BIOMEDevice
An MD&M Event

APRIL 18-19, 2018 // BOSTON, MA
BOSTON CONVENTION & EXHIBITION CENTER

Bringing Technology and Product Development Best Practices Together for Successful Innovation

AGENDA-AT-A-GLANCE (Tentative schedule)

Day One – Wednesday, April 18	
8:00 a.m.	Registration and Refreshments
8:30 a.m. – 4:00 p.m.	**Track A** – R&D: New Technologies **Track B** – Product Development: Strategy
10:00 a.m. – 10:15 a.m.	Refreshment Break
11:45 a.m. – 1:15 p.m.	Networking Lunch
2:30 p.m. – 2:45 p.m.	Refreshment Break

Day Two – Thursday, April 19	
8:00 a.m.	Registration and Refreshments
8:30 a.m. – 4:00 p.m.	**Track A** – R&D: Technology Integration **Track B** – Product Development: Design
10:00 a.m. – 10:15 a.m.	Refreshment Break
11:45 a.m. – 1:15 p.m.	Networking Lunch
2:30 p.m. – 2:45 p.m.	Refreshment Break

UBM

TRACK A | R&D: New Technologies

Track Chair: TBD

8:30 am – 9:15 am

What's New & Exciting in Medical Materials

Emerging materials that provide improvements for medical device manufacturers are crucial to developing successful medtech products. What is new today for medical devices? In this session, we'll look at 5–10-year trends in biomaterials, medical electronics, plastics, and soft materials, and explore cutting-edge applications being used by today's medical device engineers.

Topics to be covered will include:

- The role of materials in the medical device life cycle
- Advancements in materials and technologies and factors driving innovation
- Models of today's complex devices and material advancements

Asmita Khanolkar, Manager, Manufacturing Engineering, CeQur

Microfluidic Materials & Technology Platforms for Critical-Care Devices

CASE STUDY

Dr. Borenstein will discuss his recent work with novel developments in cardiopulmonary support, including acute applications such as cardiac bypass surgery and longer-term applications such as respiratory failure.

Topics to be covered will include:

- New applications of the technology in kidney failure and dialysis
- A look into next-generation technologies where stem-cell biology may be used to provide long-term device applications (e.g., wearables, implantables)
- How microfluidic materials and technology address challenges with clotting and bleeding currently faced by vascular access devices

Jeffrey Borenstein, Laboratory Technical Staff, Draper Laboratory

TRACK B | Product Development: Strategy

Gregg A. Jackson, Director of Business Development, Gershon MedTech

8:30 am – 9:15 am

PANEL

Using Cross-Pollination to Drive Medtech Innovation

Innovation comes from all corners and people. In this session, we'll look at exciting developments in industries such as alternative energy, aerospace, and automotive, and consider their crossover potential in medtech.

Topics covered will include:

- How to identify an idea with crossover potential
- Ways to lean forward and let others be the catalyst for your company's success
- Examining why successful crossover technologies from the past have worked
- Considerations for applying technology to traditionally lower volume production runs

***Moderator:** Richard Greenwald, CEO, Simbex*
***Panelists:** Dale Larson, Director of Commercial Initiatives, Draper Labs*
Vicki Barbur, Technology Transfer Office, The MITRE Corp.
Ibraheem Badejo, Senior Director, New Ventures (Med Devices), Johnson & Johnson Innovation

TRACK A | R&D: New Technologies

Track Chair: TBD

9:15 am – 10:00 am

Solutions for Powering Medical Sensors Autonomously

The healthcare sector is changing to embrace the interconnectivity of the Internet of Things for more proactive patient health management. The rapid development of sensing devices for Wireless Body Area Networks is opening opportunities for continuous health monitoring in the patient's home or the place of care provision. In this session, we'll provide a review of alternatives for powering these devices, comparing the specifications—depending on the various use case—of solutions such as conventional but miniature batteries, solid-state batteries, or supercapacitors.

