

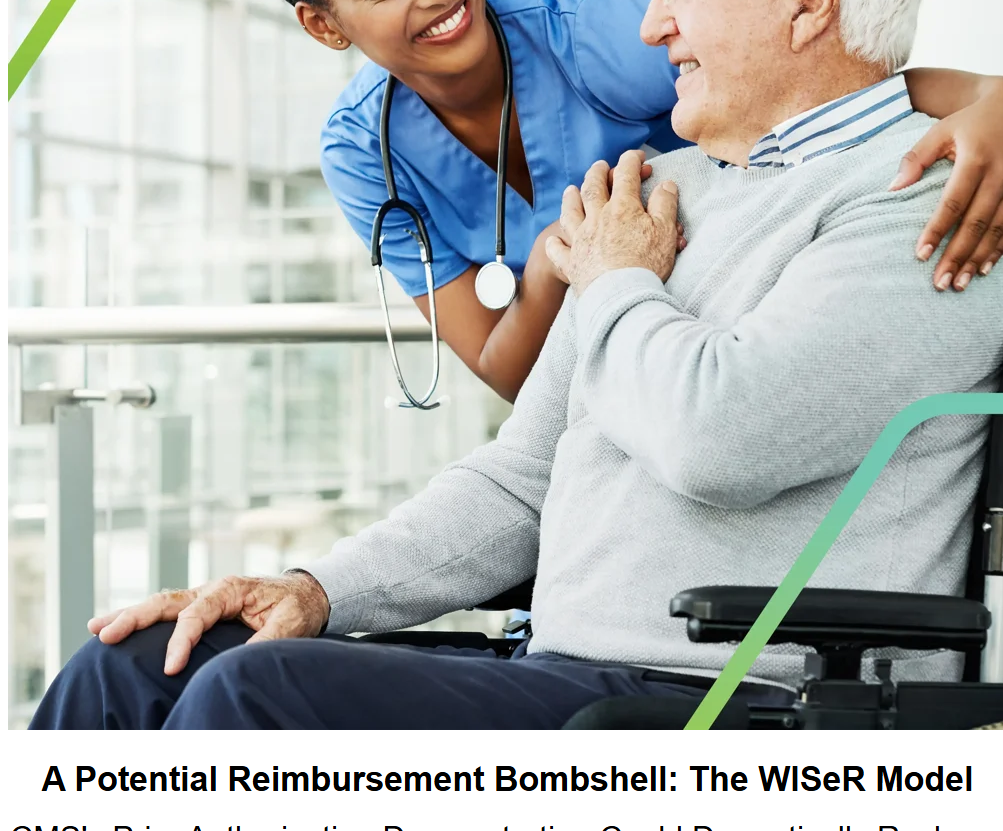


DECEMBER '25

Insights from the Cutting
Edge of Medtech

Are you evaluating quality systems and preparing for the 2026 QMSR requirements? Wondering what CMS' WISer model means for reimbursement strategies? Planning preclinical studies or evaluating histopathology experts? Want to use phased testing to unlock funding, design for non-clinical environments, or better build supplier partnerships? We offer strategic guidance that makes your business "go faster" through our monthly insights.

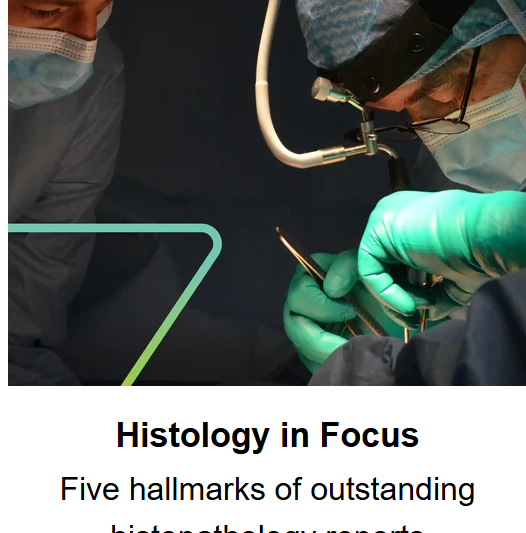
INDUSTRY INSIGHTS FROM THE VERANEX BLOG



A Potential Reimbursement Bombshell: The WISer Model

CMS's Prior Authorization Demonstration Could Dramatically Reshape Medicare Reimbursement Strategies for the Medical Device Industry.

