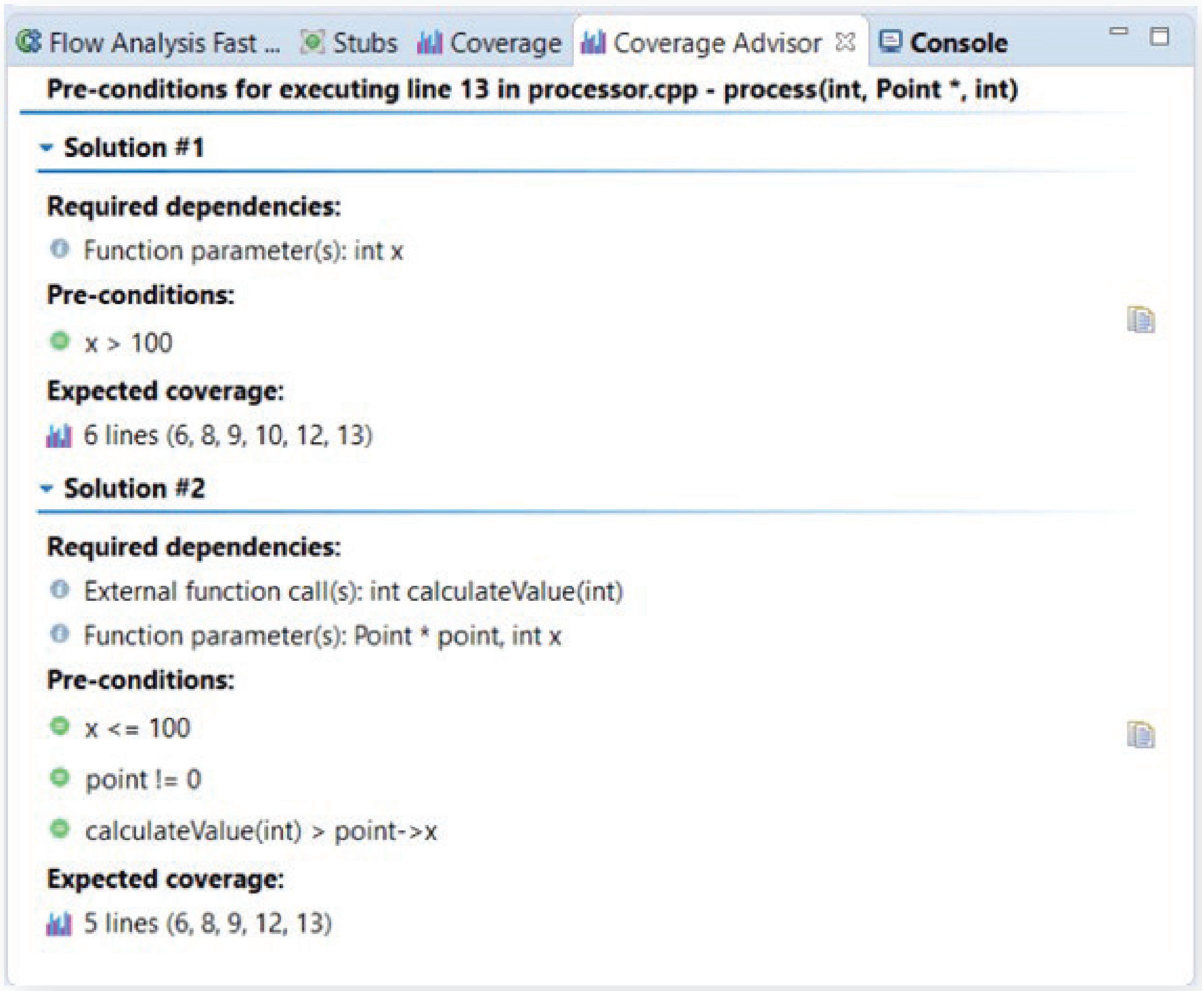
Teams require unit test cases that help them achieve their coverage goals. These goals are important even outside the realm of safety-critical software. Any code not covered by at least one test is shipping untested!

Increasing code coverage can be challenging. Analyzing branches in the code and trying to find reasons why certain code sections aren't covered, continues to steal cycles from development teams.

Resolve Coverage Gaps

Teams can resolve coverage gaps in test suites using a coverage advisor. Parasoft discovered how to use advanced static code analysis (data and control flow analysis) to find values for the input parameters required to execute specific lines of uncovered code.