Topics to be covered will include:

- Requirements of medical sensing devices in terms of their size, shape, life cycle, cost, safety, biocompatibility, and technical performance
- Alternatives for powering devices autonomously, including a comparison of the specifications for the power sources
- Options for charging these power sources wirelessly through induction or harvested energy
- Design examples will be reviewed (subcutaneous cardiac monitors; e-medicine – miniature implantable vagal nerve stimulation; and pacemaker with energy harvesting)

Gary Johnson, Director of Medical Battery Solutions, Ilika

10:00 am – 10:15 am

Morning Break

TRACK B | Product Development: Strategy

Gregg A. Jackson, Director of Business Development, Gershon MedTech

9:15 am – 10:00 am

Marrying R&D and Business Goals

Research and development leads to all kinds of exciting breakthroughs. But just because you can do something doesn't always mean you should. This session will focus on ensuring your R&D efforts support your company's broader business strategy.

Topics covered will include:

- Identifying business priorities and using them to drive R&D efforts
- Ways to ensure your R&D efforts lead to viable projects
- Signs you're heading down the wrong path

David Lucchino, Co-founder and CEO of Frequency Therapeutics
Chris Loose, Chief Science Officer and Co-founder, Frequency Therapeutics

10:00 am – 10:15 am

Morning Break

TRACK A | R&D: New Technologies

Track Chair: TBD

10:15 am – 11:00 am

Point-of-Care Biosensors: Trends, Applications & Markets

Biosensors are already commonly used in laboratories to test patients' samples. As technological advances allow for such tests to be conducted faster and on smaller devices, they are moving out of specialized laboratories and closer to the patient at the point-of-care (PoC). A shift in the PoC diagnostics market is also starting to emerge with the advent of PoC molecular diagnostics. As the addressable market for PoC biosensors expands due to a number of factors impacting the global population and technological innovations, the competitive landscape is changing.

Topics to be covered will include:

- Commercial PoC biosensor categories (lateral flow assays, electrochemical test strips, integrated cartridges, and molecular diagnostics)
- Trends in this industry, and new technologies and devices that are likely to be highly disruptive to the in vitro diagnostics market
- Recent examples in the medtech market

Laura Baers, PhD, Technology Analyst, IDTechEx

TRACK B | Product Development: Strategy

Gregg A. Jackson, Director of Business Development, Gershon MedTech

10:15 am – 11:00 am

The Future of Innovation in the Value-Based Care System

As U.S. healthcare is rapidly shifting from a volume-based to value-based system, device manufacturers must innovate through a value lens by thinking backwards to find fertile ground for innovation.

Topics covered will include:

- Defining value and looking at where device companies can find value
- The pros and cons of frugal innovation
- How device companies can incorporate value elements into the R&D process
- How regulators can help facilitate value-based innovation

Harry H. Liu, Ph.D., Lead in Technology, Health Advisory Services, RAND Corp.

TRACK A | R&D: New Technologies

Track Chair: TBD

11:00 am – 11:45 am

CASE STUDY

Silk Protein Applications in Implantable Devices

Silk's application in medicine is embedded in history. The Greek surgeon, Galen of Pergamon, notes that he used silk to suture together gladiators' severed tendons around 170AD and folklore dating back to at least 2,000 years teaches the use of spider silk to fight infections in wounds. But it wasn't until 1000 years after Galen that the first mass-produced, sterile silk sutures were invented (J&J, 1887). And since, silk sutures have become the representative for silk protein and silk engineering in the medical community. In recent decades, reversed engineered silk (liquidified silk protein) has surfaced from academic research as the next generation biomaterial that couples both superior biocompatibility and engineering controllability. Promising innovative technologies are in development for applications in medical aesthetics, orthopedic reconstructions, and organ repair.

Topics to be covered will include:

- Comparison of silk protein vs other biomaterials
- Identifying applications for new biomaterials
- Challenges with introducing a newly re-invented material to FDA

Anh Hoang, PhD, Chief Science Officer, Sofregen, Inc.

11:45 am – 1:15 pm

Lunch

TRACK B | Product Development: Strategy

Gregg A. Jackson, Director of Business Development, Gershon MedTech

11:00 am – 11:45 am

CASE STUDY

Product Innovation While Embracing Regulatory Control as a Viable Development Strategy

To prepare a new medical design for market readiness, and to achieve 510(k) success, the product development process deployed needs to incorporate medical regulatory and design control requirements. While this approach is often viewed as a "means to an end," this session will reveal the true design innovation potential that results from the proper structuring and application of control methodologies within a unique systems approach. This case study will directly correlate a systems-approach strategy that embraces the regulatory process to reveal output that yields competitive differentiation.

