TOP THREE CHALLENGES FOR MEDICAL DEVICE DEVELOPERS

Medical device engineers are driving healthcare innovation while meeting development challenges.

By Tony Crupi, August 2024

New technology and modern development methods are driving medical device advances and innovation that is raising the quality and level of patient care. This has not been without its challenges: Medical technology infrastructure must meet complex regulatory requirements, mitigate cybersecurity threats, adapt to a constantly evolving hardware landscape, and take advantage of the opportunities that cloud computing can deliver to customers and patients.

DRIVING MEDICAL DEVICE ADVANCES AND INNOVATION

Innovation in medical devices are being driven by advances in cloud computing and AI, which are enabled through more pervasive network connectivity. Medical devices are much more connected today than they have been in years past. Whether it's 5G wireless, traditional LAN-based networks, or Bluetooth connectivity, they're ultimately connected to the cloud to deliver value-added services to their customers. OEMs can vertically integrate data and process flows across related but separate solutions, as well as leverage the cloud to keep devices secure and up to date. We're seeing machine learning (ML) and artificial intelligence (AI) being used at the edge and in the cloud to improve patient outcomes and positively benefit employee productivity.

This connectivity goes beyond the large major medical equipment OEMs communicating over hospital system networks. It also includes smaller medical and health devices, such as wearables and in-home health care devices. A good example is a continuous glucose monitor (CGM) that communicates blood glucose information to an app on a patient's phone, which uses predictive analytics to determine when and how much insulin should be administered through a wearable insulin pump — essentially creating an artificial pancreas. This connectivity provides great advances in medical care and diagnostics but also introduces new cybersecurity considerations.

ABOUT TONY CRUPI

Tony Crupi is the senior director of Field Engineering for the Americas and EMEA sales regions at Wind River®. He leads a team focused on empowering companies in the medical, industrial controls, automotive, and telecom sectors to build and operate intelligent, software-driven products more rapidly, securely, and cost-effectively.

With more than 25 years of hands-on experience, he specializes in architecting safe, secure, and high-performance intelligent software systems.

Let's discuss the top three challenges that make up this overall challenge.

Challenge 1: Regulatory Requirements

First, regulatory requirements. Recently, the Food and Drug Administration (FDA) added cybersecurity requirements to the regulations for medical devices. They now constitute the number-one challenge. As a prerequisite for FDA approval, device manufacturers need to share with the FDA how they are securing their devices. Additionally, they must detail how the company will respond to cybersecurity incidents in the field.

Wind River is working with our medical device customers to address these requirements by providing secure and performance-oriented operating platforms, the system (RTOS), Yocto Linux–based Wind River Linux, and the Zephyr open source solution for microcontrollers. Additionally, Wind River customizes those platforms for the specific hardware and software needs of the OEM and often maintains the platforms for its customers to ensure that the latest relevant common vulnerabilities and exposures (CVEs) are addressed on an ongoing basis. Finally, Wind River works with customers to address other regulatory requirements, such as IEC 62304 certification, and implement modern cloud-based DevSecOps tools and processes to build in security best practices from the outset.

Challenge 2: Hardware Support

The broad array of hardware products for medical device development poses a significant challenge for developers. The extensive options for processors, semiconductors, motion controllers, sensors, and more require careful selection and evaluation. Considerable time and expertise are needed to identify the most suitable components. Next, integrating these diverse components into a cohesive medical solution introduces compatibility issues, differing communication protocols, and technical complexities, complicating the development process. And further increasing the challenge, developers must ensure that all hardware meets regulatory standards for safety and efficacy and is supportable for, usually, a decade or more.

Rapid technological advancements necessitate continuous learning and adaptation, straining resources and extending development timelines. For instance, the large choice of processors and GPUs with new AI, ML, and graphics capabilities adds to the complexity. It also creates challenges for the software system development driving the hardware components. Therefore, selecting the right operating systems, virtualization and containerization technologies, the application software, and modern development methods is crucial. Wind River has extensive expertise in providing a proven portfolio of system software, development services, and cybersecurity support that utilizes the latest hardware components.

