Agenda

1000 Humanizing MedTech

The Medical Device Conference that feels human. That feels personal.

"The single most important indicator of MedTech success, is the quality of your relationships."

-Sean Smith, 10x Co-Host and Publisher, MedTech Leading Voice





May 7-8, 2025 in Newport Beach, CA

medicaldeviceevents.com

Day 1 Laying the Foundations for MedTech Success

Day one focuses on the essential building blocks of MedTech development, from planning and funding to clinical and regulatory strategy.

7:45 AM - Breakfast & Networking

9:00 AM - Welcome and Opening Remarks - Hosts: Sean Smith and Joe Hage

9:20 AM - Speaker Session: Planning for Success in MedTech

Two presentations by industry experts discussing the key opportunities, challenges, and trends shaping the MedTech industry.

10:00 AM - Breakout Workshops 1: The Path to MedTech Innovation

Participants will split into teams to explore key topics through guided discussions and prompts.

- *Ideation to Market Research:* Explore strategies for identifying market needs, validating ideas, and conducting competitor analysis.
- **Prototype Development and IP Protection:** Guide participants through building a proof of concept and securing intellectual property.
- **Early Funding Strategies:** Help attendees navigate early-stage funding, including friends & family and angel investors.
- **Regulatory Pathway Decision-Making:** Provide clarity on choosing between 510(k), De Novo, PMA, and CE marking.

10:45 AM – Spotlight Session Round 1 - Selected participants will share their projects, challenges, and goals in 5-minute interviews.

11:15 AM - Refreshment Break

11:30 AM – Panel Discussion: Avoiding Common Pitfalls in MedTech Development Industry experts share lessons learned and actionable insights to help attendees sidestep challenges.

12:30 PM - Luncheon Provided

1:30 PM - Breakout Workshops 2: MedTech Development in Action

Participants continue to collaborate and problem-solve in hands-on workshops.

- Clinical Trial Design and Needs Assessment: Equip participants to plan clinical trials and refine product features through clinician feedback.
- **Quality Management Systems (QMS) Implementation:** Help teams understand ISO 13485 and how to start building a QMS.
- **Product Development and Engineering Innovations:** Focus on engineering best practices, including design optimization and integration of software solutions.
- **Sustainability in Medical Device Design and Packaging:** Share strategies for incorporating sustainable practices into device design, materials selection, and packaging.

2:45 PM - Networking Break (Ice Cream Social)

3:15 PM - Interactive Session: Solving Real-World Challenges

Collaborative team exercises and case studies designed to address pressing industry challenges.

4:00 PM - Speaker Session 2: Insights for MedTech Growth

Two sessions featuring expert insights on growth strategies and market success.

5:00 PM - Spotlight Session Round 2

More selected participants will share their projects, challenges, and goals in 5-minute interviews.

Day 2 Driving Innovation and Post-Market Excellence

Day two focuses on scaling success, leveraging technology, and achieving long-term sustainability.

7:45 AM - Breakfast & Networking

9:00 AM - Day One Recap & Day Two Kickoff - Hosts: Sean Smith and Joe Hage

9:20 AM - Speaker Session: What Investors Want

Two presentations by MedTech leaders provide perspectives on what investors value most.

10:00 AM - Breakout Workshops 3: Scaling and Post-Market Excellence

Participants will tackle challenges related to scaling and long-term success in the MedTech space

- **Manufacturing Scale-Up and First Commercial Launch:** Prepare participants to transition from small-scale production to market launch.
- Advanced Cybersecurity in MedTech: Provide tools and strategies to address cybersecurity challenges in connected devices.
- **Post-Market Surveillance and Feedback Loops:** Equip participants with strategies to track product performance and adapt to market needs.
- Investment and Series A Funding: Help attendees position their companies for venture capital and Series A funding.

10:45 AM – Spotlight Session Round 3 - More selected participants will share their projects, challenges, and goals in 5-minute interviews.

11:15 AM – Refreshment Break

11:30 AM - Panel Discussion: Growing Without Burnout

Industry experts share lessons learned and actionable insights to help attendees sidestep challenges.

12:30 PM - Luncheon Provided

1:30 PM - Breakout Workshops 4: Planning for Success

Participants will focus on forward-thinking strategies for success in the MedTech space.

- **Next-Gen Product Development and Iteration:** Explore strategies for gathering feedback and iterating on product design post-launch.
- **Regulatory Compliance for International Expansion:** Guide participants through regulatory requirements for entering new geographic markets.
- **Software Development and Embedded Systems in MedTech:** Learn software engineering best practices for medical devices, including embedded systems and validation.
- **Building and Leading a High-Performing Team:** Share strategies for hiring key personnel and fostering collaboration.

2:45 PM - Closing Keynote: Building Connections That Last

An industry leader discusses the power of relationships in driving growth and innovation.

3:30 PM - Conference Wrap-Up

Two 30-minute sessions featuring expert insights on growth strategies and market success.

4:00 PM - Event Ends

10x Speakers & Workshop Leaders

- Dr. David Albert, Founder and Chief Medical Officer, AliveCor
- Nic Anderson, Sr. Manager, Health Economics and Market Access, Boston Scientific
- Jose Bohorquez, PhD, President, BoldType
- Anthony Chang, Founder, CHOC and AlMed
- Maria E. Donawa, MD, President, Donawa Lifescience
- Leonard (Leo) Eisner, Principal, Compliance & Regulatory, Eisner Safety Consultants
- Matthias Fink, MD, Senior Clinical Consultant, AKRA TEAM
- Mohamad Foustok, Chief Software and Cybersecurity Architect, Bold Type
- Renae Franz, Managing Director, MedTech Commercialization, leanRAQA
- Jan Gates, President/Advisor Packaging Engineer, Adept Packaging
- Prof. Dr. Christian Johner, Owner and head of Digital Transformation, Johner Institute
- Nikhil Khadabadi, CMO, Orthopaedic and Spine Medical Devices, ECLEVAR
- Angelina Lisandrelli, Director of Regulatory and Quality, RespirTech, Philips
- Maurizio Vecchione, Chief Innovation Officer, Terasaki Biomedical
- Marc Viscogliosi, CEO, Spine BioPharma

Final speaker list subject tp change

<u>Contact us</u> to join our growing list of speakers, workshop leaders, featured startups, investors and sponsor partners

Joe Hage, 10x Co-Host and Chairman, MedicalDeviceGroup.net Sean Smith, 10x Co-Host and Publisher, MedTechLeadingVoice.com

10x Sponsor Partners











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LOCATION Hyatt Regency Newport Beach

• 1107 Jamboree Road Newport Beach, California 92660 United States

