M&M MINNEAPOLIS

November 8–9, 2017
Minneapolis Convention Center | Minneapolis, MN

FROM SPARK TO SCALE-UP

Speeding Medtech Innovation to Market

AGENDA-AT-A-GLANCE

Day One – Wednesday, November 8	
8:00 a.m.	Registration and Refreshments
8:30 a.m. – 4:30 p.m.	**Track A** Product Development & Manufacturing *Engineering to Production* **Track B** R&D and User-Centered Design *Finding Your Next Breakthrough* **Track C** Hands-On Workshops
10:00 a.m. – 10:15 a.m.	Refreshment Break
11:45 a.m. – 1:15 p.m.	Networking Lunch
2:45 p.m. – 3:00 p.m.	Refreshment Break

Day Two – Thursday, November 9	
8:00 a.m.	Registration and Refreshments
8:30 a.m. – 4:30 p.m.	**Track A** Product Development & Manufacturing *Scaling Up & Slimming Down* **Track B** R&D and User-Centered Design *Design Toolkit* **Track C** Hands-On Workshops
10:00 a.m. – 10:15 a.m.	Refreshment Break
11:45 a.m. – 1:15 p.m.	Networking Lunch
2:45 p.m. – 3:00 p.m.	Refreshment Break

UBM

8:30-9:10

Plenary Session: How to Sell Your Idea to Upper Management

Pitching a new medical device project to your boss is like selling anything else: You have to consider the cost-benefit analysis from his or her perspective. To convince your supervisor that your brainchild is worth the risk, you need to understand your company's business model and be prepared with answers to all the questions that must be considered before bringing a product to market. We've assembled a group of top medical device executives and managers who can help you speak the language of management to pitch your idea up the chain of command.

Topics covered will include:

- How can the company take an R&D product to market in the fastest possible way?
- Understanding how executives and managers identify business priorities to help drive product development efforts
- Signs you are heading down the wrong path
- Five tips to make them say "yes"
- How can the company take an R&D product to market in the fastest possible way?

MODERATOR:

***Kevin Arnal**, Owner, Beachfront Design*

PANELISTS:

***Ralph Cardinal**, Director, R&D, Boston Scientific*

***Jennifer Raeder-Devens**, Vice President, R&D, Infection Prevention, Becton Dickinson*

***Matt Adams**, Vice President and General Manager, Minnetronix Neuro*

TRACK A
Product Development & Manufacturing:
Engineering to Production

Track Chair: William Betten, Director of Business Solutions, Devicix by Nortech

9:15 – 10:00 PANEL

Product Development Across Borders

With product development teams today scattered across different facilities, countries, and even companies, how do you bring everyone together to create the best device possible? In this session, panelists will discuss how to navigate remote working relationships to ensure product development success.

Topics covered will include:

- Tools for enhancing collaboration across distance
- Structuring your team for remote working success
- Avoiding pitfalls of remote teams

MODERATOR:

***William Betten**, Director of Business Solutions, Devicix by Nortech*

TRACK B
R&D and User-Centered Design:
Finding Your Next Breakthrough

Track Chair: Derek Mathers, Director of R&D—Advanced Applications Development, Worrell

9:15 – 10:00 PANEL

Using Cross-Pollination to Drive Medtech Innovation

As the filmmaker Jean-Luc Godard said, "It's not where you take things from—it's where you take them to." 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
- How to adapt technologies from other industries for use in medtech
- Examining why successful crossover technologies from the past have worked

TRACK C
Hands-On Workshops

Presented by: Kablooe

8:30 – 11:45

Workshop: Crash Course in Design-Driven Development

In this hands-on design-thinking workshop, Minneapolis-based medical device design and development firm Kablooe will walk (and run) attendees through the Design-Driven Development (D3) process.

Topics covered will include:

- Empathy for end users
- Requirements for requirements
- Quick concept generation techniques
- Integration of user testing

***Brian Mullins**, Director of Design & Development, Kablooe*

TRACK A
Product Development & Manufacturing:
Engineering to Production

Track Chair: William Betten, Director of Business Solutions, Devicix by Nortech

PANELISTS:

***Ryan Douglas**, CEO, Nextern*

***Adam Reinhardt**, R&D Manger, Boston Scientific*

***Eric R Johnson**, Senior Engineer, Medical Devices, Nestlé HealthCare Nutrition Inc.*

10:00 – 10:15
Morning Break

10:15 – 11:00
Patient Preference Studies

FDA is increasingly considering patients' feedback during the approval process. This session will look at how you can harness that to your advantage.

