



December 6–7, 2017

San Jose Convention Center | San Jose, CA

SPEEDING MEDTECH TO MARKET:

Being First is Hard, Being Second is Harder

AGENDA-AT-A-GLANCE (Tentative schedule)

Day One – Wednesday, December 6

8:00 a.m.	Registration and Refreshments
8:30 a.m. – 4:30 p.m.	Track A – Product Development: Nurturing an Ecosystem for Innovation Track B – R&D: Finding and Adopting New Technology
10:00 a.m. – 10:15 a.m.	Refreshment Break
11:45 a.m. – 1:15 p.m.	Networking Lunch
1:15 p.m. – 2:15 p.m.	Innovation Tour: Sensors
2:45 p.m. – 3:00 p.m.	Refreshment Break

Day Two – Thursday, December 7

8:00 a.m.	Registration and Refreshments
8:30 a.m. – 4:30 p.m.	Track A – Product Development: Winning the Race to Market Track B – R&D: Disruptive Design
10:00 a.m. – 10:15 a.m.	Refreshment Break
11:45 a.m. – 1:15 p.m.	Networking Lunch
1:15 p.m. – 2:15 p.m.	Innovation Tour: Medtech Product Development Tools
2:45 p.m. – 3:00 p.m.	Refreshment Break

TRACK A

Product Development: Nurturing an Ecosystem for Innovation

8:30 am – 9:15 am

PANEL

Building Better Cross-Functional Teams for the Digital Health Explosion

Medical device developers that are incorporating digital health and digital medicine must navigate a tangled web of user, payer, regulatory, and business demands to ensure their products' success - not to mention the new convergence of healthcare and devices with IT. Therefore, it's critical that the right voices within the organization be heard during the product development process, and that this is done in the best way. In this conversation, experts from leading companies will discuss who does and does not get a seat at the table within their organizations.

Topics to be covered:

- What new team players need to join the medical device team that is incorporating Digital Health and or Digital Medicine
- Choosing the right players for your product development team
- Understanding when and why to involve different specialties
- Tips for integrating disparate departments

9:15 am – 10:00 am

CASE STUDY

Using Project Frameworks to Create Order Out of Chaos

Successful innovation in a corporate environment requires much more than a spark of creativity, especially when multiple consultants are involved. Co-learning and co-creating is key, as is a "velvet glove" that demands both rigor and flexibility within the project. This session will share the story of one client, three consultants, seven countries, 74 deliverables, and one massively successful strategy. It will explain what collaboration really looks like in a corporate environment with many stakeholders and high demands. The presenters will share how insights were gleaned from empathy and how frameworks changed corporate thinking, drove strategy, and ultimately led to success.

Topics to be covered:

- How to avoid killing innovation at your company
- Building and integrating cross-functional innovation teams
- Building meaningful frameworks that drive new strategies

TRACK B

R&D: Finding and Adopting New Technology

8:30 am – 9:15 am

PANEL

Technology Monitoring Methods for Time-Challenged Teams

Keeping in front of technology is vital. Yet, today's time and cost demands may push tech monitoring to the back burner, or off the stove completely, until it's too late. Learn time-efficient, front-burner techniques for tracking new developments from academia, startups, and technology ventures.

Topics to be covered:

- What should you be monitoring and when?
- Discussing current hot areas of technology in medtech
- Integrating new, or old, technology into your product offerings

9:15 am – 10:00 am**Evaluating New Technologies Using a Balanced Score-Card Approach**

New technology abounds, but what are the key indicators of success? In this session, you'll learn what measures are available to help you determine if a specific technology is right for your next product. And you'll discover how to support an equally quick and simple management review.

Topics to be covered:

- Establishing the stage of technology development
- Modeling and analysis to show that fundamentals of the core technology can meet the product requirements
- Demonstrating the device provides adequate performance over the expected range of conditions

TRACK A

Product Development: Nurturing an Ecosystem for Innovation

10:00 am – 10:15 am**Morning Break****10:15 am – 11:00 am****Finding & Exploiting New Niches in Healthcare**

Successful medtech companies and startups are adept at finding and exploiting new niches in healthcare that have the potential to scale. Currently, top opportunities also rely on breakthroughs and advances in technologies such as IoT, mobile/wireless, robotics, AI, VR/AR, and 3D printing. Finding market pain points that are ripe for change or disruption is both art and science. This session will enable you to find and evaluate exciting market opportunities to target for your next product.

