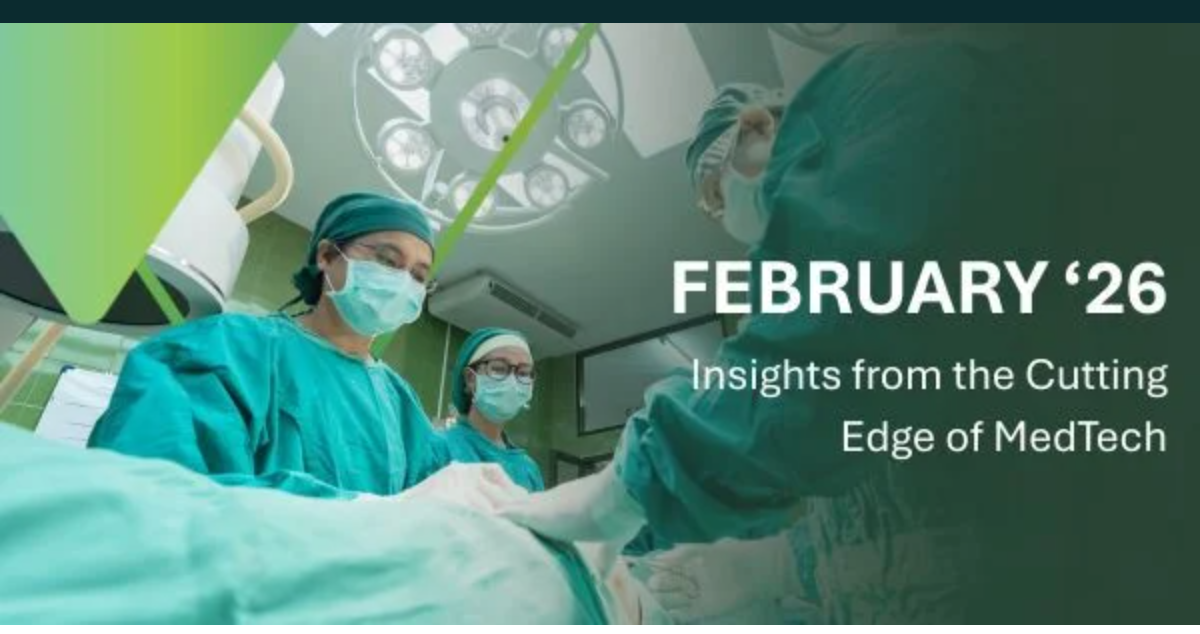




Preparing human factors questions for your FDA pre-sub? Evaluating eQMS options? Racing to complete IVDR clinical evidence before the deadline? Wondering how CMS' WISeR model changes your market access strategy, or how to turn ISO 10993-1:2025 requirements into competitive advantage?

Let us help bring *Velocity to your Vision*. This month we share expertise across the innovation pathway and feature conferences where you can meet our experts in person. We've also launched Veranex Biopharma, extending our integrated capabilities.

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A resource for biotech and pharma teams that need trusted expertise.

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**From Concept to Market:
Why Clinical Evaluation Must
Start at the First Sketch**

Núria Gresa
Scientific Affairs Manager



Date/Time: February 17th, 2026 | 11:00am Central European Time
Walk away with a practical approach to planning clinical evaluation to support MDR expectations for sufficient clinical evidence.

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What to Ask FDA About Human Factors in a Pre-Sub

Make every minute count with regulators: craft sharper Pre-Sub questions and surface key human factors risks. Our HF and regulatory teams help you surface pitfalls early and enter pre-submissions with sharper questions that make your business go faster.

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MDMA FDA Forum
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Washington, DC, USA
12-13, March 2026

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Speaker: Elena Lucano
"MDR Changes That Matter"



Nelson Labs Summit
Validation of Sterile Medical Devices
Frankfurt, Germany
24-26 February, 2026

[Event Details](#)

LSI
USA '26



Joseph Ferrara

PANEL: Maximizing Market Share and Probability of Success Through Integrated Evidence Planning



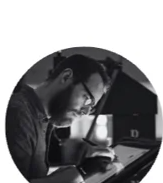
Ryan Roberts

PANEL: Advancing Neurovascular Medical Solutions Through the Startup Lifecycle

Dana Point, CA, USA | 16-20, March 2026

[Event Details](#)

HFES
Systems That Work for Humans



SPEAKER
Alex Bandazian

Getting Real on Virtual Reality: A Critical Analysis of the Value and Limitations of VR Simulation for Design Development



SPEAKERS
ShweThee Kale & Annika Hey

Beyond the Algorithm: How Systems Thinking Unlocks AI's Potential in Medical Device Innovation

International Symposium on Human Factors & Ergonomics in Health Care

New York, NY, USA | 22-25, March 2026

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Missed timelines don't have to mean lost revenue. See practical paths to compliance and how to recover without starting over.



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

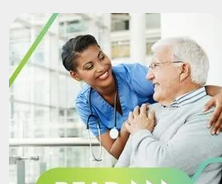
Buying eQMS software doesn't make a compliant Quality Management System. Don't let it put your regulatory approval and market success at risk.



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Expansion Into Market Adjacencies: Unlocking Growth for the "Big Strategics"

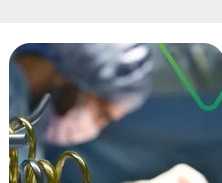
Identify and pursue compelling adjacencies that balance strategic fit and acceptable risk, while creating long-term value.



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High Reimbursement Implications: The CMS WISeR Model

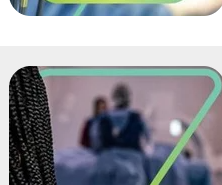
CMS's Prior Authorization Demonstration could dramatically reshape Medicare reimbursement strategies for the medical device industry.



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

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