Veranex

Successful, efficient medical device innovators know that upfront strategic work prevents downstream delays. This month we explore human factors validation that can save millions in recalls, the overlooked CMS step between IDE approval and enrollment, process validation strategies for manufacturing scale-up, and more. Whether you're planning trials, pursuing regulatory approval, or choosing research collaborators, Veranex expert insights deliver actionable guidance that accelerates your innovation.

EXPERTS LIVE AT VERANEX

FDA Veteran Jose Pablo Morales, MD Joins Veranex as Chief Medical Officer

The addition of the FDA's Cardiovascular Device and Office of Clinical Evidence leader bolsters our commitment to helping clients navigate a rapidly evolving regulatory landscape while driving clinical and commercial success. Read the news.

QMSR IS COMING ON FEBRUARY 2, 2026

Free 30-min Consultations

Most teams don't need to rebuild their QMS for QMSR. A focused review can protect what already works well and update what no longer fits the new regulation. Start with what you have, then adjust with purpose.

Request a Consultation Today

LEARNING OPPORTUNITY

Speaker: Sylvain Biéler
Date/Time: February 2nd and 3rd, 2026 Online
2 × 8:00 AM – 1:00 PM US Eastern Daylight Time (EDT)
2 × 2:00 PM – 5:00 PM Central European Time (CET)
Are your clinical investigation processes truly aligned to ISO 14155:2020, end to end? This training focuses on translating requirements into repeatable execution, so teams stay consistent across planning, conduct, and reporting.

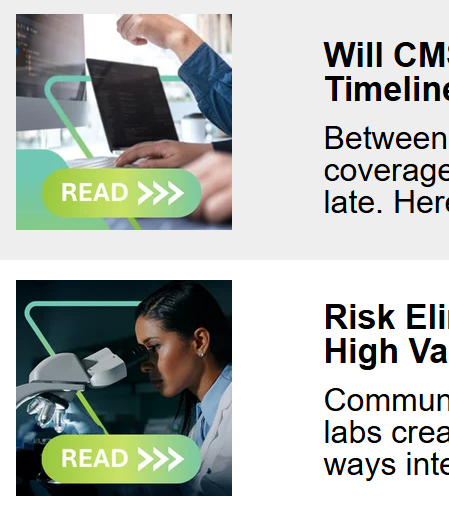
Register Here

Secure Connected Medical Ecosystems

Connected SiMD and SaMD ecosystems unlock new value and introduce new risk across devices, mobile applications, and the cloud. We design and build secure IoT and cloud connectivity in alignment with IEC 62304 and ISO 13485, with security and compliance to support FDA, HIPAA, and GDPR requirements.

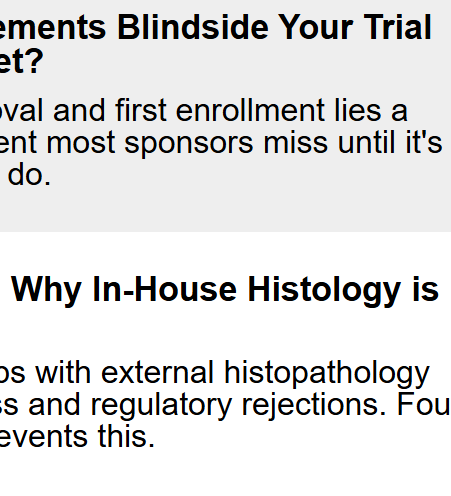
Explore

UPCOMING EVENTS: WHERE TO FIND US



OCT - Medical Devices Europe 2026
Munich, Germany
27 - 28 January 2026

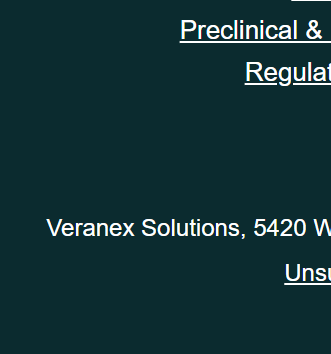
Event Details



SCOPE (Summit for Clinical Ops Executives)
Orlando, FL, USA
2 - 5 February, 2025

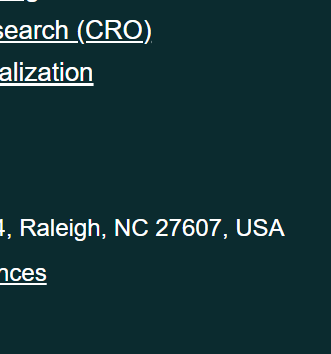
Event Details

INDUSTRY INSIGHTS FROM THE VERANEX BLOG



The Hidden Cost of Failing to Apply Human Factors Engineering

Skipping human factors? Expect 30% more trial participants and recall risks. Learn why $500K in HFE work returns 10X or better.



The #1 Way to Derisk Manufacturing: Process Validation

Between your perfect prototype and scalable production lies a critical step most companies skip: process validation. Here's why.

The CE Mark Template Trap That Derails Device Approvals

18 months lost or month one won? For Clinical Evaluation, strategic thinking beats last-minute scrambling every single time.

Will CMS Requirements Blindside Your Trial Timeline & Budget?

Between IDE approval and first enrollment lies a coverage requirement most sponsors miss until it's too late. Here's what to do.

Risk Elimination: Why In-House Histology is High Value

Communication gaps with external histopathology labs create data loss and regulatory rejections. Four ways integration prevents this.

Preclinical Research: Not a Commodity.

Any car can get you from point A to point B. But would you choose the cheapest if reliability, safety, and performance were mission-critical? Of course not.

Product Design & Engineering
Preclinical & Pathology | Clinical Research (CRO)
Regulatory Quality | Commercialization

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