Topics covered will include:

- How embracing a system-approach methodology allows for innovation
- Ways to incorporate market augmentation (unmet needs), and technology enhancement
- Advancing your usage ceremony (workflow) and human-machine interface
- Improving DFX (DFM and DFA, cost competitiveness)

Christopher Montalbano, CEO & Founder, MIDI Medical Product Development

11:45 am – 1:15 pm

Lunch

TRACK A | R&D: New Technologies

Track Chair: TBD

1:15 pm – 2:00 pm

Supply Chain Integrity Using Blockchains for Wearable Health Devices & AI

The confluence of rapid progress in wearable medical devices, advanced sensors, and in artificial intelligence (AI) and Blockchain technologies allows for new ways of collecting data while ensuring the integrity, accountability, and tracking of devices that assist with data interpretation. The availability of many different machine learning techniques and models from potentially different vendors compounds the challenges in tracking conclusions from analyzing the data. Medical device supply chains clearly need to evolve in a world with AI and wearables, and with Blockchain technology you can.

Topics covered will include:

- How modern medical device supply chains and collection of medical data need to evolve for provenance and accountability
- Exploring the various stages of data collection to improve machine learning and data interpretation
- A look at medical device examples

Chandra Narayanaswami, Principal Research Staff Member, IBM TJ Watson Research Center

2:00 pm – 2:30 pm

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 (AI) will change medtech in the coming years, as well as look forward to what might happen once true AI is here. How might AI change the development and application of diagnostic and therapeutic medical devices?

Topics covered will include:

- Reviewing the evolution of AI in imaging, and how it has improved disease detection
- Challenges for patients, doctors, and others
- Using machine learning and deep learning in medical devices

Speaker To Be Announced

TRACK B | Product Development: Strategy

Gregg A. Jackson, Director of Business Development, Gershon MedTech

1:15 pm – 2:00 pm

Creating Supply Partnerships that Span the Product Life Cycle

Few suppliers can do it all, so how do you balance the technical expertise and agility required for developing products with the discipline and controls required to transition into production, ramp, and reduce cost? Can you go fast and then faster?

Topics covered will include:

- Supplier diversity
- Planning for product transfer, pipeline management with your suppliers
- Talent development with your supply partners
- Sole source, single source, preferred source
- Maximizing the benefit of different business priorities

Charlie Dean, Senior Director Supplier Engineering, Intuitive Surgical

2:00 pm – 2:30 pm

The Portfolio Viewpoint

Establishing a portfolio management function is a big step for many companies. Medical device companies must adopt a more rigorous approach toward portfolio management to escape from the vicious circle of slipping timelines, escalating cost, and insufficient resourcing of potential breakthrough innovation. This session will explore key elements of an effective product portfolio management process, helping the R&D department to be more effective.

Topics covered will include:

- Understanding the goals of portfolio management
- Exploring the risks associated with improper balance of the product pipeline
- Integrating global market needs with existing internal capabilities

Bruce Jankowski, Vice President, Portfolio Strategy & EPMO, Medtronic

TRACK A | R&D: New Technologies

Track Chair: TBD

2:30 pm – 2:45 pm

Afternoon Break

2:45 pm – 3:30 pm

CASE STUDY

Development of a State-of-the-Art Robotic System: Lessons from the Field

Designing a surgical robot for minimally invasive surgery can be quite daunting, especially with the myriad of advanced technologies that are available. This presentation provides an overview of key findings and considerations for designing surgical robotics and includes a view into the future.

Topics covered will include:

- Trends in surgical robotics and a look at key market players
- Researching and identifying the need for medtech robotics
- Informing the design of the device

Meghan Thorne, Project Manager, MedRobotics

3:30 pm – 4:00 pm

Building a Technology Portfolio for the Future

Sometimes the problem is not coming up with new technologies, it's deciding which ones to pursue. In this session, we'll explore strategies for evaluating concepts for new medical devices and provide a case study demonstrating what represents a strong choice.

