Anakena Solutions

Anakena Solutions' contribution to QMDI focuses on applying Systems Engineering principles to create safe PnP interoperability. These goals are synergistic with the Medical Device Interoperability Safety Working Group (MDISWG) and the new UL/AAMI 2800 standard, and have been made possible through our QMDI team collaboration with FDA, NIST, and standards bodies.

QMDI and MDISWG Goals Achievable through Systems and Safety Engineering:

- Devices will be built and cleared with an intended use of interoperability, and can be shown to be safe and effective for their intended use
- Medical Device Manufacturers can update their interfaces without automatically requiring a new clearance
- A hospital can assemble a safe system from safe interoperable sub-systems
- Every sub-system (device, app, ICE component, or network infrastructure) is safe as part of the system
- Hospitals will be able to assemble devices from different manufacturers, and a hospital would not become a regulated entity for merely assembling interoperable devices, applications, and ICE components
- The architecture and interfaces can be shown to be safe through the identification and mitigation of interoperability-specific hazards

Demonstration shows the implementation of Interoperable Safety Features and Functions, e.g.:

How can the hazards specific to interoperability be identified, mitigated, or prevented?

- The ICE Hub and Spoke architecture supports the solution to hazards created by interoperability. All information on all interactions is available in the ICE Hub (the Network Controller) from the devices' capabilities (State Models) or interactions (Messages)
- Some hazards belong to the device itself (e.g. SpO_2 LED not burning the patient, or LCD screen not catching on fire)
- Some hazards can only be mitigated by clinicians (same as stand-alone devices), but interoperable devices must reliably identify and communicate these situations to the clinician operator

MD PnP Getting Connected for Patient Safety

National Institutes of Health