Topics to be covered:

- Identifying niches with potential to scale
- Ways to assess target markets, market size, and rate of adoption
- Understanding how advanced technologies can amplify market potential
- Elements of a successful business case
- Identifying warning signs and learning from past failures

11:00 am – 11:45 am**Connect & Compete Through Open Innovation**

The health care eco-system is changing. Today more than ever it is essential that medical devices deliver new outcomes and value. Medical device developers can achieve a host of benefits—from engaging with patients, working with health care system advisors, forming new partnerships to accelerate the speed of development and the design of useful products—by looking outside their existing networks for technology solutions. In this session, you'll learn how to harness open innovation to supplement your in-house innovation efforts.

Topics to be covered:

- Strategies for engaging in open innovation
- Examples of how open innovation has been applied
- Review a case study on its impact on value, accelerating time to market

TRACK B

R&D: Finding and Adopting New Technology

10:00 am – 10:15 am**Morning Break****10:15 am – 11:00 am****Assessing and Sourcing Technology for New Product Development and Manufacturing**

Understanding the risks associated with a new technology is key to determining if it's right for your application. Once assessed, how is componentry sourced? In this session, we'll discuss strategies for translating technology into the next groundbreaking medtech product.

Topics to be covered:

- Understanding implications of multiple technology risks
- Determining that the technology can scale to volume manufacturing and distribution
- Looking at supply chain processes for bringing new technology on board

11:00 am – 11:45 am**How Artificial Intelligence Is Changing Medical Devices**

Machine learning and deep learning are poised to have a dramatic impact on the medical device field. The session will consider how artificial intelligence will change medtech in the coming years as well as look forward into what might happen once true artificial intelligence is here and how that may change the development and application of diagnostic and therapeutic medical devices.

Topics to be covered:

- Reviewing the evolution of robotics and AI in medical devices and how it will change medical device development and use
- Assessing robotics and automation in device development
- Using machine learning and deep learning in medical devices today and tomorrow

TRACK A

Product Development: Nurturing an Ecosystem for Innovation

11:45 am – 1:15 pm**Lunch****1:15 pm – 2:15 pm**

PANEL

Anatomy of a Breakthrough

Big ideas often start with humble beginnings. In this session, representatives from leading medical device companies will explain what sparked their most successful products and what you can learn from their stories.

Topics to be covered:

- What makes the genesis of successful medical devices?
- Ways to overcome early hurdles
- How to nurture an ecosystem for innovation

2:15 pm – 2:45 pm

CASE STUDY

How Innovation Beyond Line Extensions Can & Should (Also) Happen Within Established Organizations

Moving fast is critical in the medtech industry, especially with truly novel devices. Through several case studies, this session will cover how and why innovation can and should be done at a startup pace within larger companies.

Topics to be covered:

- Enabling and encouraging innovative thinking
- Avoiding the stakeholder quagmire
- Charting a course to FIH through a large corporate quality system
- Clinical introduction
- Lessons for companies of any size pursuing innovation

2:45 pm – 3:00 pm**Afternoon Break****TRACK B**

R&D: Finding and Adopting New Technology

11:45 am – 1:15 pm**Lunch****1:15 pm – 2:15 pm****Innovation Tour: Sensors**

The BIOMEDevice San Jose Expo is the best place to see sensor innovations that could make your next medical device smarter. In this session, our tour guide will introduce you to suppliers and service providers showcasing innovative sensor solutions.

- Meet promptly at 1:15 p.m. outside the meeting room to begin the tour
- Tour the BIOMEDevice Expo Hall to visit 4-6 suppliers
- Tour stops will be announced closer to show date

2:15 pm – 2:45 pm**Redefining Rapid Prototyping**

Virtual prototyping could be an additive tool, or in some cases, a unique means for gaining medical device approvals. This session will explore how various research groups and teams are employing digital modeling and/or virtual prototyping to aid in the design of medical devices.