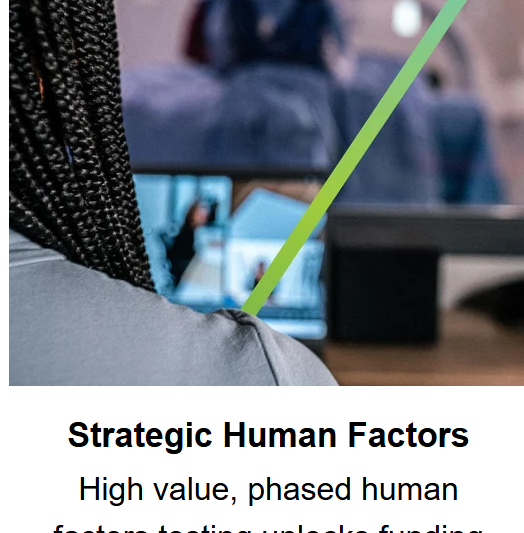
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Histology in Focus

Five hallmarks of outstanding histopathology reports reviewers will appreciate, with high likelihood of accelerating commercialization timelines.

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Strategic Human Factors

High value, phased human factors testing unlocks funding while building regulatory compliance, solving the startup funding-validation paradox.

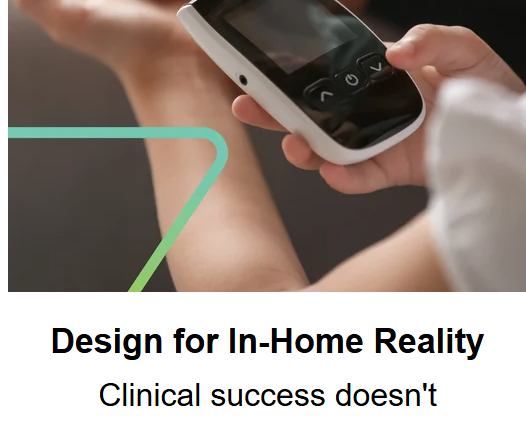
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Don't Confuse Software with a System: The eQMS Trap

Buying eQMS Software Doesn't Mean You're Buying a Quality Management System. That Misconception Could Cost Medical Device Innovators Regulatory Approval and Market Success.

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Design for In-Home Reality

Clinical success doesn't guarantee home success. How medical device innovators can design for the real constraints, users, and behaviors of a \$75B market.

[Learn More](#)

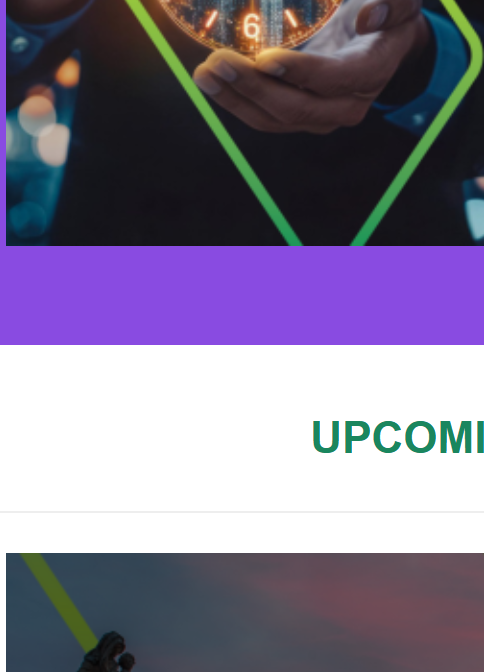


Build Supply Chain Resilience

Strategic supplier evaluation, regulatory compliance verification, and redundancy planning today prevents costly delays and quality failures.