Challenge 3: Cloud Integration

The utilization of cloud technology and services has grown tremendously over the last decade, and the medical and healthcare industries have become part of this technology change. Medical device developers face several challenges in integrating cloud technology and services in new devices. These challenges can be broadly categorized into regulatory, technical, security, and operational issues.

- **Regulatory:** The regulatory challenge when cloud technology is part of the solution is, as with the other device components, compliance with stringent requirements set by agencies such as the FDA (USA) and the EMA (Europe). Validation and documentation processes can be complex.

- **Technical:** Ensuring interoperability between different systems and platforms is a significant technical hurdle. Medical devices must seamlessly communicate with each other and with IT systems. The difficulty is achieving this given diverse cloud services and the need to function across network security boundaries.

- **Security:** Patient data, the operation of the medical device, and the entire medical facility system must be secure and protected. The security of data both in transit and at rest in the cloud is crucial, and it requires major effort to meet regulatory requirements.

- **Operational:** The operational challenge with cloud technology as part of a medical device is the complexity of integrating cloud services into existing workflows and infrastructure. Developers must ensure that new cloud-based solutions don't disrupt current operations or compromise performance.

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Wind River has deep experience and expertise in using cloud technology and services to enhance software development and in supporting cloud services as a component of equipment, systems, and devices across industries, including medical and healthcare.

Wind River Support for Development Challenges

Solving these top three challenges for medical device developers is a priority. Wind River has been working closely with developers to provide a proven portfolio of products and modern cloud-based development tools and services that help companies meet regulations; achieve certification; strengthen cybersecurity, safety, and reliability; and modernize software development.

- **Wind River Studio Developer:** Based on what we've seen, DevOps is still in the early stages of implementation by medical device developers. Wind River Studio Developer is a full DevOps platform, providing a complete set of cloud-based platform services that a team can use to develop its medical device and to collaborate and share work, driving the full capabilities of the new product. Studio Developer consists of five main components: Wind River Studio Pipelines, Wind River Studio Virtual Labs, Wind River Studio Test Automation, Wind River Studio Over-the-Air Updates, and Wind River Studio Digital Feedback Loop. >> Learn More About Studio Developer

- **VxWorks CERT Edition:** Pre-certified for medical applications (IEC 62304) and other industries including IEC 61508 SIL 3, DO-178C DAL A, and ISO 26262 ASIL-D, this RTOS platform helps meet regulatory and certification needs and save time and development work. >> Learn More About VxWorks Cert Edition

- **Wind River Linux:** The industry's most advanced embedded Linux platform has a comprehensive suite of tools and lifecycle services to build and support intelligent edge solutions. It enables development of robust, reliable, and secure embedded medical solutions with long-term support. Wind River provides CVE monitoring and fixes to help maintain strong cybersecurity protections. >> Learn More About Wind River Linux

- **Wind River Studio Linux Services:** This support delivers embedded Linux platform services for solution design, safety and certification, security, and lifecycle management capabilities. It helps reduce project risk while accelerating time-to-application-deployment, so teams can lower total cost of ownership and focus on innovation. >> Learn More About Studio Linux Services

RESOLVE MEDICAL DEVICE DEVELOPMENT CHALLENGES

Wind River has a portfolio of products and services as well as a skilled team of experts who will help resolve the challenges of regulation, cybersecurity, hardware support, and cloud technology implementation. Speed progress and success in bringing innovative medical technology to market, advance healthcare quality and results, and save lives. Start solving your challenges and increasing success by contacting Wind River medical solutions experts today.

ABOUT WIND RIVER

Wind River is a global leader in delivering software for the intelligent edge. The company's technology has been powering the safest, most secure devices in the world since 1981 and is found in more than 2 billion products. Wind River offers a comprehensive portfolio supported by world-class global professional services and support and a broad partner ecosystem. Wind River software and expertise are accelerating digital transformation of critical infrastructure systems that demand the highest levels of safety, security, performance, and reliability. To learn more about Wind River medical use cases and support for modern development tools and services, visit www.windriver.com/studio/developer or www.windriver.com/solutions/medical.

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