Topics to be covered:

- 3D modeling, 3D printing, and virtual reality tools for medical device design
- How these technologies can augment and expedite medical device design
- Real-life examples of how these technologies have been utilized

2:45 pm – 3:00 pm**Afternoon Break**

TRACK A

Product Development: Nurturing an Ecosystem for Innovation

3:00 pm – 3:45 pm**Last Concept Standing: Choosing Which Idea to Pursue**

Sometimes the problem is not coming up with new technologies, it's deciding which ones to pursue. In this session, we'll explore strategies or evaluating concepts for new medical devices and ensuring that only the strong survive.

Topics to be covered:

- Failing fast to ensure future success
- Strategies for weighing your options
- What to do with concepts you don't immediately pursue
- A look at industry examples that you can apply

3:45 pm – 4:30 pm**Taking Innovations to Product Reality Using NAV Principles**

Product development environments that have 10X thinking, who have an open culture, and who are transparent and of high trust, will make innovation their core operational philosophy. But how do you use nimble, agile, and velocity principles to bring concepts to market faster?

Topics to be covered:

- Understanding nimbleness, velocity, and agility – 3 terms that are part of the “development” portion of R&D
- Deploying a proper balance of task and relationships
- Explore examples in medical device

TRACK B

R&D: Finding and Adopting New Technology

3:00 pm – 3:45 pm

PANEL

How Augmented Reality and Virtual Reality Technologies Are Moving the Needle for Medical Devices

Augmented reality (AR) and virtual reality (VR) are all the rage right now, but what's really being done with these technologies in the realm of healthcare? In this session, we'll talk with startups and established companies exploring this exciting space to gauge the potential of AR and VR in medtech.

Topics covered will include:

- Exploring existing and potential applications for AR and VR in healthcare
- Ways to overcome technological challenges
- Discussing the pros and cons of AR and VR hardware and software

3:45 pm – 4:30 pm**Next-Gen Innovative Wearables Using Medical – Style Validation**

Consumer wearables grew into a huge global market based on relatively simple technology that counted steps, calories, and overall activity levels. More recently, as technologies such as optical heart rate monitors have been added to wearables, the technology in these devices has accelerated to the point where it is accurate enough for some medical purposes. In fact, in some ways consumer wearables innovation is actually outpacing medical technology. Advanced wearable tech is now enabling new capabilities in mobile healthcare with a focus on prevention, screening, and disease management. This session will discuss where, how, and why that is happening.

Topics to be covered:

- A look at optical biometric sensor technology (PPG) that is accurate enough for at least some ambulatory medical applications
- Merging the chaotic exploration and rapid innovation of consumer wearables with the methodical discipline of clinical validation
- Reviewing examples of companies that have applied medical-style validation to innovative wearable sensor technologies

TRACK A

Product Development: Winning the Race to Market

8:30 am – 9:15 am**The Impact of New Reimbursement Models on Product Development**

As healthcare moves toward a fee-for-value system, new reimbursement models are being tested by Medicare and other payers. New payment models will be explained in the context of how they impact physician and hospital reimbursement, and how this may redirect the type of value providers are seeking from new medical devices. The session will also discuss potential policy changes that may impact medical device reimbursement and the ability to move products to market faster.

Topics to be covered:

- A look at new provider payment models
- Reviewing the new physician payment model under MACRA
- Discussing major Medicare policy changes that may impact medical device reimbursement going forward
- Potential impact in defining “value” under these new payment models
- Using a simple worksheet that helps determine what options to pursue

9:15 am – 10:00 am**Forecasting Market Adoption Prior to Product Development**

Dealing with setbacks is tough, and it’s something medtech companies dread. This session will cover two important factors for adoption success: understanding what customers really need in a new or updated product and determining who will be most likely to purchase the device. This will help you determine, prior to product development, the intended market for your product.

Topics to be covered:

- Demonstrating meaningful differentiation across medical goals
- Exploring issues with clinical efficacy, workflow efficiency, usability, and hospital/clinician expectations
- Assessing if the device provides value through reclaimed user satisfaction, time savings, ease of use, and improved outcomes

TRACK B

R&D: Disruptive Design

8:30 am – 9:15 am

PANEL

Secrets of Disruptive Innovation

Have you ever seen a truly disruptive medical device and wondered what the designers were thinking? In this session, you’ll hear right from the source.

