

The Strategic Imperative of Automated Testing in Medical Devices





\$5.23B

expected MedTech
market growth by 2032¹

Introduction

As medical technology advances, the need for faster product development with strict compliance is becoming more urgent. This convergence highlights the importance of investing in automated testing – an essential strategy for organizations dedicated to producing high-quality, safe, and effective medical devices. Automated testing goes beyond being just a tool; it's a game changer that helps your organization stay ahead of rapid technological shifts while meeting rigorous regulatory standards. With the market expected to grow from USD \$10.6 billion in 2023 to USD \$15.83 billion by 2032,¹ automated testing is set to play a pivotal role in MedTech innovation, enhancing both efficiency and compliance.

In this paper, we'll explore how automated testing can be the key to your organization's success – not only in navigating market dynamics and regulatory challenges, but in delivering safe, effective products that enhance patient outcomes and elevate the clinician and caregiver experience.

¹ Straits Research, [Medical Device Testing and Certification Market Size Report](#), July 12, 2024.

Accelerating MedTech Innovation with Comprehensive Automated Testing

The medical device industry faces intense pressure to innovate quickly while upholding the highest standards of safety and compliance. Automated testing has emerged as a critical solution. It transforms traditionally lengthy testing cycles into streamlined processes that can keep up with the fast pace of modern MedTech development and improves product quality at the same time.



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Automated testing eliminates the need to analyze what needs to be tested for any given change because it is faster simply to run the whole test suite again. And in edge cases and unusual scenarios that do require some manual testing, automating the bulk of the testing frees up critical resources to enhance whatever manual testing is required.

Historically, full testing cycles for medical devices could take up to six months – a timeline that's no longer feasible in today's rapid environment. Automated testing slashes this timeframe to weeks or even days, enabling your organization to bring innovations to market at unprecedented speed. This acceleration is vital as the lifecycle of medical products continues to shorten, driven by relentless technological advancements and rising expectations among patients, caregivers, and clinicians.

The integration of AI-powered accelerators and cloud technologies into automated testing frameworks has further amplified the efficiency and effectiveness of the testing process. AI-driven tools enhance verification and validation by identifying issues that might elude even the most meticulous human testers. These tools not only improve the accuracy of tests but also enable continuous improvement through iterative learning, ensuring that each test cycle becomes more refined than the last.

Benefits of automated testing

- Streamlines testing cycles and processes
- Reduces re-testing analysis time
- Frees up critical resources
- Enables faster time-to-market
- Improves accuracy with AI-driven tools

Ensuring compliance

Beyond speed and efficiency, automated testing is indispensable for ensuring compliance with the complex regulatory frameworks governing medical devices. These frameworks demand comprehensive verification processes to confirm that devices are safe, effective, and reliable. Automated testing frameworks are meticulously designed to adhere to these standards, conducting comprehensive tests that leave nothing to chance. This rigorous approach not only minimizes risks but also builds trust with regulatory bodies, which is crucial for securing the approvals necessary to bring products to market.

Moreover, automated testing frameworks offer consistency and repeatability — two essential factors in the regulated medical device space. While manual testing is essential, it demands careful planning and strict control to achieve consistency and repeatability, making it a labor-intensive task. Automated testing, on the other hand, naturally delivers these qualities, executing tests precisely and producing results that are consistently reliable. This inherent consistency is crucial not just for compliance, but also for safeguarding product integrity over its entire lifecycle, significantly lowering the chances of variability and human error that manual processes may introduce.

For your organization, investing in automated testing is not just about meeting today's demands; it's about future-proofing your operations. As the regulatory landscape continues to evolve, having a robust automated testing framework in place ensures that your products remain compliant with new standards without the need for constant reinvention. This adaptability is key to staying ahead in a competitive market.



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Ensuring Quality and Compliance in MedTech through **Advanced Automated Testing**

The stakes are incredibly high in the regulated world of medical devices. Ensuring that every product not only meets but exceeds regulatory standards is essential for protecting patient safety, maintaining trust with regulatory bodies, and securing a competitive edge in the marketplace. Advanced automated testing plays a pivotal role in achieving these goals, offering your organization the ability to ensure consistent, repeatable processes that align with the most stringent regulatory requirements.

A key benefit of automated testing is the automatic generation of critical documentation, including test plans, reports, coverage analyses, and traceability records. These documents are vital for regulatory submissions and are integral to the Design History File (DHF). Automation streamlines this process, cutting down on time and costs and freeing engineers from the tedious task of manually compiling reports. This approach not only guarantees consistent, accurate documentation but also bolsters quality assurance processes and supports future product improvements, enhancing both compliance and efficiency across your organization.

Automated testing frameworks are designed to provide comprehensive verification across all stages of product development, significantly reducing the burden associated with manual testing. In a highly regulated environment, even the smallest oversight can lead to substantial consequences, from delayed product launches to costly recalls or, worse, patient harm. By automating the verification process, you can ensure that every aspect of your product is thoroughly tested, with any potential issues identified and resolved long before the product reaches the market.

Automated testing ensures a level of consistency that is crucial for regulatory compliance.

Consistency and Repeatability

Consistency and repeatability are the hallmarks of a robust automated testing framework. Unlike manual testing, which can vary from one execution to another, automated testing ensures that every test is conducted in exactly the same way, every time. This level of consistency is crucial for regulatory compliance, particularly in the medical device industry, where precise documentation and traceability are required. Automated testing frameworks not only ensure consistency but also generate detailed reports instantly, speeding up the process, reducing costs, and eliminating the risk of human error in documentation.



Automated testing can be designed to manage and analyze vast amounts of data residing in various locations.

