Veranex

The Innovation CRO

# Insights from the Cutting Edge of Medtech

From preclinical strategy and FDA pre-submission tactics to QMSR compliance and the shift toward in-home care, we share insights from Veranex experts at the forefront of their fields. Whether you're navigating your first IDE submission, preparing for preclinical research, or positioning devices for emerging markets, we deliver strategic guidance that moves you forward.

## INDUSTRY INSIGHTS FROM THE VERANEX BLOG

**The Art of the Specific Question for FDA Pre-Sub Guidance and Human Factors**

Make every minute count with regulators: craft sharper Pre-Sub questions and surface key human factors risks.

Learn More

**The Strategic Science of Optimal Preclinical Model Determination, Selection and Development**

Pick the right model, the first time. Deliver rigor without wasted time, cost, or complexity.

Learn More

**Readiness Checklist: Preparing for FDA's 2026 QMSR**

On February 2, 2026, FDA's new Quality Management System Regulation (QMSR) takes effect, replacing the current Quality System Regulation (QSR) and incorporating ISO 13485:2016 by reference. If you're a physician innovator, engineer, or medical device startup, understanding these changes now is crucial for your product development journey.

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**Core Clinical Considerations for IDE Success**

IDE submissions often stall on first review especially when engineering brilliance meets clinical blind spots. We reveal six clinical foundations that separate approval from rejection.

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**Navigating Challenges and Opportunities for Medical Devices at Home**

The home medical device market will surge from *$43B to $75B by 2032*. But the in-home care environment is different and dynamic. Explore why devices at home demand different research for success.

Learn More

## Veranex Pathology: Advancing the Science of Discovery

With two world-class laboratories and specialized tissue-implant processing, our GLP-compliant experts advance preclinical insights, drive innovation, validate safety, and set the standard for scientific excellence. Whether supporting studies conducted within Veranex or providing independent evaluations for external researchers, we bring precise insights to every sample.

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## UPCOMING EVENTS

**London Valves**

📍 London, England

🗓️ Nov 16–18, 2025

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**RSNA**

📍 Chicago, IL

🗓️ Nov 30–Dec 4, 2025

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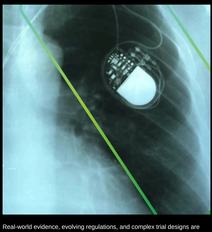
## Therapeutic Area Spotlight: Cardiovascular



Real-world evidence, evolving regulations, and complex trial designs are raising the bar for cardiovascular approvals. Success demands seamless coordination across every function.

The bar is high. You need a different kind of partner.

Veranex is the Innovation CRO. We transform breakthroughs into patient impact. We turn your vision to velocity.

Explore our Cardio Solutions

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

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