This analysis computes preconditions for function parameters, global variables, and external function calls required to execute a specific line of code. The Coverage Advisor view presents a collection of solutions for the user-selected lines of code. Presented values are used for creating new unit test cases. The functionality boosts the productivity of developers working on unit test cases to improve code coverage.



Pre-conditions for executing line 13 in processor.cpp - process(int, Point *, int)

Solution #1

Required dependencies:
- Function parameter(s): int x

Pre-conditions:
- x > 100

Expected coverage:
- 6 lines (6, 8, 9, 10, 12, 13)

Solution #2

Required dependencies:
- External function call(s): int calculateValue(int)
- Function parameter(s): Point * point, int x

Pre-conditions:
- x <= 100
- point != 0
- calculateValue(int) > point->x

Expected coverage:
- 5 lines (6, 8, 9, 12, 13)

*Figure 5:
Coverage Advisor displays what input values, global variables, and external calls are needed for a test case to obtain the needed code coverage.*

Each coverage solution includes:

- » **Required dependencies.** Dependencies that need to be customized to cover the selected line. These may include function parameters, external function calls, global variables, local variables, and class members.
- » **Preconditions.** Conditions that must be satisfied by the required dependencies to cover the selected line. Clicking a precondition navigates to the related code line.
- » **Expected coverage.** Code lines that will be covered if all of the preconditions are satisfied.

AUTOMATE BIDIRECTIONAL TRACEABILITY

Requirements traceability is defined as "the ability to describe and follow the life of a requirement, in both a forwards and backwards direction (i.e. from its origins, through its development and specification, to its subsequent deployment and use, and through periods of on-going refinement and iteration in any of these phases)."

In the simplest sense, requirements traceability is needed to keep track of exactly what you're building when writing software. This means making sure the software does what it's supposed to and that you're only building what's needed.

Traceability works both to prove you satisfied the requirements and to identify anything that doesn't. If there are architectural elements or source code that can't be traced to a requirement, then it's a risk and shouldn't be there. The benefits go beyond providing proof of the implementation. Disciplined traceability is an important visibility into development progress.

It's important to realize that many requirements in medical device software are derived from safety analysis and risk management. The system must perform it's intended functions, of course, but it must also mitigate risks to greatly reduce the possibility of injury. Moreover, in order to document and prove that these safety functions are implemented and tested fully and correctly, traceability is critical.

Maintaining traceability records on any sort of scale requires automation. This is particularly important in a CI/CD pipeline since manual maintained traceability would slow down each iteration. Application life cycle management tools include requirements management capabilities that are mature and tend to be the hub for traceability.

Integrated software testing tools can complete the verification and validation of requirements by providing an automated bidirectional traceability to the executable test case, which includes the pass or fail result and traces down to the source code that implements the requirement.

Parasoft integrates with market-leading requirements management and Agile planning systems like Intland, codebeamer, Polarion from Siemens, Jama Connect, Atlassian Jira, CollabNet, VersionOne, and TeamForge.

As shown in the image below, each of Parasoft's test automation tools, C/C++test, Jtest, dotTEST, SOAtest, and Selenic, support the association of tests with work items defined in these systems. That includes requirements, stories in IT, defects, test runs, test cases, and more. Traceability is managed through a central reporting and analytics dashboard, Parasoft DTP.