Topics covered will include:

- Identify the parameters of an unmet need
- Strategies for weighing your options
- What to do with concepts you don't immediately pursue
- A look at a case study that demonstrates the potential

Brian McGlynn, Founder, Executive Vice President, and Chief Technology Officer, BioDirection Inc.

TRACK B | Product Development: Strategy

Gregg A. Jackson, Director of Business Development, Gershon MedTech

2:30 pm – 2:45 pm

Afternoon Break

2:45 pm – 4:00 pm

The Essentials of Medical Device Product Life Cycle Management

Design and development engineers make significant decisions throughout a medical device product life cycle. These decisions may impact not only the cost of a product, but also the product function and quality. Moreover, regulations are constantly changing to capture and control these linkages. This session will explore how to balance these often-conflicting requirements.

Topics covered will include:

- How decisions made by development engineers at all stages of a product life cycle may impact product performance
- Ways regulatory agencies are adapting their requirements to ensure consistent controls for safe and effective medical devices
- Strategies you can use to help product development engineers and regulatory teams get faster global approvals

Eri Hirumi, Regulatory Affairs Specialist, MicroVention

TRACK A | R&D: Technology Integration

Gregg A. Jackson, Director, Business Development, Gershon MedTech

8:30 am – 9:15 am

Evaluating New Technologies Using a Balanced Score-Card Approach

New technology abounds, but how do you find and confidently select a new technology to meet your specific product needs? In this session, you'll learn a proven multi-step process to identify and assess available technologies to minimize risk while determining the best fit for your next product.

Topics covered will include:

- Establishing key requirements and identifying candidate technologies from multiple markets
- Performing analyses to show that fundamentals of the technology can meet the product requirements
- Demonstrating the selected technology provides adequate performance over the expected range of conditions

Megan Moore, Program Director, Battelle

9:15 am – 10:00 am

At the Fuzzy Front End, How Much Engineering is Enough?

Product developers play a unique role during the fuzzy front-end development process. Successful innovation requires that new products live at the intersection of feasibility, viability, and desirability. Often, market research or concept preference testing is used to help determine if a proposed concept will be desired and unique in the marketplace. Correspondingly, business modeling, proforma income statements, and pricing research can help assess if the business has a viable path to profitability. Assessing feasibility early can present a unique challenge.

Topics covered will include:

- How to avoid selecting concepts and technologies that might be fatally flawed
- Ways to strike a balance between risk and reward when focusing engineering efforts
- Tools, techniques, and methods that can be used to assess feasibility while maintaining flexibility for innovation
- Different approaches to risk mitigation, tools for identifying risk, and tools for minimizing risk

Dave Franchino, President, Design-Concepts Inc.

TRACK B | Product Development: Design

Bill Betten, President, Betten Systems Solutions LLC

8:30 am – 9:15 am

Product Development Management Styles: What's Yours?

Many companies today are living through the advent of choosing from various new product development philosophies. Do you follow an agile or waterfall method? Amalgamating product development practices from both methodologies is tough. Choosing only one method is just as hard.

Topics covered will include:

- What are the differences in philosophies and why does it matter? Why should it matter?
- Decision tools for product development philosophies
- Can you use various methods depending on your product portfolio?

Stuart Kozlick, Vice President, Medical Robotics, Kinova

9:15 am – 10:00 am

A Systems Approach to Better Product Development

Medical devices are evolving and becoming more complex. In this day and age, there is an ever-increasing demand and need to develop and produce systems that are robust, reliable, high-quality, supportable, cost-effective, and responsive to the needs of the customer or user. As a result, the definition of systems engineering is changing. The industry has already started to shift, albeit slowly. Have you?

