

# IMPROVING HEALTH CARE. IMPROVING *Lives.*



THE  
**MEDTECH**  
CONFERENCE

SEPTEMBER 23-25, 2019  
BOSTON, MA

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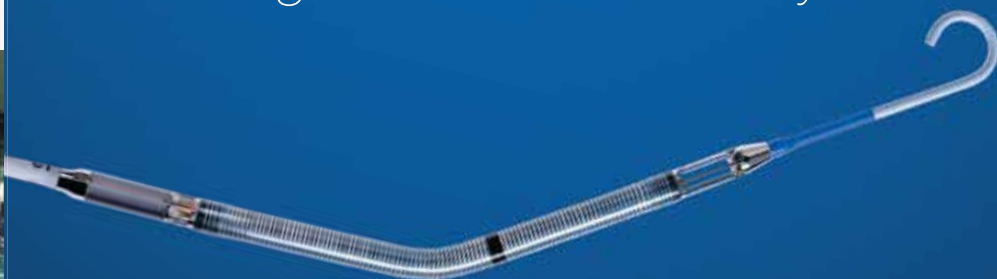


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# Welcome



Dear Colleague,

Thank you for joining us and welcome to The MedTech Conference powered by AdvaMed – the leading event for the medical technology industry. This is our conference's 13th year, and we are very excited to be in Boston, a city widely known as a global hub for medical technology and the life sciences.

For anyone who may be joining us for the first time this year, AdvaMed (the Advanced Medical Technology Association) is the world's leading medical technology trade association. AdvaMed supports the needs of members of all sizes – from the smallest start-ups to the largest multinationals – so they can provide life-changing medical technologies to more patients in need around the world. Serving as the voice for a unified industry, AdvaMed is uniquely positioned to promote policies that foster the highest ethical standards, timely patient access to safe and effective products, appropriate reimbursement and access to international markets.

In that same vein, The MedTech Conference is a forum for the industry to gather, share ideas and find new inspiration to develop the technologies and solutions impacting patient lives. This year's conference theme – "Improving Health Care. Improving Lives." – was developed around the idea that at the core of every medical breakthrough is a life that would be lacking without it. The rapid innovation we see across our industry is driven by the patients who need it. Whether it's lifesaving NICU equipment, a cardiovascular pump that treats heart disease or a groundbreaking device to manage chronic pain, the quality of patient lives is dramatically improved by medical technology. This year, you will hear from several patients sharing their journeys from diagnosis

to treatment to management. Their stories will amaze and inspire you.

We encourage you to spend time in the Exhibit Hall, which features a variety of presentation stages, including the Patient Pavilion, a demo theater dedicated to our patients and the technologies that have bettered their quality of life. Also, be sure to take advantage of our series of phenomenal plenary sessions. A detailed agenda for the conference can be found in the following pages.

Throughout the week, there will be many moments for celebration and networking. We will honor former KCI CEO and Chairman Cathy Burzik with the 7th Annual AdvaMed Lifetime Achievement Award. We will also select the winner of this year's MedTech Innovator Finals, during which four emerging companies will present their technologies and compete for more than \$500,000 in cash prizes, scholarships and in-kind services.

We hope you leave Boston with an expanded network, valuable insights to share with colleagues and a renewed commitment to improving patient lives. Thank you and enjoy your time at The MedTech Conference!

Kevin Lobo  
Chairman and Chief Executive Officer, *Stryker*  
Chairman of the Board, *AdvaMed*

Scott Whitaker  
President and CEO, *AdvaMed*

Thank you to our local partners



# Letter from the CHAIRMAN



As this year's conference chairman, I'm excited to welcome everyone to Boston, a city rich in history, culture and innovation. With more than 1,800 life sciences companies — 300 of which are device manufacturers — located in Massachusetts, it was a natural choice to bring the foremost gathering of medtech professionals to Boston this year. I hope you'll spend some of your time onsite exploring the numerous organizations representing Massachusetts that have joined us here this week.