Topics covered will include:
- FDA's current thinking on patient preference studies
- How to design and conduct patient preference studies
- Using patient preference studies to speed approval

***Stephanie Christopher**, Program Director, Medical Device Innovation Consortium (MDIC)*

***Anindita Saha**, Director, External Expertise & Partnerships, CDRH*

TRACK B
R&D and User-Centered Design:
Finding Your Next Breakthrough

Track Chair: Derek Mathers, Director of R&D—Advanced Applications Development, Worrell

- Considerations for applying technology to traditionally lower volume production runs

MODERATOR:

***Bonnie Kee-Bowling**, Senior Engineering Manager, New Wave Design and Verification*

PANELISTS:

***Srihari Yamanoor**, President, DesignAbly*

***Dale Larson**, Director of Commercial Initiatives, Draper Labs*

***Alex Thaler**, Senior Global Product Manager, Smiths Medical*

10:00 – 10:15
Morning Break

10:15 – 11:00
How Innovation Beyond Line Extensions Can Happen Within Established Organizations

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

Topics covered will include:
- Enabling and encouraging innovation thinking
- Avoiding the stake-holder quagmire
- Charting a course to first in human through a large corporate quality system
- Clinical introduction
- Lessons learned for companies of any size pursuing innovation

***Steve Geist**, Research & Development, Edwards Lifesciences Transcatheter Mitral & Tricuspid Therapies*

TRACK C
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DAY 1 — Wednesday, November 8

TRACK A
Product Development & Manufacturing: *Engineering to Production*

Track Chair: William Betten, Director of Business Solutions, Devicix by Nortech

11:00 – 11:45

Busting Medical Device Development Myths

Correcting major misconceptions around the process of medical device product development makes for a more elegant approach. What many may think is a best practice is probably not ideal and could actually be an inefficient process. A lot of conventional wisdom is flat out backwards and contradicts simple logic.

Topics covered will include:

- Defining current development vs. ideal development practices
- Rethinking our standard tools and techniques to bust myths
- Creating and utilizing an efficient development strategy
- Looking at a case study of serial commercial success

***John Crombie**, Vice President, Research & Development, ZSX Medical*

11:45 – 1:15

Lunch

1:15 – 2:00 CASE STUDY

Case Study: Developing MR-Conditional Devices

Recent years have seen the successful development and approval of MR-conditional pacemakers. This session will cover best practices for the development of MR-conditional medical devices from a large company, small company, and regulatory perspective.

Topics covered will include:

- Exploring options for managing MRI interactions, including static, gradient, and RF fields

TRACK B
R&D and User-Centered Design: *Finding Your Next Breakthrough*

Track Chair: Derek Mathers, Director of R&D—Advanced Applications Development, Worrell

11:00 – 11:45

Low-Cost, High-Impact Research

No matter what the size of your R&D budget, it never seems like enough. This session will look at ways you can pinch pennies without sacrificing on innovation.

Topics covered will include:

- How to identify and eliminate waste in your R&D budget
- Cost-efficient tools to enhance innovation
- Tips to get the biggest bang for your research buck

***Nikhil Murdeshwar**, Core Team Leader/Principal Research Engineer, Olympus*

11:45 – 1:15

Lunch

1:15 – 2:00

The Micro/Nano Materials Revolution

Small but mighty materials innovations at the micro and nano levels could lead to big advances in medtech. This session will look at some recent developments in the biomedical applications of nanotechnology and how these developments could relate to your next project.

Topics covered will include:

- Exploring applications of nanoparticles for imaging, diagnostics, and drug delivery
- Discussing advanced biomedical devices enabled by nanotech
- Considering emerging micro- and nanostructured materials for medical applications

***James Marti**, PhD, Senior Scientist & Outreach Coordinator, University of Minnesota, Minnesota Nano Center*

TRACK C
Hands-On Workshops

Presented by: University of Minnesota, Worrell, and Medtronic

1:15 – 5:00

Workshop: Redefining Rapid Prototyping

Virtual prototyping could be an additive tool or, in some cases, a unique means for gaining medical device approvals. This workshop 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 covered will include:

- 3D modeling, printing, and creating virtual reality tools of medical device/tissue interfaces
- How these technologies will augment and expedite medical device design
- Real-life examples of how these technologies have been utilized

