QNX

Medical Devices

The power to save lives

More Than Ever, Medical Devices Need a Solid Software Foundation

Modern medical devices depend on software to sense, analyze, and act in clinical environments where timing, certainty, and accuracy directly affect patient safety. An unfaltering software foundation, built for real-time performance, ensures that medical devices can operate as designed, even under the most demanding and unpredictable conditions.

Without a proven software foundation, medical devices are more vulnerable to timing issues, security weaknesses, and unsafe system behavior that may lead to service interruptions, incorrect results, or unintended therapy delivery. These risks can harm patients or operators and increase organizational exposure to recalls, compliance findings, and post-market interventions.

QNX lays the foundation for medical devices with a secure, deterministic, pre-certified, real-time operating system that supports manufacturers throughout the full product lifecycle as required by regulatory authorities.

Explore how QNX enables each phase in the product lifecycle as defined by the FDA:

Device Discovery and Concept

- Reduce Rework
- Shorten Development Cycles
- Ensure Continuity From Concept to Market

Manufacturers have immediate access to QNX foundational software to begin early product discovery and development. QNX software is readily accessible via the QNX Everywhere initiative which allows free non-commercial access and use. By taking advantage of this program, you will be building on the same stable, real-time software platform that you can later deploy commercially. This enables your teams to easily scale-up and build on a secure, deployable foundation from day one, eliminating significant rework and retooling that is typical from product discovery to product release. Only a licensing change is required prior to moving to commercial release.

Preclinical Research–Prototype

- Optimize Early
- Strengthen Stability
- Simplify Development and Deployment

By eliminating foundational layer retooling or configuration management, your teams can focus on early optimization of your medical device which will provide compound benefits throughout your development iterations. Building early with QNX immediately leverages the advantages of the QNX microkernel architecture, maximizing the gains for your product. This will lead to direct and indirect cost savings in areas such as boot time optimization, cybersecurity hardening, and long-term maintenance

planning—all can be proactively addressed right from early design to boost the benefits and savings. Additionally, the QNX Professional Services team can be an extension of your workforce to further optimize ramp-up time and gain the perspective of QNX experts who have multiple decades of experience building safety-critical systems in regulated environments.

Pathway to Approval & Regulatory Review

- Build on Recognized Safety Standards
- Simplify Regulatory Review
- Accelerate Innovation

Regulators globally recognize and utilize the IEC 62304 standard. QNX's pre-certifications, including IEC 62304 Class C, provide assurance that the software foundation used in your product can meet the highest safety levels recognized by regulatory bodies around the world. Reducing regulatory uncertainty allows manufacturers to innovate differentiated clinical functionality rather than fixate on justifying core platform safety.

Post-Market Safety Monitoring

- Secure by Design
- Future-proof Architecture
- Supported by Experts

QNX is built on a microkernel architecture with modular, compartmentalized design. This approach supports controlled, isolated updates during your product's lifetime, aligning with regulatory requirements. Additionally, this architecture is secure by design—it reduces attack surfaces, simplifies updates, and strengthens your device's long-term cybersecurity posture. QNX has a security-first culture, grounded in certified, secure development practices which translates to confidence during your entire product lifecycle. And with the QNX Product Cybersecurity Team continuously monitoring for emerging risks, new CVEs, and threat intelligence evolution, manufacturers gain both stronger protection and more bandwidth to innovate.

About QNX

QNX, a division of BlackBerry Limited, enhances the human experience and amplifies technology-driven industries, providing a trusted foundation for software-defined businesses to thrive. The business leads the way in delivering safe and secure operating systems, hypervisors, middleware, solutions, and development tools, along with support and services delivered by trusted embedded software experts. QNX® technology has been deployed in the world's most critical embedded systems, including more than 275 million vehicles on the road today. QNX® software is trusted across industries including automotive, medical devices, industrial controls, robotics, commercial vehicles, rail, and aerospace and defense. Founded in 1980, QNX is headquartered in Ottawa, Canada.

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