As I reflect on my year as conference chairman, I think about the significance of this year's theme — "Improving Health Care. Improving Lives." The work we do has helped countless individuals live longer, better and more fulfilling lives, and I believe for many of us, this is the reason we are part of this remarkable industry that puts patients first. The MedTech Conference serves as a reminder of our purpose. It is more than just a chance for education and networking, it is a chance to find new inspiration and reaffirm our commitment to the life-changing work we do.

I am grateful to all of the people involved in planning and shaping this year's conference, and to everyone in attendance as well. Thank you for joining us for what is sure to be our best event yet. I would encourage everyone to take full advantage of these three days — sit in on educational sessions, visit the Exhibit Hall, hear patient stories and source new solutions and ideas to bring back to the office. Leave this conference with a renewed dedication to furthering innovation and helping improve the quality of patient lives. I wish everyone a productive, successful and enjoyable conference experience.

A handwritten signature in black ink that reads "Michael Minogue". The script is fluid and cursive.

Michael R. Minogue  
Chairman, President & CEO, *Abiomed, Inc.*  
Chairman, *The MedTech Conference 2019*





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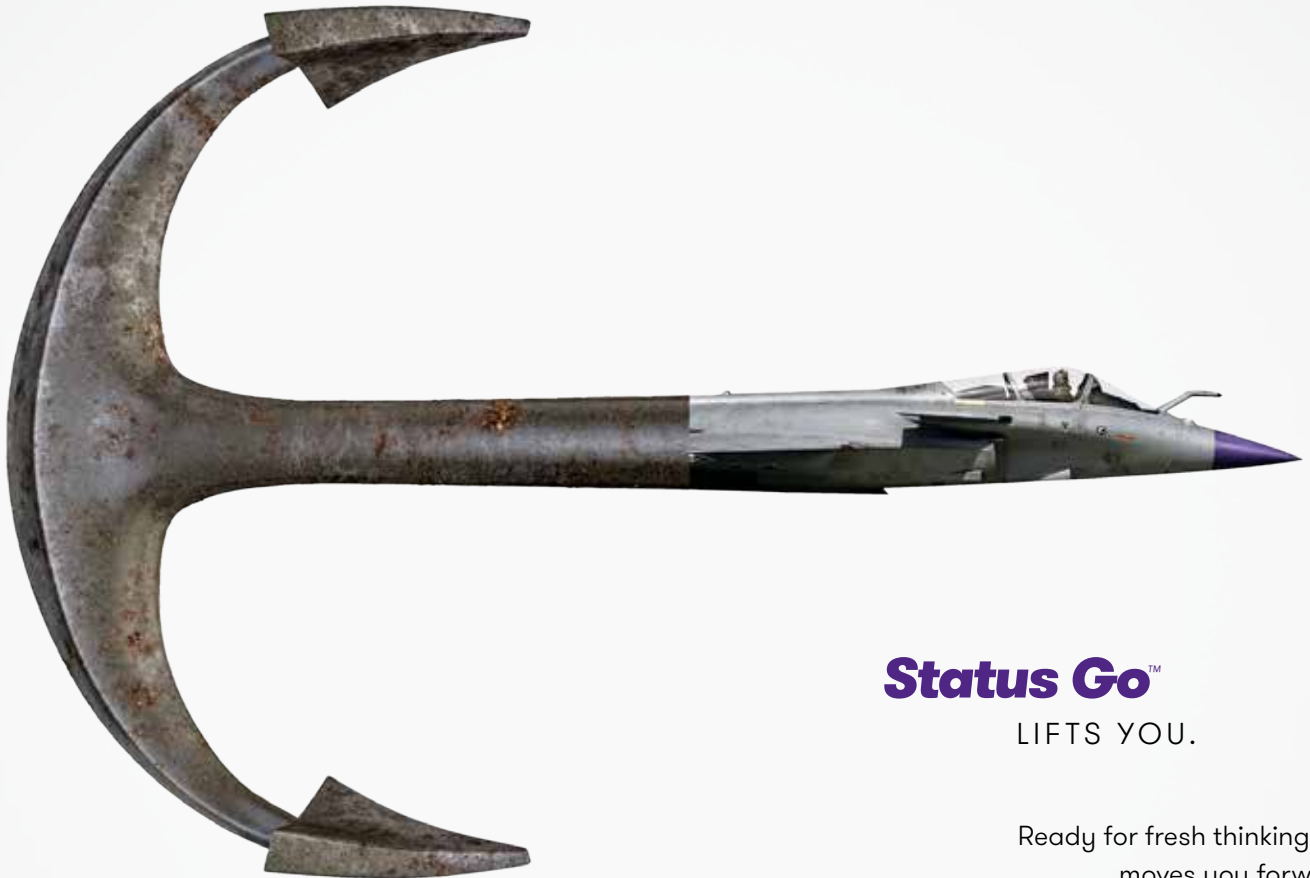
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[ICONplc.com/new-EU-regulations](https://ICONplc.com/new-EU-regulations)