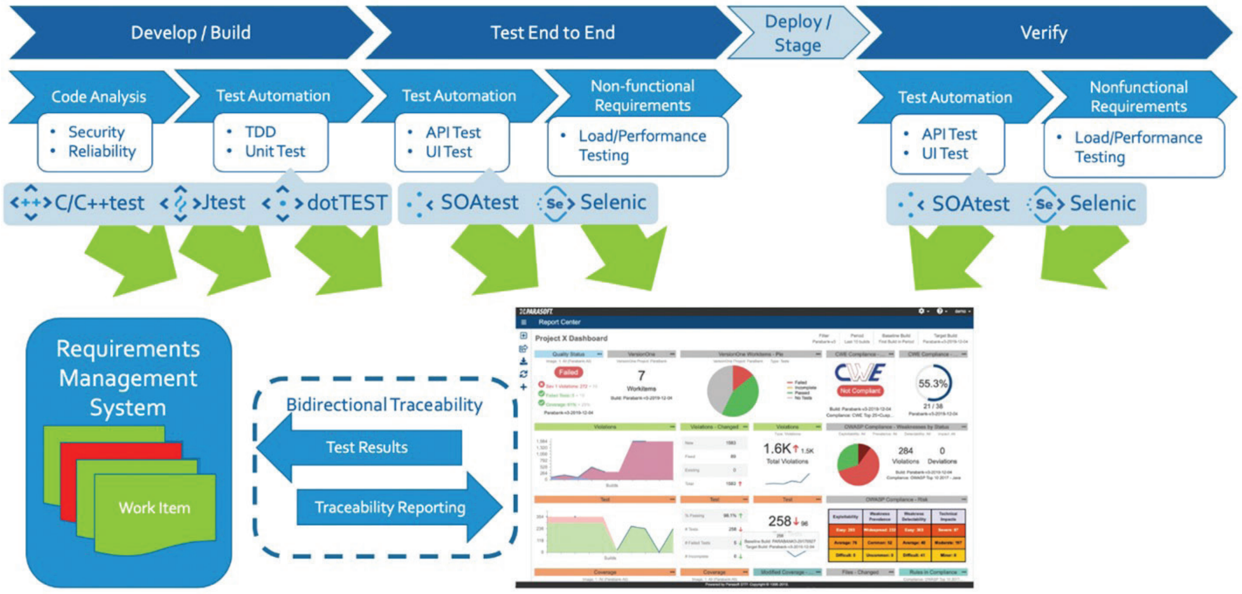
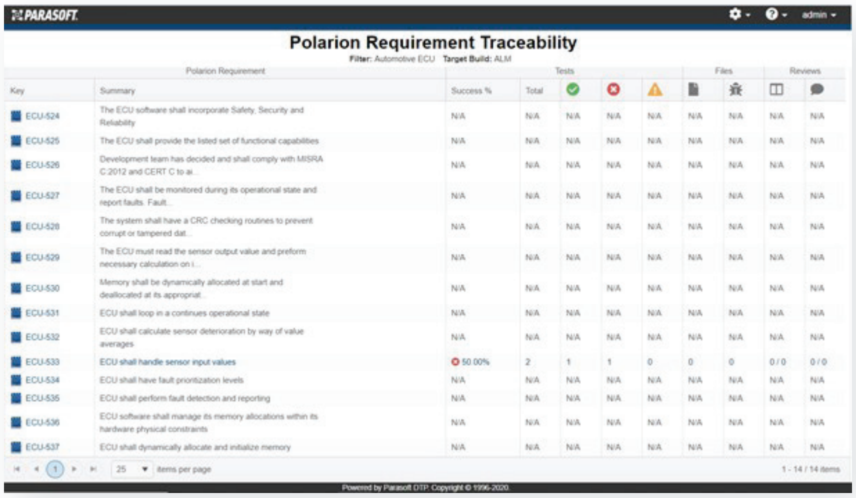


Figure 6:
Bidirectional traceability from work items to test cases and test results. Traceability reports are displayed, and results are sent back to the requirements management system.

Parasoft DTP correlates the unique identifiers from the management system with static analysis findings, code coverage, and test results from unit, integration, and functional tests. Results are displayed within traceability reports and sent back to the requirements management system. They provide full bidirectional traceability and reporting as part of the system's traceability matrix.

The traceability reporting is highly customizable. The following image shows a requirements traceability matrix template that traces to the test cases, static analysis findings, source code files, and manual code reviews.



Polarion Requirement Traceability

Filter: Automotive ECU **Target Build:** ALM

Polarion Requirement		Tests					Files		Reviews	
Key	Summary	Success %	Total	✓	✗	⚠	📄	🐞	◫	💬
ECU-524	The ECU software shall incorporate Safety, Security and Reliability	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ECU-525	The ECU shall provide the listed set of functional capabilities	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ECU-526	Development team has decided and shall comply with MISRA C:2012 and CERT C to ai...	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ECU-527	The ECU shall be monitored during its operational state and report faults. Fault...	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ECU-528	The system shall have a CRC checking routines to prevent corrupt or tampered dat...	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ECU-529	The ECU must read the sensor output value and preform necessary calculation on i...	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ECU-530	Memory shall be dynamically allocated at start and deallocated at its appropriat...	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ECU-531	ECU shall loop in a continues operational state	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ECU-532	ECU shall calculate sensor deterioration by way of value averages	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ECU-533	ECU shall handle sensor input values	✗ 50.00%	2	1	1	0	0	0	0 / 0	0 / 0
ECU-534	ECU shall have fault prioritization levels	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ECU-535	ECU shall perform fault detection and reporting	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ECU-536	ECU software shall manage its memory allocations within its hardware physical constraints	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ECU-537	ECU shall dynamically allocate and initialize memory	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

1 | 25 items per page | 1 - 14 / 14 items

Powered by Parasoft DTP. Copyright © 1996-2020.