Topics to be covered:

- What it takes to disrupt the dominant care paradigm
- When to proceed with a disruptive design and when to play by the rules
- Real-life examples of disruptive medical devices

9:15 am – 10:00 am

CASE STUDY

Driving Patient Compliance

When Bioventus added a patient compliance calendar to its Exogen Ultrasonic Bone Healing System, post-launch monitoring revealed that the feature reinforced patient compliance with the prescribed treatment. In this session, the company will detail its successful solution.

Topics to be covered:

- Gathering voice of the customer research
- Drilling down to design requirements
- Exploring the intricacies of adding features to a device used in global market
- Examining post-Launch compliance review and findings for action

TRACK A

Product Development: Winning the Race to Market

10:00 am – 10:15 am**Morning Break****10:15 am – 11:00 am****The Latest in Best Practices for Formal Design Review**

While FDA lays out a number of requirements for design reviews, much is left manufacturers' discretion. In this session, you'll learn best practices for ensuring successful design reviews.

Topics to be covered:

- Reviewing the difference between formal and informal design reviews
- Exploring the number of design reviews needed and what should be covered
- Identifying which parties should be involved in design reviews
- Discussing new tools for virtual design reviews

11:00 am – 11:45 am

PANEL

Untangling the Cybersecurity Rules for Faster Design & Integration

High-profile hacks have hospitals and other healthcare customers on high alert. In this session, experts will discuss the state of cybersecurity in medtech and cover what standards and tests you need to consider.

Topics to be covered:

- Understanding the various standards and testing bodies you need to listen to during the design phase
- Exploring what hospital customers expect when it comes to medical device security
- Scaling your cybersecurity strategy

TRACK B

R&D: Disruptive Design

10:00 am – 10:15 am**Morning Break****10:15 am – 11:00 am****Designing a Patient User Interface for Improved Engagement & Behavior Change**

Chronic conditions are reaching epidemic proportions around the globe and effective treatment requires behavior change on the part of patients. This session will explore how to design medical device user interfaces that can help patients make the adjustments they need to improve their health.

Topics to be covered:

- Theories and models of behavior change
- Strategies for behavior change (what works and what doesn't)
- How to apply these principles in the design process

11:00 am – 11:45 am

PANEL

Medical Device Interoperability

Unlike the interconnected, "plug-and-play" world of modern computers and consumer electronics, most medical devices used for the care of high-acuity patients are designed to operate independently and do not employ open networking standards for data communication or device control. One-off connections are complicated and expensive. The adoption of appropriately robust connectivity standards and technologies by healthcare will enable the plug-and-play integration of medical devices.

Topics to be covered:

- FDA, EU, and other regulations governing interoperability
- The latest in adoption of open standards and technology for medical device interoperability
- Tactics for advancing your connected health device

TRACK A

Product Development: Winning the Race to Market

11:45 am – 1:15 pm**Lunch****1:15 pm – 2:15 pm****Innovation Tour: Medtech Product Development Tools**

The BIOMEDevice San Jose Expo is the best place to find trusted partners to augment your in-house product development capabilities. In this session, our tour guide will introduce you to suppliers and service providers on the show floor that help can bring your efforts to the next level.

- Meet promptly at 1:15 p.m. outside the meeting room to begin the tour
- Tour the BIOMEDevice Expo Hall to visit 4–6 suppliers
- Tour stops will be announced closer to show date

2:15 pm – 2:45 pm**Identifying & Avoiding Patent Pitfalls**

Have you ever invested significant time, effort, and money into a new idea only to be told later on that you have either missed deadlines to patent or are now infringing a third party's patent rights? This happens frequently because the road to patent protection or freedom to operate is fraught with bumps and traps. In fact, the Supreme Court has addressed similar issues very recently. In this session, you'll learn about tools and guidelines to help you spot problematic issues, avoid roadblocks, and maintain patent protection during your continued development.