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## **GOING FURTHER, TOGETHER**

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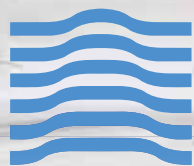
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# GENERAL *Information*

## REGISTRATION AND BADGES

Registration is in the NE Lobby A of the BCEC. All guests must present a photo ID to obtain their badge. Your registration fee and type determine your admission level and badges are color-coded to enforce access limitations to The MedTech Conference events. Badges are required for admittance to all events and activities. Badges are nontransferable once printed; swapping or sharing is strictly prohibited.

Substitutions must be made prior to badge pick-up, before the original registrant has attended any portion of the conference. Onsite substitutions require hard copy, written permission from the original registrant granting the substitution.

### Registration Hours

**Sunday, September 22 | 12:00 PM – 7:00 PM**

**Monday, September 23 | 7:00 AM – 6:00 PM**

**Tuesday, September 24 | 7:00 AM – 6:00 PM**

**Wednesday, September 25 | 8:00 AM – 1:00 PM**

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## VISITOR SERVICES DESK

The Visitor Services desk is located in the North Lobby of the BCEC and is completely complimentary. The Greater Boston Convention and Visitors Bureau staff are available to assist with area-related questions, information on attractions, transportation and making restaurant reservations. The desk is open during the following hours:

**Monday, September 23 | 8:00 AM – 6:30 PM**

**Tuesday, September 24 | 8:00 AM – 6:30 PM**

**Wednesday, September 25 | 9:00 AM – 1:00 PM**

## WIFI

The MCCA offers free wireless internet service throughout meeting rooms, lobbies and the Exhibit Hall; just open your internet browser and look for the BCEC Wireless Network. This service is designed for casual use and is not guaranteed.

## EMERGENCY CONTACT INFORMATION

To report an emergency, dial 2222 on any house phone or 617.954.2222 from your mobile device. This number connects directly to the BCEC Public Safety Command Center, which is staffed 24/7. The Command Center is in direct contact with all local emergency services and will call 911 on your behalf and ensure that there is no delay in response. House phones are located inside meeting rooms, on outside walls of meeting rooms and on outside walls of exhibit halls.

## UNAUTHORIZED SOLICITATION AND DISTRIBUTION OF MATERIALS

Solicitation of business on the premises of the conference and exhibition hall by anyone other than official AdvaMed conference exhibitors is strictly prohibited. Solicitation of business in sessions and meetings is entirely prohibited. Distribution of flyers, pamphlets, notices and brochures in any session, without the prior written consent of AdvaMed, is expressly prohibited.

## SPECIAL ACCOMMODATIONS

The Boston Convention and Exhibition Center is fully ADA compliant and accessible. Each level has elevators, and special hearing devices can be connected to the MCCA sound system. AdvaMed supports the ADA and attendees requiring specific equipment or services should have identified themselves during the registration process. AdvaMed will make every reasonable effort to accommodate those needs.

## ALLERGENS AND FOOD SAFETY

Allergens may be present in food served at AdvaMed meetings. It is the responsibility of each attendee to contact the catering staff or show management about specific food allergies. AdvaMed provides a meal request space during the registration process.