3D Modeling and Virtual Prototyping in the Visible Heart Laboratory

***Paul A. Iaizzo**, PhD, FHRS, Professor, Visible Heart Research, University of Minnesota*

Virtual Prototyping of Medical Devices, the Worrell Experiences

***Brandon Bogdalek**, Business Development Manager, Worrell*

AR for the Simulation of a Micra (Leadless) Pacemaker Implant

***Pamela Omdahl**, Procedure Development Consultant, Medtronic*

***Jay Reid**, Director of Procedure Training, Medtronic Global Medical Education*

Post-Device Implant Imaging and Analyses

***Michael Bateman PhD**, Assistant Professor, University of Minnesota Visible Heart Lab*

TRACK A
Product Development & Manufacturing: *Engineering to Production*

Track Chair: William Betten, Director of Business Solutions, Devicix by Nortech

- Reviewing current testing standards and best practices
- Clinical implications of labeling and strategies to streamline the regulatory review process

***John Rondoni**, Vice President Product Development, Operations, & Quality, Inspire Medical Systems*

***Sandy Wixon**, MRI Technology Group Leader, Medtronic CRHF*

***Terry Woods**, Solid Mechanics Laboratory Leader, CDRH*

2:00 – 2:30

Intended Use vs. Indications for Use: How to Get Your Regulatory Submission Right the First Time

Intended use and indications for use are two terms that are often mistakenly treated as interchangeable. This session will explain why the difference between the two matters from a regulatory perspective.

Topics covered will include:

- What is the difference in terminology?
- Why does product classification matter?
- Understanding the impact on design controls and quality measures

***Karen Corallo**, Of Counsel, Greenberg Traurig*

2:30 – 2:45

Afternoon Break

TRACK B
R&D and User-Centered Design: *Finding Your Next Breakthrough*

Track Chair: Derek Mathers, Director of R&D—Advanced Applications Development, Worrell

2:00 – 2:30

CASE STUDY

Assistive Tactile Feedback on the Neck to Enhance Situational Awareness

Surgical robotics and other technologies are taking away the sense of touch physicians have often relied upon in their work. This session will explore how haptics can help replace tactile sensation and provide enhanced control for users.

Topics covered will include:

- Exploring technologies that enable haptic feedback
- Understanding how different applications can benefit from kinesthetic and tactile feedback
- Addressing challenges associated with incorporating haptics into medical devices

***Reza Taghavi**, PhD, Founder, Tactile Image Inc.*

2:30 – 2:45

Afternoon Break

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Hands-On Workshops

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TRACK A
Product Development & Manufacturing:
Engineering to Production

Track Chair: William Betten, Director of Business Solutions, Devicix by Nortech

2:45 – 3:15

The Power of Extractable/Leachable Chemistry Testing for 3D-Printed Plastic Medical Devices

This presentation will teach you the three most important points of extractable/leachable chemistry testing for medical devices: how it will save you time and money, how it provides detailed information that protects patient safety, and how it will keep you at the forefront of an evolving approach to the evaluation of biocompatibility. The discussion focuses on special concerns in the context of 3D-printed polymer medical devices.

Topics covered will include:

- The fundamentals of extractable/leachable chemistry testing
- Pros and cons of additive manufacturing of polymer medical devices
- The testing and analysis process using a real 3D-printed device

***Audrey Turley**, Research Scientist, Nelson Labs*

3:15 – 4:00

Effective Prototype Development

As a medical product moves close to production, a rigorous development and documentation process is required. Early feasibility studies require no less discipline and attention to detail. This session will describe a simplified approach to early feasibility studies that captures the essential deliverables while minimizing unnecessary and burdensome activities.

Topics covered will include:

- Identification of stakeholders
- Confirmation of stakeholder needs
- Analysis of current state
- Development of requirements
- Design of the product
- Verification and validation of results

TRACK B
R&D and User-Centered Design:
Finding Your Next Breakthrough

Track Chair: Derek Mathers, Director of R&D—Advanced Applications Development, Worrell

2:45 – 3:15

Controlling Materials-Related Costs in Implantable Devices

Healthcare customers are increasingly concerned with the cost of medical devices. In this session, we'll explore how, by working with material suppliers, product designers, and processors, you can control costs for implantable devices.

