



MEDSEC

Cybersecurity for Medical Device Manufacturers

We'll meet you where you are.

We specialize in providing a comprehensive cybersecurity program tailored to the unique needs of our clients. With a deep understanding of the technical and compliance challenges you face, we empower you to establish an effective cybersecurity program by delivering what you need, when you need it.



Engagement & Subscription Programs

We support on-going security efforts and collaboration with industry experts and peers.

The MedSec Community (MC)

Join the community and engage with MedSec leaders to discuss the most relevant regulatory intelligences topics.

Your subscription includes:

- Bi-Monthly Regulatory Intelligence Session
- Review of new and emerging global regulatory issues

MedSec Partner Program (MPP)

A subscription program that gives you access to our team when you need it. You receive a set number of support hours per month for answering questions, strategizing your approach, or maturing your program.

Your subscription includes:

- MedSec Community (MC) Offerings
- Advisory Hours
- Corporate and Executive Briefings
- Discounts on Other Services
- Newsworthy Updates
- Access to Webinar Recordings



Security Risk Management Support Programs

We enable your team to confidently create submission-ready document for your products.

Accelerator Program

Accelerate the development of your products and build internal bench strength in the process. Offerings include Security Risk Management, Threat Modeling, or an aligned combination of both.

Threat Modeling



Adopt

SOPs, templates, and work instructions



Learn

Live training and self-directed learning modules



Fly

Build your own documents with CoPilot support

Security Risk Management



Technical Services

We assess the unique security aspects of your medical devices and take your cybersecurity program to the next level.

Our services include:

- Penetration Testing
- Threat Model Report
- Design Reviews for Security
- Technical Advisory Support

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Compliance

We support your teams with their next submission, responding to deficiencies, or aligning your product security program with compliance expectations.

Our services include:

- Mock Submission
- Regulatory Submission Support
- Presubmission Development and Support
- Deficiency Response Support
- IEC 81001-5-1 Readiness Audit
- Postmarket Security Program Development and Support
- Coordinated Vulnerability Disclosure Program Stand-up including SOP, Policy Language, Training, and Templates

Templates to help you accelerate your program:

- Secure Design SOP aligned with IEC 81001-5-1
- Cybersecurity Management Plan
- Vulnerability Management SOP
- Secure Product Development Framework (SPDF) aligned with IEC 81001-5-1

*Comply with
ConfidenceSM*

Expanded
Offerings!

Cybersecurity remains one of the biggest challenges for medical devices across the globe. Regulators continue to raise the bar to address this ever-growing threat.

MedSec is experienced in addressing regulatory and quality expectations across the globe.



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