## WHEELCHAIRS

The MCCA has a limited number of wheelchairs available for attendees, free of charge. A form of ID is required to sign out a wheelchair.

## ATTENDANCE POLICY

Attendance is for members of AdvaMed's industry ONLY. AdvaMed reserves the right to accept or reject registrations and to cancel any previously accepted reservation, at any time, at its sole discretion, without liability to the registrant or any other party.

Loud, abusive, or defamatory language, harassment, unprofessional or inappropriate behavior is not permitted at any time. If such conduct is engaged in by a registrant, AdvaMed may cancel any previously accepted registration, at any time, at its sole discretion, without liability to the registrant or any other party, and the registrant agrees to exit the premises immediately.

AdvaMed has sole discretion over admission at all times and shall strictly enforce all event rules. Attendees agree to abide by AdvaMed's attendance rules. Violators risk immediate confiscation of their event badge without refund and removal from the premises.

To review the full attendance policy, visit [themedtechconference.com/policies](http://themedtechconference.com/policies).

## PHOTO AND VIDEO POLICY

Attendees are permitted to use hand-held cameras to take photographs and capture digital images within public areas of The MedTech Conference for personal, non-commercial use. Public areas include the Exhibit Hall, session rooms, press rooms, hotel lobby areas, and hallways. Rarely, AdvaMed event management will ask attendees to refrain from taking photos or videos of sessions based upon special request by a speaker.

Large cameras, photo or video equipment, or ancillary equipment such as lighting, tripods, cables, etc., are prohibited (except in instances where approval from AdvaMed event management is obtained).

To review the full policy, visit [themedtechconference.com/policies](http://themedtechconference.com/policies).

## SOCIAL MEDIA POLICY

The MedTech Conference permits and encourages the use of social media provided that only content excerpts are used, the presentation material is not reproduced in full, and the speaker is referenced and cited appropriately. Please respect the intellectual property rights and copyrights of AdvaMed and its speakers when using social media. Speakers do have the right to prohibit the use of social media during their individual sessions.

## BAG AND COAT CHECK

We are pleased to offer bag and coat check in Room 158 of the Boston Convention and Exhibition Center. This service is available during the following days and times:

**Monday, September 23 | 7:00 AM – 7:00 PM**

**Tuesday, September 24 | 7:00 AM – 6:00 PM**

**Wednesday, September 25 | 8:00 AM – 3:00 PM**

Sponsored by  **MARWOOD GROUP**

## NURSING MOTHERS ROOM

The Boston Convention and Exhibition Center features a Mamava Nursing Pod located in the SE Lobby on Level 1. To access the pod, download the Mamava app for iPhone or Android and reserve your time slot and receive an access code. For more information, visit [mamava.com](http://mamava.com).

## ATMs

Guests will find ATMs on Level One in the North Lobby and the Wicked Good Market, and on Level 0 East.

## LOCAL TRANSPORTATION

### Public Transit

South Station, the premier regional transportation center, is a ten-minute walk from the front door of the BCEC. Services available at South Station include the MBTA's Red and Silver lines, Amtrak regional service, bus service, and commuter rail.

### Taxi and Rideshare Information

Level 1, North Entrance at 415 Summer Street is the required location for taxicab drop-off and pick-up.

Rideshare vehicles (such as Uber and Lyft, etc.) are only permitted to pick up and drop off at designated locations. These locations will appear in the app when you open it to request a vehicle.

## LOST AND FOUND

During event operating hours, lost and found is located at the Public Safety desk on Level 1 (North Lobby) at the Summer Street entrance. After event hours, lost and found items are stored in the Public Safety Command Center. To inquire about a lost item or report a found item, contact 617.954.2222, or go to [signatureboston.com/attend/lost-and-found](http://signatureboston.com/attend/lost-and-found).