Advanced automated testing frameworks also enhance the repeatability and consistency of tests, which are essential in the medical device sector. Automated tests can be run repeatedly across a full range of parameters, from “acceptable” to “not allowed,” ensuring consistent, reliable results and confirming that your product handles all scenarios as required. This repeatability is crucial for maintaining product integrity and for meeting the rigorous demands of regulatory bodies, which often require multiple rounds of testing and validation.

One of the key advantages of automated testing is that it can be designed to manage and analyze vast amounts of data residing in various locations. Medical devices today are more complex than ever, often involving multiple components that interact across various platforms, including embedded systems, mobile devices, and cloud-based applications. Managing the data generated by these components is a significant challenge, but it is one that automated testing frameworks are well equipped to handle. By integrating test strategies and verification solutions across all platforms, automated testing ensures comprehensive coverage, confirming the security and reliability of your devices.

Security Testing

Security is another critical aspect that automated testing addresses. In today’s connected world, medical devices are increasingly vulnerable to cyberthreats, making it imperative that they are thoroughly tested for security vulnerabilities. Automated testing frameworks can simulate a wide range of attack scenarios, ensuring that your devices are not only functional but also secure. This level of testing is essential for protecting patient data and maintaining compliance with regulations like the General Data Protection Regulation (GDPR) and the Health Insurance Portability and Accountability Act (HIPAA).

At this stage, it’s clear that automated testing is indispensable for maintaining the quality and compliance of medical devices. However, not all automated testing frameworks are created equal. The next section will introduce GlobalLogic’s DeviceSure solution, a comprehensive testing solution that not only meets but also exceeds the demands of today’s regulated medical device market. DeviceSure provides your organization with the advanced tools and expertise needed to ensure that your products are safe, effective, and ready for market — delivering peace of mind in an industry where there is no room for error.

Why You Should Make a Strategic Investment in Automated Testing for Long-Term MedTech Success

With the pressing need for innovation, and with regulatory demands in constant flux, investing in automated testing has become a necessity rather than an option. Though the up-front cost of automated testing might seem high, the long-term return on investment (ROI) is undeniable. Our advisory services can demonstrate this ROI, helping you secure the budget to drive your organization toward lasting success and industry leadership in MedTech.

Manual testing often demands a rushed, large-scale effort under tight deadlines — surge capacity — that stresses teams and increases risk. In contrast, automated testing allows continuous testing throughout development, easing the workload, reducing last-minute scrambles, and eliminating bottlenecks. Moreover, automated tests can be run repeatedly with minimal intervention, significantly reducing the costs associated with testing cycles. GlobalLogic's automation framework also allows for faster and more frequent testing, accelerating time-to-market — a critical advantage in a competitive industry where being first can make all the difference. By cutting down the time and costs involved in product development, automated testing helps your organization stay ahead of the competition while maintaining high standards of quality and compliance.



Agile Development

Beyond cost savings, automated testing fosters a more agile development process. The MedTech industry is characterized by rapid technological advancements and ever-changing regulatory requirements. GlobalLogic DeviceSure's automated testing framework enables your organization to quickly adapt to these changes, whether they involve new regulatory guidelines, shifts in market demand, or technological updates. This agility is crucial for maintaining compliance and staying competitive, without the need to constantly overhaul your testing processes.

Automated testing also plays a vital role in enhancing product quality. These frameworks are designed to detect and address potential issues early in the development process before they escalate into costly problems.

This proactive approach not only improves the reliability of your products but also enhances their safety and effectiveness. In the highly regulated MedTech industry, where product failures can have severe consequences, ensuring the highest level of quality is essential.

Investing in automated testing also means investing in your organization's capacity to innovate. Automation frees up valuable resources — both time and talent — that can be redirected toward more strategic activities, such as developing new products or exploring emerging technologies. By automating routine testing tasks, your engineers can focus on innovation, driving the development of cutting-edge medical devices that meet the evolving needs of patients and Healthcare providers.



Automate routine testing tasks
and let your engineers focus
on innovation to improve lives.



Regulatory Compliance

The benefits of automated testing with GlobalLogic's DeviceSure services extend to regulatory compliance as well. Medical device manufacturers must navigate a complex web of regulations, and automated testing frameworks are specifically designed to ensure adherence to these standards. Automation allows for faster delivery of products that meet stringent regulatory requirements, providing the necessary documentation for product approvals and market entry. This reduces the risk of non-compliance, builds confidence with regulatory bodies, and streamlines the approval process by providing comprehensive documentation that demonstrates thorough testing in line with IEC62304, an engineering standard recognized by regulators.

GlobalLogic's DeviceSure solution exemplifies the strategic value of investing in automated testing. DeviceSure offers a holistic approach to software assurance, covering everything from chip to cloud. By integrating proven test strategies, automation frameworks, and verification solutions, DeviceSure ensures that all phases of your device development are robust, compliant, and efficient. This comprehensive solution not only enhances product quality but also improves market responsiveness, positioning your organization as a leader in the MedTech industry.



Forging the Path Forward

In the fast-evolving world of MedTech, your organization's commitment to delivering better outcomes — for patients, caregivers, and clinicians — is what truly distinguishes you. Embracing automated testing is more than just a technological upgrade — it's a declaration of your dedication to quality, safety, and innovation. The decisions you make today about your testing strategies will shape the future of your products, your market position, and, ultimately, patient outcomes. As technology continues to advance, so must your approach to ensuring that every device you bring to market not only meets but exceeds expectations.

Investing in GlobalLogic's DeviceSure services and automated testing is an investment in the future of Healthcare — where your organization leads with confidence, delivering solutions that transform lives with the reliability and trust that only cutting-edge technology can provide. The future of MedTech belongs to those ready to automate, innovate, and elevate the standards of care.

Learn more at
globallogic.com/healthcare.

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