Topics covered will include:

- What does it mean to really take a "systems" approach to product design development?
- Effective ways to integrate multi-disciplinary teams of disparate talent to cover a true "system"
- Product development life cycle approaches to truly streamline the design and development process

Stuart Kozlick, Vice President, Medical Robotics, Kinova

10:00 am – 10:15 am

Morning Break

TRACK A | R&D: Technology Integration

Gregg A. Jackson, Director, Business Development, Gershon MedTech

10:00 am – 10:15 am

Morning Break

10:15 am – 11:00 am

Criteria for Choosing the Right Material for Your Device

Selecting the best materials for use in your medical device is critical to optimizing your design for manufacturing, assembly, packaging, sterilization, and testing. Depending on the application and classification of a medical device and its accessories, the use of the right material will make all the difference. In this session, we'll look at a number of important factors to consider, so you can make the right choice for your device.

Topics covered will include:

- Criteria for design elements
- Conditions of cost, availability, reliability, and supply chain
- Considerations for commercialization and speed to market
- Recent medtech examples

Vipul Davé, Research Director & Fellow, Global OTC Technology, Johnson & Johnson

11:00 am – 11:45 am

Effective Prototype Development

As a medical product moves close to production, a rigorous development and documentation process is required. You'll need to understand how to work with different materials and processes to bridge the gap between prototype and finished product.

Topics covered will include:

- Detailing various methods of developing prototypes
- Reviewing limitations of prototypes and how they can effectively be tested and utilized in the development process
- Exploring the stages of prototype refinement and testing to support a pre-submission meeting with FDA

Speaker To Be Announced, Proto Labs

TRACK B | Product Development: Design

Bill Betten, President, Betten Systems Solutions LLC

10:15 am – 11:00 am

Moving Products to Market Faster

Efficient product development comes through the implementation of a systematic project management process. There are time-honored strategies for accelerating time-to-market, but how do these work best?

Topics covered will include:

- Organizing and planning the development process
- Streamlining the critical path to success
- Avoiding known pitfalls and focusing on better practices
- How to avoid regulatory compliance misses

Bill Betten, President, Betten Systems Solutions LLC
Tom Waddell, CEO, Waddell Group

11:00 am – 11:45 am

CASE STUDY ROUNDTABLE

Using Voice & AR Technologies to Better Understand Users and Accelerate Product Development

Understanding your end user is crucial for launching a successful product. Advances in technology, such as augmented reality (AR), are transforming this process by enabling companies to share product concepts quickly and dynamically. These tools can be used to more quickly prototype and validate user needs. This session will focus on the collaboration needed between the designers and engineers to concurrently design, develop and test system assumptions to meet the client needs.

Topics covered will include:

- Hear 3 case studies where new technology was used to quickly and efficiently bring a product from sketch to production
- Learn how to introduce new technology and processes, such as holograms on AR headsets, to the product development cycle
- Highlight additional AR applications throughout the product development life cycle – including compliance

Brandon Bogdalek, Product Development Consultant, Worrell
Bobby Boyer, Senior Mechanical Engineer, HS-Design
Jesse Rusk, Medical Devices Directgor, Boston Engineering

TRACK A | R&D: Technology Integration

Gregg A. Jackson, Director, Business Development, Gershon MedTech

11:45 am – 1:15 pm
Lunch

1:15 pm – 2:00 pm CASE STUDY

From XPRIZE to CES: Commercialization of a Medical Tricorder

In 2017, Cloud DX was named the first-ever XPRIZE Bold Epic Innovator for delivering Vitlaiti, a fully-functioning autonomous medical diagnostic platform, powered by artificial intelligence, modeled after the famous "Medical Tricorder" from Star Trek. Vitaliti records and streams all the vital signs to the cloud with gold-standard accuracy. It analyzes minute blood, saliva and urine samples using Nobel-prize winning lab-on-a-chip technology, developed at Stanford University and the on-board AI can diagnose 19 separate medical conditions completely autonomously. In 2018, a new commercial iteration Vitaliti enters clinical validation trials for full FDA clearance of the wearable continuous vital sign monitor. If you've ever wondered how a product inspired by science fiction makes it in the real world, this talk should not be missed!