# AGENDA *at-a-glance*

## SUNDAY, SEPTEMBER 22

START	END	EVENT TYPE	TITLE	LOCATION
8:00 AM	5:00 PM	Special Program	Pediatric Device Symposium	Room 052
12:00 PM	7:00 PM	Registration	Registration Open and Badge Pick-Up	NE Lobby A (Level 1)
12:30 PM	5:00 PM	U.S. Market Access Seminar	U.S. Market Access Seminar	Room 156 C
5:30 PM	7:30 PM	Networking Event	International Reception	Legal Harborside

## MONDAY, SEPTEMBER 23

7:00 AM	6:00 PM	Registration	Registration Open and Badge Pick-Up	NE Lobby A (Level 1)
8:00 AM	1:00 PM	Panel Session	AdvaMed Accel Leadership Seminar and Lunch*	Room 052
8:30 AM	9:00 AM	Super Session	Medtech as IT	Room 156 AB
8:30 AM	3:30 PM	Partnering	MedTech Connect Partnering Open	Hall B
9:00 AM	10:30 AM	Super Session	Revolutionizing the Silver Economy	Room 156 AB
9:30 AM	10:45 AM	Panel Session	A Values-Based Approach to MedTech Business Integrity	Room 157 C
9:30 AM	10:45 AM	Panel Session	Articulating the Value of Diagnostics: Moving Toward Value Based Approaches	Room 156 C
9:30 AM	10:45 AM	Panel Session	Case for Quality	Room 157 B
9:30 AM	10:45 AM	Panel Session	The Business Value of Design: How Do the Best MedTech Design Performers Increase Their Revenues and Shareholder Returns at Nearly Twice the Rate of Their Industry Counterparts?	Room 157 A
9:30 AM	11:00 AM	Special Program	Pediatric Innovation Framework — Working Meeting with FDA	Room 153 B
11:00 AM	12:15 PM	Panel Session	Delivering Great Care and Technology Transformation in the World's Largest Integrated Health System	Room 157 B
11:00 AM	12:15 PM	Panel Session	Efficiently Collect Real World Data: Industry, Policy and Regulatory Perspectives	Room 156 C
11:00 AM	12:15 PM	Panel Session	SME MedTech Innovations That Are Transforming Health Care in the U.S. and Abroad	Room 157 A
11:00 AM	12:15 PM	Panel Session	Value Based Arrangements: New Proposed Rules — Implications for Future Arrangements and Activities	Room 157 C
12:00 PM	1:30 PM	Networking Event	Welcome Lunch	East Registration
12:15 PM	1:30 PM	Super Session	Health 2040: Medtech's Role in a Transformed Future	Room 156 AB
12:30 PM	1:45 PM	Panel Session	Value Based Care: Lessons and Learnings in LATAM Impacting MedTech Industry	Room 157 B
12:30 PM	1:45 PM	Panel Session	The U.S. - China Relationship: From Cooperation to Confrontation	Room 157 C
1:00 PM	2:00 PM	Panel Session	Developing a Framework for Patient Input in Medical Device Clinical Trials	Room 157 A