Topics to be covered:

- Ways to avoid designs which infringe on existing patents
- Revising strategies for avoiding inadvertently giving up your right to patent
- Ensuring that your design efforts will actually produce patentable subject matter

TRACK B

R&D: Disruptive Design

11:45 am – 1:15 pm**Lunch****1:15 pm – 1:45 pm**

CASE STUDY

Speeding Up Your Development Process with Human-Centered Design

Delays getting new devices to market often occur when companies perform human factors validation After the majority of the development has already been completed. This approach stagnates the regulatory approval process and drives up costs dramatically. However, conducting research with users early and often can streamline the product development cycle and ensure a successful validation study. Doing so, will speed time to market and significantly reduce costs along the way. This presentation will showcase how the early adoption of a human-centered design approach produced significant time-to-market benefits for a total artificial heart.

Topics to be covered:

- Analyzing design research methods that help manufacturers uncover user needs, design usable devices, and get to market faster
- Making sure the usability validation requirements flow from the hazard analysis
- Exploring vital strategies for conducting contextual research with device users in their natural environments of use
- Looking at specific examples of a human-centered design approach used in the development of a total artificial heart

TRACK A

Product Development: Winning the Race to Market

2:45 pm – 3:00 pm**Afternoon Break****3:00 pm – 3:45 pm****Streamlining Your Scale-Up Processes to Accelerate Speed to Market**

Determining that a product can scale to volume manufacturing and distribution is critical. Understanding innovative, cost-effective approaches to scale-up and mass production are key and can enable rapid commercial launches and scale-ups.

Topics to be covered:

- Exploring 5 pacesetters for speed to market
- Analyzing 5 strategies to scale quickly and efficiently
- Discussing the benefits of speed to market and efficient scaling

3:45 pm – 4:30 pm**Cost-Cutting Strategies**

Designing a less expensive product than the competition is important, as is offering value over other market options by targeting customer needs. How do you lower systemic costs and provide better overall cost management of your process?

Topics to be covered:

- Exploring key ways to reduce hidden costs when scaling-up your product
- Overcoming cost constraints and budget cuts
- Takeaways from practical examples

TRACK B

R&D: Disruptive Design

1:45 pm – 2:15 pm**5 Key Principles for Designing the Ideal Medical Device for In-Home Use**

Most medical technologies were originally designed for well-educated, highly trained personnel working in a specialized medical environment. Improved technology, miniaturization, extended lifespans, and increased costs have resulted in many devices now being used in patients' homes. However, designs have not changed accordingly. This session will consider several recent usability projects involving the use of technologies in the home and focus on lessons learned from continuous glucose monitoring, total artificial hearts, and in-home cancer screening.

Topics to be covered:

- Identifying design criteria that make devices useful, usable, and desirable in the home
- Exploring use cases with the goal of getting patients back into the home, requiring the design approach to adapt
- Discussing what user-centered design principles should remain and what design criteria and assumptions need to change

2:15 pm – 2:45 pm**The Internet of Things Is Here—Are You Ready?**

From smart refrigerators and televisions to connected cars, the Internet of Things (IoT) has arrived—at least in the world of consumer technology. In this session, you'll learn how medtech can catch up.

Topics to be covered:

- Designing for the IoT
- Reconfiguring legacy products to gather data and accept remote control
- When IoT capabilities are necessary (and when they're not)

2:45 pm – 3:00 pm**Afternoon Break**

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TRACK B

R&D: Disruptive Design

3:00 pm– 3:45 pm

Don't Let Cognitive Bias Sink Your Usability Study

Investigator bias can impact usability studies in unexpected ways that are only apparent after it's too late to make corrections. Fortunately, there are time-tested methods to insure the quality of result needed for internal development and to support regulatory filings. In this session, you'll learn how to mitigate the effects of cognitive bias in your usability testing to improve accuracy and effectiveness.

Topics covered include:

- Understanding cognitive bias
- Identifying key cognitive biases before, during and after usability testing
- Exploring strategies for mitigating cognitive biases

3:45 pm – 4:30 pm

Where's My Screen? Designing for Screenless Voice Technology

The future is screenless. As consumer-based voice-control technologies such as Amazon's Alexa, Apple's Siri, and Google Assistant become more ubiquitous, users will increasingly demand voice capability in medical devices, too. This session will cover the basics of designing for voice technology.

Topics to be covered:

- Understanding the landscape of voice control
- How voice user interfaces differ from graphical user interfaces
- Exploring principles for designing for voice user interfaces

4:30 pm

CONFERENCE CONCLUDES