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The Countdown to QMSR Compliance: Feb 2nd, 2026



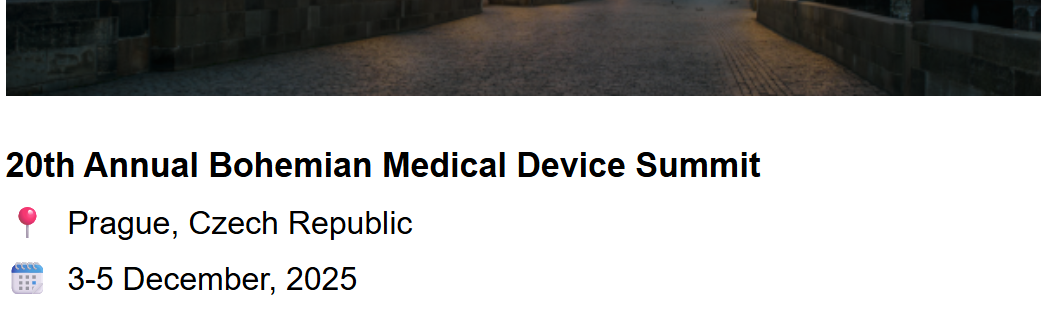
FDA Regulatory Changes Around:

- ISO 13485 compliance
- Risked-Based Thinking
- Documentation Alignment
- FDA Inspections

Do not wait for the deadline, reach out to our experts today and turn your compliance into a competitive advantage

[Explore](#)

UPCOMING EVENTS



20th Annual Bohemian Medical Device Summit

 Prague, Czech Republic

 3-5 December, 2025

We are proud to sponsor this exclusive gathering of senior medtech leaders and innovators in Prague. Our team is excited to join the conversation on the future of medical technology, explore new ideas, and deepen partnerships that accelerate impactful solutions for patients worldwide.

[Event Details](#)

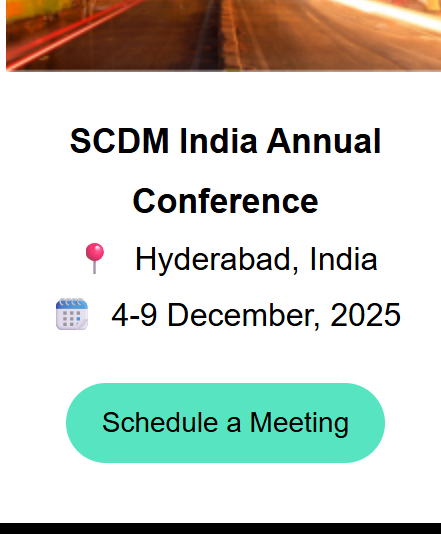


RSNA - Radiology Society of North America

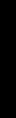
 Chicago, IL

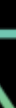
 30 Nov - 4 Dec, 2025

[Event Details](#)



SCDM India Annual Conference

 Hyderabad, India

 4-9 December, 2025

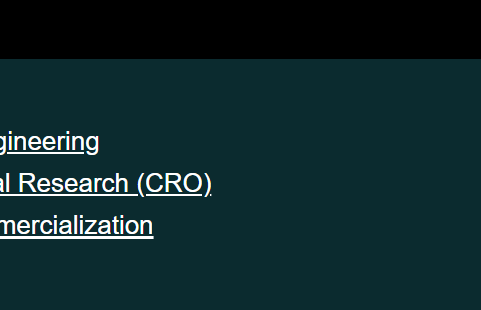
[Schedule a Meeting](#)

Jose Pablo Morales, MD - Our New Chief Medical Officer

Advancing MedTech Innovation

Dr. Morales joins Veranex following a distinguished career at the U.S. Food and Drug Administration (FDA), where he provided clinical and regulatory oversight for more than 1,000 medical device submissions, including PMAs, IDEs, and breakthrough designations.

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