\*Separate registration required



START	END	EVENT TYPE	TITLE	LOCATION
1:00 PM	2:00 PM	Panel Session	Using Data and Analytics to Demonstrate the Value of Diagnostics	Room 156 C
1:15 PM	2:00 PM	Meetup	Emerging Leaders Meetup	Meetup Zone, East Registration
1:45 PM	2:00 PM	Special Program	Ribbon Cutting Ceremony	Hall B
2:00 PM	3:15 PM	Panel Session	AdvaMed's New Code of Ethics: Is Your Company Prepared to Comply?	Room 157 C
2:00 PM	3:15 PM	Panel Session	Chasing Value: Understanding How to Work with GPOs to Introduce New Health Care Innovation in the Supply Chain	Room 157 B
2:00 PM	3:15 PM	Super Session	The New World of 510(k)	Room 156 AB
2:00 PM	4:00 PM	Special Program	AdvaMed Accel and MedTech Innovator Partnering Forum (invite-only)	Room 052
2:00 PM	6:30 PM	Exhibit Hall	Exhibit Hall Open	Hall B
2:15 PM	2:45 PM	CEOs Unplugged	Improving Lives by Adding to the Quality of Life	Hall B, 300 Aisle
2:15 PM	3:15 PM	Panel Session	Establishing the Value of Your Medtech Innovation — It's Never Too Early	Room 156 C
2:15 PM	3:15 PM	Panel Session	More Value for Patients and Society Through Data-Driven Health Care: U.S. and International Perspectives	Room 157 A
2:45 PM	3:15 PM	Meetup	Global Innovation Meetup	Meetup Zone, East Registration
2:55 PM	3:25 PM	CEOs Unplugged	Culture, Leadership and Perseverance	Hall B, 300 Aisle
3:30 PM	5:00 PM	Plenary Session	Opening Plenary	Hall B, Plenary Theater
5:00 PM	6:30 PM	Networking Event	Welcome Reception	Hall B
6:00 PM	7:30 PM	Networking Event	LGBTQIA+ Reception	Committee Bar, 50 Northern Ave., Boston, MA
6:00 PM	10:00 PM	Special Program	MedTech Insight Awards*	State Room, 60 State St., Boston, MA

## TUESDAY, SEPTEMBER 24

7:00 AM	6:00 PM	Registration	Registration Open and Badge Pick-Up	NE Lobby A (Level 1)
7:30 AM	9:00 AM	Special Program	Networking Breakfast Hosted by MedTech Color*	Room 052
8:30 AM	12:15 PM	Panel Session	China Market Access Updates — Regulatory, Clinical, Reimbursement and IP	Room 157 A
9:00 AM	6:00 PM	Partnering	MedTech Connect Partnering Open	Hall B
9:00 AM	6:30 PM	Exhibit Hall	Exhibit Hall Open	Hall B
9:15 AM	9:45 AM	MedTech Innovator Showcase	MedTech Innovator Showcase — Cardiovascular	Hall B, 500 Aisle
9:15 AM	10:00 AM	CEOs Unplugged	Transformational Innovation: Delivering Outcomes, Fueling the Future	Hall B, 300 Aisle
9:15 AM	10:30 AM	Panel Session	FDA's New Approaches to Software Regulation: Pre-Certification and Artificial Intelligence	Room 156 C
9:25 AM	9:55 AM	MedTech Exec Talk	Bridging Commercial and Military Market Needs to Advance Medical Device Development	Hall B, 500 Aisle
9:45 AM	10:15 AM	Innovation Pavilion	Investor Trends in Medtech	Hall B, Innovation Pavilion (#441)

