

Medical Device Cybersecurity

Healthcare solutions

In today's data-driven, connected healthcare ecosystem, exposure to cyber risks is a growing threat. Medical devices and their maintenance processes must be cyber-resilient to ensure patient safety and performance throughout their lifespan

Healthcare organizations own a vast amount of personal data, generated by diagnosis and therapy paths and, more and more, by connected medical devices.

Smart devices can be entry points for cyberattacks, and their long lifecycles might result in them falling behind the rapid advancements of digital technologies as well as the shifts in the cyberthreat landscape.

Recent regulations, such as the FDA "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" and the updated EU Cybersecurity Strategy have strengthened the call to action for medical manufacturers toward increased security protection in devices.

With deep cybersecurity knowledge and expertise, Flex ensures that your products meet the highest security standards.



Support in defining the security and privacy requirements of the entire ecosystem



Risk-based design approach during the whole lifecycle



UI/Alignment to international cybersecurity standards



Integration of all steps in our QMS to support product submission



Best practices for secure development and testing: GDPR/HIPAA analysis and compliance



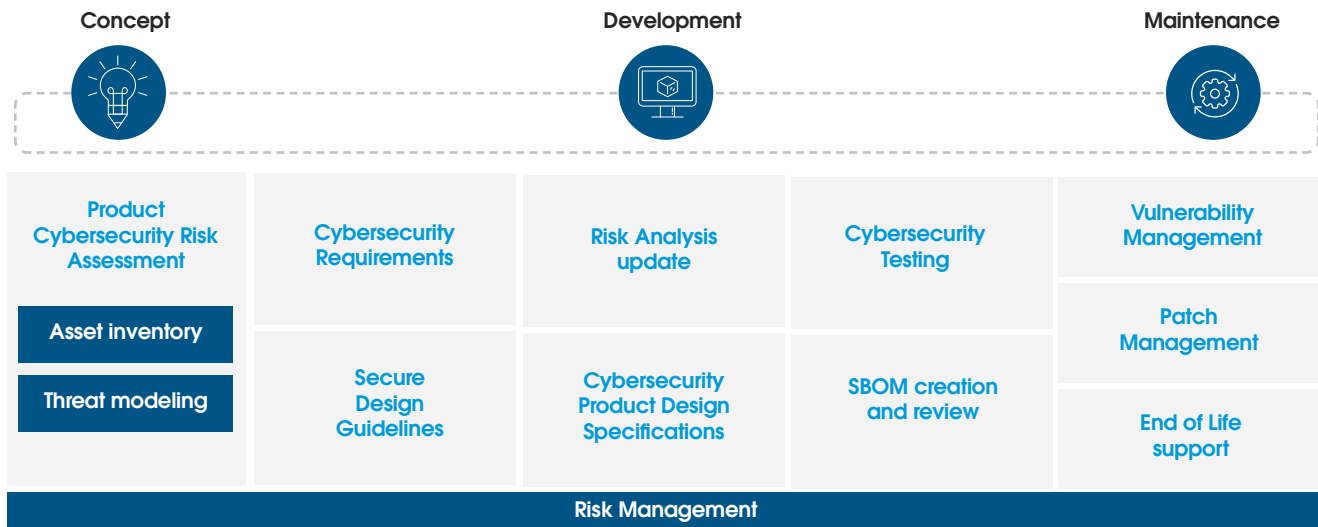
Support during maintenance and value analysis

Flex product security framework

Flex can handle product cybersecurity throughout the entire product lifecycle, from requirement definition to long-term management.

Our approach includes a secure product development lifecycle embedded in our Quality Management System, which is continuously maintained with the latest regulations and industry best practices.

Product design relies on secure guidelines and cybersecurity risk management processes, including verification & validation activities, such as reviews and cybersecurity security testing. In addition, Flex supports the creation of a SW Bill Of Material (SBOM), its validation via SW Composition Analysis, and the related maintenance activities: vulnerability monitoring, end-of-life support, and patch management.



IN-MARKET AND LEGACY DEVICES

Flex can help analyze in-market products under the cybersecurity lens, identifying potential legacy technology and regulatory gaps, which might affect the product or its accompanying documentation.

INTERNAL AWARENESS AND TRAINING

Recognizing that cybersecurity is a shared responsibility, Flex can also support you in cultivating internal awareness, providing tailored regulatory guidance and product security training.

Partner with Flex and stay ahead of the curve

The healthcare solutions team at Flex can help you reach the full potential of connected devices and related technologies to address emerging challenges and seize new opportunities in patient care. Our cross-industry expertise and 35 years' experience in the design, development, and manufacture of medical products help you navigate increasing complexity across the value chain while optimizing operations. Our comprehensive portfolio of product lifecycle services enables us to create your medical products at scale with increased quality, productivity, and speed. With 21 medical manufacturing sites in four regions and 13 countries, our global footprint gives you the ability to quickly adjust to changing regional, trade, and manufacturing dynamics.



Let's collaborate to create the extraordinary in connected, secure medical devices

For more information, visit flex.com/healthcare



Flex (Reg. No. 199002645H) is the manufacturing partner of choice that helps a diverse customer base design and build products that improve the world. Through the collective strength of a global workforce across 30 countries and responsible, sustainable operations, Flex delivers technology innovation, supply chain, and manufacturing solutions to various industries and end markets.