Topics covered will include:

- Exploring the various polymers on the market for implantable devices
- Understanding how complete testing can ease or simplify the selection process
- Why iterative design based on test results is key
- Working with materials suppliers and processors on cost containment

***Len Czuba**, President, Czuba Enterprises*

3:15 – 4:00

Marrying R&D & 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

***Binita Sinha**, Director—Global R&D, Cantel Medical*

TRACK C
Hands-On Workshops

Presented by: University of Minnesota, Worrell, and Medtronic

1:15 – 5:00

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TRACK A
Product Development & Manufacturing:
Engineering to Production

Track Chair: William Betten, Director of Business Solutions, Devicix by Nortech

***Mark Wehde**, Section Head, Technology Development, Mayo Clinic—Division of Engineering*

4:00 – 4:30

The Impact of New Reimbursement Payment Models on Product Development

- A look at new provider payment models (i.e., bundled payments, accountable care organizations, etc.)
- A review of the new physician payment model under the Medicare Access and CHIP Reauthorization Act
- Major CMS policy changes that may impact medical device reimbursement going forward
- Potential impact in defining "value" under these new payment models

***Mark Domyahn**, President, Pursuance Consulting LLC*

4:30 – 5:00

Engineering Must-Knows: Transitioning from Concept to Market

- How to quickly get to a minimum viable product
- Knowing when to let go of the minimum viable product
- Recognizing that good manufacturing practices are on your side
- How to plan for the transition to manufacturing early
- The value-add of structured sales, marketing, and support programs

***Laura Zumbrunnen**, President, InControl Health*

***Mike Zumbrunnen**, CEO, InControl Health*

***Dan Spores**, Chief Commercial Officer, InControl Health*

TRACK B
R&D and User-Centered Design:
Finding Your Next Breakthrough

Track Chair: Derek Mathers, Director of R&D—Advanced Applications Development, Worrell

4:00 – 5:00

Show Floor Tour: Emerging Technologies

- Meet promptly at 4:00 p.m. outside the meeting room to begin the tour
- Tour the Minneapolis MD&M Expo Hall to visit 4-6 suppliers
- Tour stops will be announced closer to show date

***Jamie Hartford**, Director of Content, Medtech Brands, UBM Americas, Advanced Manufacturing Group*

TRACK C
Hands-On Workshops

5:00 - 6:30

MD&M Minneapolis Networking Cocktail Reception
Sponsored by: Spartan
Room 103B-E

Join the medtech community for some casual networking with cocktails!

Compliments of our esteemed sponsor, Sparton Corporation - a contract manufacturing and design company specializing in design, manufacturing, and distribution for outsourcing OEMs.

DAY 2 — Thursday, November 9

TRACK A
Product Development & Manufacturing:
Engineering to Production

Track Chair: Ryan Douglas, Chief Executive Officer, Nextern

8:30 – 9:15

Improving Process Control to Reduce Time to Market

In the medical device industry, increased competition and limits on reimbursement have forced a cost-reduction philosophy in what was once a highly profitable business. Manufacturers now need to retain or improve time to market and quality while keeping costs down.

Topics covered will include:

- Understanding where your waste is during manufacturing
- Recognizing process variability and capability by obtaining and using data
- Improving processes through effective product and process design
- Explore better practices and case examples

***Cushing Hamlen**, Principal Consultant, DPM Insight LLC*

9:15 – 10:00

Process Capabilities: Finding the Right Partner

Although using a contract manufacturer can benefit almost all medical device companies, the primary benefits include collaborative innovation, the efficient use of limited funds, and minimizing or eliminating the need for direct capital investment.

Topics covered will include:

- Understanding innovative, cost-effective approaches to scale-up and mass production
- Exploring considerations for quality, performance, and efficiency
- Improving long-term commercialization partnerships

***Brian Loushine**, Head of Business Development, Nextern*

TRACK B
R&D and User-Centered Design:
Design Toolkit

Track Chair: David Copeland, Director of Human Factors Industrial Design, Ximedica

8:30 – 9:15

Zero UI Can Provide a More Natural UI That Can Drive Patient Engagement

More natural user interfaces can allow patients to be more engaged with their healthcare. These interfaces need to support people's humanity to understand and shape positive health behaviors.

Topics to be covered include:

- How zero UI can solve healthcare's biggest problem
- Why a monolithic technology approach doesn't account for user behavior
- How natural UIs can make a difference in the OR, at the point of care, and for aging in place

***Aidan Petrie**, Cofounder, Ximedica*

9:15 – 10:00

Deep Design: Using Technology to Improve Clinical Work Processes

Designing human-centered systems using deep design at the granular level is key to shaping behavior to achieve desired outcomes. The focus is on clinicians' work to improve the patient experience.