# AGENDA *at-a-glance*

## TUESDAY, SEPTEMBER 24 cont.

START	END	EVENT TYPE	TITLE	LOCATION
9:45 AM	11:00 AM	Panel Session	Seeing Is Not Always Believing — Tackling Legal Advertising Disguised as Medical Alerts	Room 157 C
9:45 AM	11:00 AM	Panel Session	The New World of Medtech M&A Valuation: Strategies to Adapt and Thrive	Room 157 B
9:50 AM	10:20 AM	MedTech Innovator Showcase	MedTech Innovator Showcase — Vascular Solutions	Hall B, 500 Aisle
10:00 AM	10:20 AM	Solutions Showcase	Preparing for Medical Device Cybersecurity in 2020	Hall B, 200 Aisle
10:10 AM	10:50 AM	CEOs Unplugged	Realizing Organizational and Global Value with Sustainable Business Actions	Hall B, 300 Aisle
10:30 AM	10:50 AM	Solutions Showcase	From Data to Data Science	Hall B, 200 Aisle
10:30 AM	11:00 AM	MedTech Exec Talk	Connected Ecosystems for Smarter Decisions	Hall B, 500 Aisle
10:30 AM	11:00 AM	MedTech Innovator Showcase	MedTech Innovator Showcase — Oncology	Hall B, 500 Aisle
10:30 AM	11:00 AM	Innovation Pavilion	NIH SBIR/STTR Company Presentations	Hall B, Innovation Pavilion (#441)
10:30 AM	12:30 PM	Meetup	GPOs Meetup	Meetup Zone, East Registration
11:00 AM	11:45 AM	CEOs Unplugged	How Data Will Transform Patient Outcomes, Medtech and Practice of Health, Why It Hasn't Happened	Hall B, 300 Aisle
11:00 AM	12:15 PM	Super Session	It Takes a Village: How the Health Care Community Is Working Together to Tackle Cybersecurity	Room 156 AB
11:05 AM	11:35 AM	MedTech Innovator Showcase	MedTech Innovator Showcase — Molecular Diagnostics	Hall B, 500 Aisle
11:15 AM	11:45 AM	Innovation Pavilion	Successful Elevator Pitches and Investor Interactions	Hall B, Innovation Pavilion (#441)
11:15 AM	11:45 AM	MedTech Exec Talk	When Data-Driven Training, Marketing and Sales Came Together to Turn a Product Around: A Powerful Case Study	Hall B, 500 Aisle
11:15 AM	12:15 PM	Panel Session	Diverse Perspectives on Developing and Deploying Digital Technologies	Room 157 B
11:15 AM	12:15 PM	Panel Session	Small Companies Selling Big Ideas to Huge Corporations	Room 157 C
11:30 AM	11:50 AM	Solutions Showcase	Device Connectivity Platform as a Service: Build vs. Buy, Accelerate Time to Market	Hall B, 200 Aisle
11:45 AM	12:15 PM	MedTech Innovator Showcase	MedTech Innovator Showcase — Neurotechnology	Hall B, 500 Aisle
11:55 AM	12:25 PM	MedTech Exec Talk	Everyone Knows Health Care Is DOJ's Favorite Target; What Does That Mean for MedTech Executives?	Hall B, 500 Aisle
11:55 AM	12:25 PM	CEOs Unplugged	Future of Surgery	Hall B, 300 Aisle
12:30 PM	2:00 PM	Plenary Session	Plenary Lunch	Hall B, Plenary Theater
2:10 PM	2:50 PM	MedTech Exec Talk	Emerging Issues Regarding the HCPCS Coding Process for Medical Devices	Hall B, 500 Aisle

START	END	EVENT TYPE	TITLE	LOCATION
2:15 PM	2:45 PM	MedTech Innovator Showcase	MedTech Innovator Showcase — Chronic Disease Management	Hall B, 500 Aisle
2:15 PM	2:45 PM	Innovation Pavilion	Perfecting Partnership	Hall B, Innovation Pavilion (#441)
2:15 PM	2:55 PM	CEOs Unplugged	Leadership Views on Diagnostics	Hall B, 300 Aisle
2:15 PM	3:30 PM	Panel Session	Going Viral: Best Practices in Social Media	Room 157 A
2:15 PM	3:30 PM	Panel Session	Medtech, Look to Marketing for the Solution	Room 156 C
2:15 PM	3:30 PM	Super Session	Pulse of the Industry 2019	Room 156 AB
2:15 PM	3:45 PM	Special Program	Global Markets: Where to Invest?	Hall B, 200 Aisle (Solutions Showcase Stage)
2:30 PM	3:45 PM	Panel Session	International Digital Health: Perspectives on Data, Partnerships and Scaling Internationally	Room 157 B
2:45 PM	3:15 PM	Panel Session	Price Monitoring of Medical Devices in Brazil	Room 157 C
2:50 PM	3:20 PM	MedTech Innovator Showcase	MedTech Innovator Showcase — Precision & Personalized Medicine	Hall B, 500 Aisle
3:00 PM	3:30 PM	Innovation Pavilion	NIH SBIR/STTR Company Presentations	Hall B, Innovation Pavilion (#441)
3:05 PM	3:45 PM	CEOs Unplugged	Advancing Inclusion and Diversity	Hall B, 300 Aisle
3:15 PM	3:45 PM	Panel Session	ANVISA — The State of Regulatory Efficacy at 20 Years	Room 157 C
3:45 PM	5:00 PM	Panel Session	EtO Sterilization of Medical Devices: The Impact of Evolving Regulatory Requirements	Room 157 A
3:45 PM	5:00 PM	Super Session	MDR/IVDR — What Now?	Room 156 AB
3:45 PM	5:00 PM	Plenary Session	MedTech Innovator Finals	Hall B, Plenary Theater
4:00 PM	5:00 PM	Panel Session	How Major New Players Are Challenging the Current Health Care Ecosystem	Room 157 C
4:00 PM	5:00 PM	Panel Session	The Role of Diagnostics in Promoting the Health and Health Care of Women	Room 157 B
5:00 PM	6:30 PM	Networking Event	Chairmen's Networking Reception	Hall B
5:00 PM	6:00 PM	Networking Event	AdvaMed Advance Reception Powered by WEN	Hall B, AdvaMed Booth (#229)
8:30 PM	10:00 PM	Networking Event	MTC LIVE! (Formerly MedTech After Party)	Lawn on D

