



MEDSEC

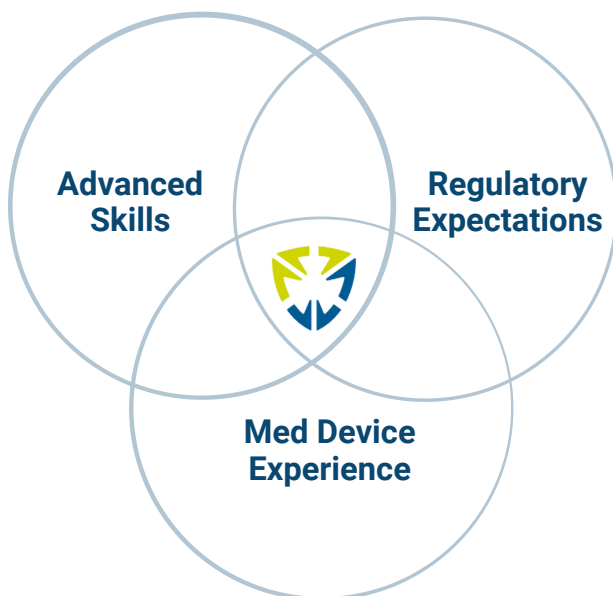
Specialized Solutions for Medical Device Penetration Testing

WHAT IS PEN TESTING?

Penetration testing, or pen testing, is a type of ethical hacking that simulates a cyberattack on a system or device, with the purpose of evaluating its security.

Experienced ethical hackers look at a system from a different perspective than do the engineers who designed it. They will look for opportunities to misuse the system and circumvent the controls put in place to achieve their desired result.

Our pen testers have 3 unique qualities that set them apart:



WHY DO PENETRATION TESTING? ✓

Medical device manufacturers are increasingly grappling with the challenge of cybersecurity threats and hackers. Penetration testing of medical devices has become an expectation of both regulators and customers as it tests the cybersecurity robustness by applying realistic hands-on hacking scenarios by an experienced hacker. Finding the right ethical hacker, with extensive experience in medical devices is difficult.

The robustness of a penetration test is directly proportional to the skill of the tester. This is important because the utility of a pen test is two-fold:

1. It serves to inform the design team on the adequacy of security controls.
2. Regulatory submissions also rely on this testing to provide evidence of a properly secured device.

A poorly executed pen test fails to meet these goals.

HOW ARE MEDSEC PEN TESTS? ✓

MedSec has carefully selected and developed their pen testers to specialize in medical devices. Our penetration testers are selected for their expertise in medical devices, including embedded systems, SaMD, infusion pumps, robotics, implantable medical devices, external defibrillators, physiological monitors, imaging systems, insulin delivery systems, endoscopy devices, immunodiagnostic devices, and wireless communications.

MedSec is also uniquely qualified to provide you with a pen test report that is designed specifically to meet the rigorous demands of global regulators. The US FDA, in particular, has very specific expectations in both their report content as well as how they expect this testing to be scoped to include the entire medical device system.

Trust MedSec to help you meet this bar.



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OTHER SERVICES



COMPLIANCE

- Maturity Assessments
- Submission and Pre-Submission Support
- SOP Procedural Support
- Product Classification



RISK MANAGEMENT

- Security Risk Management
- Threat Modeling



TRAINING & WORKSHOPS

- Product Security Program Review/Program Maturity Workshop
- Threat Modeling
- Security Risk Management
- Incident Response Tabletop Exercises (TTX)
- Secure Design
- Postmarket Security
- Cybersecurity Standards and Regulatory Review
- Digital Health Security
- Interoperability



ADVISORY & STAFF AUGMENTATION

- Compliance
- Technical
- Virtual PSO



TECHNICAL OFFERINGS

- Penetration Testing
- Architectural Design Review
- Source Code Analysis
- SBOM

IT'S EXPECTED !

Penetration tests are now an expected deliverable for U.S. FDA regulatory submissions. Many other countries also expect this type of testing.

MedSec closely follows the regulatory expectations and trends to ensure that our testing aligns with them.