Topics covered will include:

- Improving human performance and error reduction
- Working with processes, technology and infrastructure to shape behavior
- Eliminating barriers using simple, elegant design
- Sharing of examples and use cases

***Kathleen Harder**, PhD, Director, Center for Design in Health & Director of Graduate Studies, Human Factors Program, University of Minnesota*

TRACK C
Hands-On Workshops

8:30-11:45

Workshop: Transforming Healthcare with Augmented & Virtual Reality

Augmented and virtual reality (AR and VR) applications in healthcare are opening up new possibilities for both patients and providers. In this hands-on workshop, attendees will learn how to incorporate AR and VR elements into their medical devices and get the chance to demo cutting-edge AR and VR platforms such as Google Cardboard, Oculus Rift, and Microsoft HoloLens.

Topics covered will include:

- The difference between AR and VR
- Mobile VR and 360-degree video techniques
- How to empower healthcare professionals with gesture, gaze, and voice control
- Strategies for designing for a world without screens

***Brandon Bogdalek**, Business Development Manager, Worrell*

TRACK A
Product Development & Manufacturing:
Engineering to Production

Track Chair: Ryan Douglas, Chief Executive Officer, Nextern

10:00 – 10:15
Morning Break

10:15 – 11:00
Aligning Design of Experiments

The focus by FDA on design and process validation underscores the need for well-planned experimentation. Such experiments can provide data that will enable device manufacturers to identify the causes of performance variations. They can then eliminate or reduce such variations by controlling key design and process parameters, thereby improving product quality.

Topics covered will include:
- How to ensure your design of experiments aligns with regulatory expectations
- Lessons from the field
- Identifying problems before it's too late

***Perry Parendo**, President, Perry's Solutions Inc.*

TRACK B
R&D and User-Centered Design:
Design Toolkit

Track Chair: David Copeland, Director of Human Factors Industrial Design, Ximedica

10:00 – 10:15
Morning Break

10:15 – 11:00
How Usability Research & Engineering Are Changing Medical Device Development

Usabilty engineering is an intrinsic part of the development process. It is an adjunct discipline with risk management; both exist to keep your project and company out of

trouble. Usability engineering can help your company meet new regulatory requirements and help ensure that you design the right device for real-world needs. It does not have to burden your project with more cost and time if it is harmoniously integrated with project planning, feasibility, and development.

Topics covered will include:
- Looking at the differences between clinical and home-use devices and the cross-pollination of consumer design attributes
- Balancing function and aesthetics, use of materials, and interface technologies, while mitigating use-error opportunities
- The interrelationship of risk management, use safety, and user interface design
- Weighing ruggedness, ease of use/servicing/cleaning, and high-volume (disposable) and low-volume (durable) manufacturing strategies

***Sean Hägen**, Principal, Director of Research & Synthesis, BlackHägen Design*

***Michael Lynch**, Managing Consultant, Intertek*

TRACK C
Hands-On Workshops

8:30-11:45
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***Brandon Bogdalek**,*

DAY 2 — Thursday, November 9

TRACK A
Product Development & Manufacturing:
Engineering to Production

Track Chair: Ryan Douglas, Chief Executive Officer, Nextern

11:00 – 11:45

Is 3D Printing Viable for Manufacturing?

It's already a tried-and-true tool for prototyping, but is additive manufacturing beneficial for production? This session will look at when it can make sense.

Topics covered will include:

- Exploring applications where 3D printing makes sense for part complexity and high value parts
- The challenges of scaling up 3D printing
- Examples where the technology is improving

***Thomas Davis**, Applications Engineer, Proto Labs*

11:45 – 1:15

Lunch

1:15 – 1:45

Form 483s: Reading Between the Lines

So, you've received a Form 483. What do those observations mean anyway? This session will help you make sense of it all and get back on track.

Topics covered will include:

- Translating a Form 483 into actionable steps
- Observation and deficiency trends and how to prevent them in your product
- Correcting problems quickly in a positive collaboration with FDA
- Lessons learned from industry

***Mark Gardner**, MBA, JD, President, Gardner Law*

TRACK B
R&D and User-Centered Design:
Design Toolkit

Track Chair: David Copeland, Director of Human Factors Industrial Design, Ximedica

11:00 – 11:45 CASE STUDY

How Human-Centered Design Disrupted Cancer Treatment

Varian Medical Systems recently unveiled a new cancer treatment system that is changing the way image-guided volumetric intensity modulated radiotherapy is delivered. In this session, representatives from the company will explain the design thinking behind the Halcyon System.