Topics covered will include:

- Hear about the engineering, firmware, software and regulatory steps taken to move this award-winning technology out of the lab and into production
- Discuss the machine learning algorithms employed to measure 7 different respiratory illnesses and how those will be tested in a multi-thousand patient study
- Explore the hurdles to achieving FDA clearance for multi-channel medical devices, including bio-safety, electrical safety, proof of efficacy and more

Robert Kaul, President & CEO, CloudDX, Inc

TRACK B | Product Development: Design

Bill Betten, President, Betten Systems Solutions LLC

11:45 am– 1:15 pm
Lunch

1:15 pm – 2:00 pm

Bridging User Needs & Design Requirements

Your users can be your greatest source of inspiration, but how do you turn what they tell you into a viable product? In this session, you'll learn how to translate user needs into formal design requirements that pass regulatory muster and result in a successful product.

Topics covered will include:

- How to read between the lines of user feedback
- Best practices for drafting design requirements
- A systems approach to requirement management
- De-risking Validation through better Verification

Nick Lesniewski-Laas, Director of Systems Engineering, Sunrise Labs Inc.

TRACK A | R&D: Technology Integration

Gregg A. Jackson, Director, Business Development, Gershon MedTech

2:00 pm – 2:30 pm

CASE STUDY

An Innovative Brainstem Biosignal & Non-Invasive Wearable Sensor

In this session, CEO and biomedical pioneer Michael Baltay will provide an overview and demonstration of recent advances in the development of a miniature, non-invasive wearable neurosensor device and nano biosignal being used to generate groundbreaking insights into the function and condition of the brainstem—your body's vital control center—applicable in clinical, consumer, and industrial applications.

Topics covered will include:

- Introduction of this brainstem biosignal (500–1500nm and 0–180 Hz) measured on the eyelid
- The story behind the design and development of this thin-film-printed piezo electric sensor and wearable amplifier (live physical demonstration)
- Examples of signal acquisition and analysis indicative of various brain states and conditions, including the live awake normal record of the speaker
- Future product and technology innovation roadmap

Mike Baltay, President and CEO, BrainStem Biometrics Inc.

2:30 pm – 2:45 pm

Afternoon Break

TRACK B | Product Development: Design

Bill Betten, President, Betten Systems Solutions LLC

2:00 pm – 2:30 pm

CASE STUDY

Case for Quality: Implementing the Medical Device Company Maturity Model

The Medical Device Innovation Consortium (MDIC) is driving quality improvements for medical device companies through the Case for Quality (CfQ) project, specifically developing a maturity model assessment for the industry. In July 2017, FDA introduced the Medical Device Discovery Appraisal Program (MDDAP) and is now offering regulatory incentives to sign-up for the program. Innovize is one of the first companies to go through pilot assessments.

Topics covered will include:

- How the program focuses on project management best practices to accelerate time to market
- Exploring how the program looks at efficient implementation of design controls
- Ways the new program can save you time and money on FDA approvals
- A review of the MDDAP program, FDA incentives, and the Innovize experience

Mark Rutkiewicz, Vice President, Quality, Innovize

2:30 pm – 2:45 pm

Afternoon Break

TRACK A | R&D: Technology Integration

Gregg A. Jackson, Director, Business Development, Gershon MedTech

2:45 pm – 4:00 pm

Creating Your Minimum Viable Product

Let's assume you've gone through multiple cycles of design updates, informed by your project goals and requirements, regulatory considerations, and your long-term business or clinical strategy. Now it's time to select a technology platform and begin developing a fully functioning prototype of your innovation: your minimum viable product (MVP). In this session, we'll look at technical and tactical considerations to ensure both the success of your MVP and your company's long-term success and sustainability.

Topics covered will include:

- Technology selection tradeoffs
- Balancing development of your MVP and long-term product
- First steps toward commercialization and 'feature creep'
- Medical device case examples

Steve Weisner, President & CEO, Nihon Kohden Innovation Center

TRACK B | Product Development: Design

Bill Betten, President, Betten Systems Solutions LLC

2:45 pm – 4:00 pm

5 Tips for Getting New Products Through FDA

Getting medical devices with new technology through the regulatory pathway is no easy task. In this session, you'll hear tips offered through case examples from companies with digital health products or other new devices that are moving the needle on innovation within a regulated environment.

Topics covered will include:

- Challenges faced by disruptive devices
- Exploring innovative regulatory strategies
- Ways to assess regulatory burden

Mike Drues, President, Vascular Sciences