Runtime Verification and Assurea Partner to Strengthen Software Safety for Medical Devices, SaMD and Artificial Organs

The partnership brings together formal verification expertise and practical implementation support for companies creating safety-critical medical technologies.

Software-enabled artificial organs are medicine's next frontier, and reaching it safely means proving the software behaves exactly as intended.

RALEIGH, NC, UNITED STATES, August 18, 2026 /EINPresswire.com/ -- Runtime Verification and Assurea have announced a new partnership to help medical technology companies strengthen the safety, reliability and regulatory readiness of software used in medical devices, Software as a Medical Device (SaMD), and software-enabled artificial organs.

Software is now responsible for critical decisions across technologies such as insulin-delivery systems, ventilators, infusion pumps, neurostimulators, diagnostic platforms and closed-loop therapeutic systems. As these products become more connected and software-dependent, manufacturers need stronger ways to demonstrate that their software will behave as intended.

> “Together, we can help companies go beyond conventional testing and build stronger evidence that critical software will perform safely and reliably.”
>
> *Krisha Patel, Co-founder of Assurea*

Runtime Verification brings formal verification to critical software, proving with mathematical evidence that key safety and security properties always hold. Assurea will serve as Runtime Verification’s implementation partner for medical-device and regulated life-sciences organizations.

Together, the companies will help medical technology teams:

• Identify the software properties that present the greatest potential risk to patients or product performance.
• Translate critical safety requirements into clearly written and formally evaluable properties.
• Build a formal model encompassing the system's most critical attributes, components, and decision pathways.
• Implement continuous testing and verification built on the team's CI system and AI processes.
• Incorporate the resulting evidence into quality-system and regulatory documentation.
• Establish automated methods to identify unexpected software behavior as the product evolves and new releases are introduced.

"Medical-device companies need industrial formal verification to safely advance to the next generation of devices," said Everett Hildenbrandt, CEO of Runtime Verification. "We need practical ways to define what critical software must do, evaluate whether those properties consistently hold, and use that evidence throughout development. Assurea brings industry experience in validation, and Runtime Verification brings production-ready formal verification."

Formal verification does not replace traditional software testing, clinical evaluation, usability engineering or risk management. Instead, it provides an additional layer of assurance for functions where software failure could directly affect a patient.

For medical-device manufacturers, that could mean examining whether:

• An insulin-delivery system remains within defined dosing limits.
• An infusion pump responds safely to abnormal inputs.
• A neurostimulator avoids unintended system states.
• A software-controlled artificial organ remains within defined operating parameters.
• A diagnostic or treatment algorithm performs according to its specified rules.
• A closed-loop system responds safely when sensors, inputs or operating conditions change.

"Software is becoming the intelligence behind the next generation of medical devices, and that creates an incredible opportunity to raise the standard for how we demonstrate safety," said Krisha Patel, Co-founder of Assurea. "Together, we can help companies go beyond conventional testing and build stronger evidence that critical software will perform safely and reliably."

How the Partnership Will Work

Runtime Verification will provide the formal-methods and software-assurance expertise, including support for:

• Formalizing critical software requirements.
• Developing properties that can be mathematically evaluated.
• Reviewing software design and architecture.
• Conducting formal verification and advanced software analysis.

• Identifying subtle defects, unexpected states, and edge cases.

Assurea will lead implementation within the regulated medical-product lifecycle, including:

• Intended use and software impact assessments.
• Risk based software assurance strategies.
• Requirements and risk control traceability.
• Integration with design controls and software lifecycle documentation.
• Validation and regulatory-readiness support.
• Procedures, training, change control, and lifecycle governance.

The partnership is intended to give medical-device innovators a practical path from critical software requirements to stronger, traceable evidence that supports both product development and regulatory review.

About Runtime Verification

Runtime Verification is a software assurance company founded on research at the University of Illinois Urbana-Champaign. Its team develops formal verification tools and methods for complex, safety-critical software, bringing experience from aerospace, rail, semiconductors, and other high-assurance industries to emerging areas such as medical technology.

www.runtimeverification.com

About Assurea

Assurea is a digital implementation partner that helps life sciences and medical technology companies implement and validate digital systems, maintain digital compliance, and develop custom AI solutions.

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