BLUE GOAT CYBER

Complete Medical Device Cybersecurity

Who We Are

At Blue Goat Cyber, we specialize in medical device cybersecurity. We ensure manufacturers meet FDA, EU MDR, and global regulatory compliance while protecting patient safety. With decades of experience, we help MedTech innovators secure their devices against cyber threats and streamline regulatory approval.

✔ FDA cybersecurity compliance experts

✔ 100% success rate in FDA cybersecurity submissions

✔ Fixed-fee pricing with unlimited retests

✔ Industry leaders in penetration testing, SBOM management, & risk assessments

The Problem We Solve

Medical device manufacturers face increasing cybersecurity challenges:

- Stricter FDA cybersecurity requirements
- Growing cyber threats targeting medical devices.
- Access to professional guidance from seasoned agents.
- Regulatory deficiencies leading to delays & lost revenue.
- Lack of in-house cybersecurity expertise.

Without proper cybersecurity, your device could be vulnerable to attacks, regulatory rejection, or costly delays.

We ensure your cybersecurity meets FDA expectations—preventing delays and securing approval.

How We Help

We guide you through every phase of medical device cybersecurity, ensuring compliance and security from design to postmarket.

Our Services

✔ Premarket Cybersecurity for FDA Submission

✔ Medical Device Penetration Testing

✔ Threat Modeling & Risk Assessments

✔ Cybersecurity Documentation for FDA & EU MDR Compliance

✔ Postmarket Security Monitoring & SBOM Tracking

We don't just test—we ensure compliance, risk mitigation, and ongoing security.

Why Blue Goat Cyber?

Unlike traditional cybersecurity firms, we focus *exclusively* on medical device security. Our deep industry knowledge and regulatory expertise set us apart.

Traditional Cybersecurity Firms:

- 🚫 General IT security testing.
- 🚫 No regulatory expertise.
- 🚫 Limited postmarket support.
- 🚫 Hourly-based pricing with extra fees.

Blue Goat Cyber:

- ✓ FDA & MedTech cybersecurity specialists.
- ✓ 100% focused on regulatory approval & patient safety.
- ✓ Fixed-fee pricing with unlimited retests.
- ✓ Continuous postmarket support.

We don't just find vulnerabilities—we ensure your device is FDA-ready.

FDA APPROVED

Proven Success

We've helped industry leaders secure FDA approval and protect their devices.

Recent clients include: bioMérieux, Inogen, Natera, Nova Biomedical

100% FDA submission success rate.

Accelerating time to market while ensuring security & compliance.

Let's Get Started

Don't risk cybersecurity deficiencies delaying your approval. Work with experts who know how to secure medical devices while meeting FDA expectations.

Schedule a Discovery Session ->