Topics covered will include:

- Increasing efficiency vs. cutting cost
- Incorporating patient feedback into your design
- Simplifying complex technology

***Mu Young Lee**, Director of New Product Solutions, Varian Medical Systems*

11:45 – 1:15

Lunch

1:15 – 1:45

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.

Topics covered will include:

- How to read between the lines of user feedback
- Best practices for drafting design requirements
- Meeting both design requirements and user needs

***Mike Drues**, President, Vascular Sciences*

TRACK C
Hands-On Workshops

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***Brandon Bogdalek**,*

TRACK A
Product Development & Manufacturing:
Engineering to Production

Track Chair: Ryan Douglas, Chief Executive Officer, Nextern

1:45 - 2:15

Smart Industry: Using Database Systems & Analytics to Improve Operations & Reduce Costs for Effective Supply Chain Management

Connected systems, advanced analytics, and optimization tools are being integrated into internal operations and contract manufacturing at a quickening pace, setting the foundation for long-term supply chain improvement in medical device manufacturing.

Topics covered will include:

- Digitally modeling, connecting, and communicating your products and supply chain activities
- Establishing Manufacturing Intelligence Systems to understand and optimize your supply chain
- Understanding regulations and other barriers to implementation and their effect on deployment time and costs
- Industry examples and benefits of smart industry adoption

***Nicholas Paradis**, Manufacturing & Supply Chain Engineer, Paradis Professional Solutions*

2:15 – 2:30

Afternoon Break

TRACK B
R&D and User-Centered Design:
Design Toolkit

Track Chair: David Copeland, Director of Human Factors Industrial Design, Ximedica

1:45 - 2:15

Designing Surgical Robots: 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 to the future.

Topics covered will include:

- Researching and identifying needs
- Informing the design of the device
- Considering cost and efficacy
- A look to the future of surgical robots

***Meghan Thorne**, Project Manager, Medrobotics*

2:15 – 2:30

Afternoon Break

TRACK A
Product Development & Manufacturing:
Engineering to Production

Track Chair: Ryan Douglas, Chief Executive Officer, Nextern

2:30 – 3:00

The Power of Process Development

The world of product development and manufacturing lives and dies by quality and on-time delivery. Taking a product from R&D to production is full of complex decisions and potential land mines. This session will show you how Boston Scientific approaches the commercialization of its products.

Topics covered will include:

- A look at values and talent density
- What winning looks and feels like
- The idea-to-commercial process used by Boston Scientific

***Luke Christianson**, Vice President, Process Development, Boston Scientific*

3:00 – 4:00

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TRACK B
R&D and User-Centered Design:
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2:30 – 3:00

From Inception to Validation: A Comprehensive Approach to Optimizing Usability While Meeting FDA Requirements

Incorporating a robust usability approach throughout device development can optimize design while meeting FDA expectations.

Topics covered will include:

- Identifying usability activities that can be conducted at every stage of development
- Thinking about potential usability problems from a work systems perspective
- How to meet and exceed FDA expectations
- Avoiding common mistakes when starting in medical human factors

***Natalie Abts**, Program Manager, Usability Services, National Center for Human Factors in Healthcare, MedStar Institute for Innovation, MedStar Health*

3:00 – 3:30

Smart Design for Sustainable Market Evolution

Investing in market research is a dynamic opportunity to incorporate customer needs into continuous product design improvement. Proper use of 3D printing technology allows strategic product design. Customer interaction's feedback with the product design allows a better understanding on the improvements required on product sustainability.

Topics covered will include:

- Exploring how smart 3D printing can speed design
- Designing for the customer expectations
- Using feedback for continuous improvement on product design

***Jorge Chaves**, R&D Engineer, Boston Scientific*

***Carol Piedra**, Biotechnology Engineer, Boston Scientific*

TRACK A
Product Development & Manufacturing:
Engineering to Production

Track Chair: Ryan Douglas, Chief Executive Officer, Nextern

TRACK B
R&D and User-Centered Design:
Design Toolkit

Track Chair: David Copeland, Director of Human Factors Industrial Design, Ximedica

3:30 – 4:00

CASE STUDY

How the Home Environment Affects the Usability of Medical Devices

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 the patients' homes. However, designs have not changed accordingly. This presentation will cover several recent usability projects involving the use of technologies in the home and will focus on lessons learned from continuous glucose monitoring, total artificial hearts, and in-home cancer screening.

Topics covered will include:

- 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

***Russell Branaghan**, President/Chief Scientist, Research Collective*

4:00 pm
CONFERENCE CONCLUDES