Figure 7:
Requirements traceability matrix template.

The bidirectional correlation between test results and work items provides the basis of requirements traceability. Parasoft DTP adds test and code coverage analysis to evaluate test completeness. Maintaining this bidirectional correlation between requirements, tests, and the artifacts that implement them is an essential component of traceability.

Bidirectional traceability is important so that requirement management tools and other life cycle tools can correlate results and align them with requirements and associated work items.

MONITOR COMMITS MADE INTO THE SOFTWARE REPOSITORY

Continuous quality in a CI/CD pipeline requires monitoring of all inputs into the software build. A good way to do this is to monitor commits made into the software repository. In other words, when developers check in their code after making additions or other changes, it triggers the CI pipeline, resulting in a compile, build, and test cycle. If code doesn't meet coding standards or if tests fail, the code/branch is not merged into the master branch. This maintains code quality at all times for the master branch.

Developers facing failed coding rules or SAST tool warnings will have to fix or justify the deviation at the time of writing the code. This documentation trail is critical for later audit preparation. Plus, performing this early detection and documentation is the easiest and most efficient point in the cycle. Similarly, with failed tests, developers need to document fixes to either the code or the tests to confirm verification and validation.

Trying to use SAST tools or code standard checks on a large body of code all at once is a tedious and time-consuming task. Instead, introducing quality control at the earliest stages of development, built into a developer's workflow, lessens the impact of tool adoption, and increases quality and security.

IMPROVING SECURITY WITH DEVSECOPS

It's worth mentioning that DevOps and DevSecOps methodologies share the use of automation and continuous processes for establishing collaborative cycles of development. While DevOps prioritizes delivery speed, DevSecOps shifts security to the left, which is more important in software that's classified as embedded safety- and security-critical.

DevSecOps represents a shift in software development processes that stresses a significant focus on security with collaboration between end users and developers. Software test automation can enhance these connections and help organizations accelerate secure software development.

Software test automation plays an important role but it's just one piece of the DevSecOps puzzle. Testing is often one of the greatest constraints in the SDLC so optimizing security processes that allow testing to begin earlier—and shrink the amount of testing required—has a significant impact on the security of the software and development efficiency.

ACCELERATE SECURITY WITH CI/CD

Modern DevSecOps initiatives require the ability to assess the risks associated with a release candidate—instantly and continuously. Continuous testing within the CI/CD pipeline provides an automated, unobtrusive way to obtain immediate feedback on the security risks associated with a software release candidate. It guides development teams to meet security requirements and helps managers make informed trade-off decisions to optimize the release candidate.

Continuous testing delivers a quantitative assessment of risk as well as actionable tasks that mitigate risks before they progress to the next stage of the SDLC. The goal is to eliminate meaningless activities while improving quality and security and driving development towards a successful release.

SUMMARY

Continuous integration and delivery has a role to play in medical device development. Migrating a waterfall process to CI/CD and Agile development pays off with risk reduction and quality and security improvements. Security is top of mind for medical device developers and CI/CD is an enabler for DevSecOps, which introduces security requirements and controls into all aspects of the pipeline.

Containers are a perfect fit with CI/CD. They support rapid deployment and portability across different host environments with support for versioning and centralized control. Containerized development environments are important for secure development in a DevSecOps pipeline since it's possible to provide a reproducible application environment with built-in security controls.

Testing is by far the most time and resource consuming activity in medical device development. Continuous testing is a necessary component of a well-oiled CI/CD pipeline and provides a framework to shift testing earlier in the life cycle.

With the right application of automation and focus on the highest risk areas of the application, it's possible to streamline testing to be less of an inhibitor in continuous processes. Continuous testing requires tool support for automation and optimization. Tools that drive larger code coverage, smart test execution, and bidirectional traceability further improve continuous testing.

TAKE THE NEXT STEP

Request a demo to see how your medical device software development organization can streamline testing with continuous integration and continuous delivery.

ABOUT PARASOFT

Parasoft helps organizations continuously deliver quality software with its market-proven, integrated suite of automated software testing tools. Supporting the embedded, enterprise, and IoT markets, Parasoft's technologies reduce the time, effort, and cost of delivering secure, reliable, and compliant software by integrating everything from deep code analysis and unit testing to web UI and API testing, plus service virtualization and complete code coverage, into the delivery pipeline. Bringing all this together, Parasoft's award winning reporting and analytics dashboard delivers a centralized view of quality enabling organizations to deliver with confidence and succeed in today's most strategic ecosystems and development initiatives — security, safety-critical, Agile, DevOps, and continuous testing.