Critical Factors for Connected Medical Devices of the Future

Agenda

9:00 am – 9:30 am	Registration	
9:30 am – 9:45 am	Opening Address	BlackBerry QNX & ICS
9:45 am – 10:15 am	Medical Device Case Study	BlackBerry QNX & ICS
10:15 am – 11:00 am	Simplifying Software Integration and Safety Certification for Medical Devices	BlackBerry QNX
11:00 am – 11:45 am	Building Testability into the Software Architecture of Your HMI	ICS
11:45 am – 1:00 pm	Lunch & Networking	
1:00 pm – 1:45 pm	How Your Choice of Software Impacts the Security of Medical Devices	BlackBerry QNX
1:45 pm – 2:00 pm	Anticipating Machine Learning in Medical Devices	ICS
2:00 pm – 2:15 pm	Wrap-up	

Critical Factors for Connected Medical Devices of the Future

Simplifying Software Integration and Safety Certification for Medical Devices

As medical devices become more capable and connected, the risk of malware infecting sensitive equipment increases. In addition, the onus to mitigate risk is shifting to medical device manufacturers. Accelerated development timelines, increased competition, complex technology and stringent regulatory processes add to the risk of successfully launching a product.

As leaders in embedded software, BlackBerry QNX helps reduce risk and cost by providing a deterministic RTOS and Connectivity Framework that is ready for safety certification. We will also discuss how POSIX compliance helps you accelerate the transition from research to production, and how to simplify the certification of your regulated product.

Building Testability into the Software Architecture of Your HMI

We'll outline how to design a robust software architecture, taking the requirements of medical device creation into special consideration. When designing software for medical devices it is most important that the overall system can be validated and verified. Part of these requirements is to introduce testability at the component level, both for system design and for individual software components. This leads to a layered system architecture where each component fulfills a specific role. The idea is also extended to software. Components of software components must also be individually testable. We'll demonstrate our layered architecture model that allows testing of the software as a whole and at the individual layer/component level. We'll also provide an example on how to include testability into the software architecture from the beginning to ensure stable and safe software, and avoid expensive rework.

How Your Choice of Software Impacts the Security of Medical Devices

Recent changes by the United States Food and Drug Administration (FDA) seek to bring software under the umbrella of medical device regulation. As connectivity becomes a standard feature in medical devices, security requirements are also surfacing. To improve its approach towards medical device safety, including cybersecurity, the FDA will require device makers to have a clear inventory of the software used in the device through a "software bill of materials," which would include software developed by the device makers, as well as that obtained off-the-shelf.

Can your choice of OS make your device regulation go smoother? Learn about the FDA's new approach and how it affects IEC 62304, and inform your choice between open source and commercial software.

Anticipating Machine Learning in Medical Devices

The FDA is trying to figure out how to embrace Machine Learning (ML) Artificial Intelligence (AI). While it's early, the seminal issues regulating this recently enabled technology are quickly resolving. The tempo of Machine Learning (ML) development has changed recently with advances in other safety critical fields; most notably, automotive. In turn, the FDA is updating its mission to ensure patient safety while taking advantage of the benefits of breakthrough technology. In April of 2019, the FDA issued a discussion paper defining a regulatory framework for medical devices containing ML/AI. In this presentation we identify the challenges of ML in medical devices and analyze the FDA's recent proposals to deal with them.

- Machine Learning and its unique challenges in medical devices
- The types of problems ML will solve
- The FDA's compartmentalization of ML
- The FDA's new tools for regulating ML-enabled products
- Projections of how regulations may evolve