## WEDNESDAY, SEPTEMBER 25

8:00 AM	9:00 AM	Networking Event	Networking Breakfast with Exhibitors	Hall B
8:00 AM	1:00 PM	Registration	Registration Open and Badge Pick-Up	NE Lobby A (Level 1)
8:00 AM	2:00 PM	Exhibit Hall	Exhibit Hall Open	Hall B
8:15 AM	8:45 AM	MedTech Exec Talk	Innovation, Regulation and Adaptation: Emerging Legal Issues in Digital Health	Hall B, 500 Aisle
8:15 AM	9:00 AM	CEOs Unplugged	What's on the Top of Your Mind?	Hall B, 300 Aisle
8:30 AM	9:30 AM	Panel Session	Health Care Fraud: The Government View and the Compliance Perspective	Room 157 C
8:30 AM	9:30 AM	Panel Session	Value Based Health Care in Action: Enhancing Patient Outcomes and Managing Costs	Room 157 B
8:30 AM	12:30 PM	Partnering	MedTech Connect Partnering Open	Hall B
8:45 AM	12:15 PM	Special Program	EU MDR Workshop	Room 052
9:00 AM	9:30 AM	MedTech Exec Talk	Beyond Silos: Fusing Digital Across the Enterprise	Hall B, 500 Aisle

# AGENDA *at-a-glance*

## WEDNESDAY, SEPTEMBER 25 cont.

START	END	EVENT TYPE	TITLE	LOCATION
9:15 AM	9:45 AM	MedTech Innovator Showcase	MedTech Innovator Showcase — Critical Care	Hall B, 500 Aisle
9:15 AM	10:00 AM	CEOs Unplugged	Buyers, Sellers and Facilitators: An M&A Discussion	Hall B, 300 Aisle
9:15 AM	10:30 AM	Panel Session	Inspections and MDSAP	Room 156 C
9:15 AM	10:30 AM	Panel Session	The Democratization of Personalized Medicine — Bringing It Closer to the Community	Room 157 A
9:45 AM	10:15 AM	MedTech Exec Talk	Digital Transformation of the Medical Technology Market — the Disruptor or Enabler?	Hall B, 500 Aisle
9:45 AM	11:00 AM	Panel Session	Solving the Addiction Crisis with Devices, and Mobile Health and Digital Therapeutics	Room 157 B
9:45 AM	11:00 AM	Panel Session	Strategic Use of Postmarket Real-World Evidence and Data Regarding Value and Quality	Room 157 C
9:50 AM	10:20 AM	MedTech Innovator Showcase	MedTech Innovator Showcase — Surgical Advancements	Hall B, 500 Aisle
10:00 AM	10:20 AM	Solutions Showcase	Evolving Commercial Models in the New Health Care Ecosystem	Hall B, 200 Aisle
10:00 AM	11:30 AM	Panel Session	Academic/Tech Transfer Session and Meetup	Room 153 C
10:10 AM	10:50 AM	CEOs Unplugged	Massachusetts — The Who, What and Why of This Medtech Miracle Metropolis	Hall B, 300 Aisle
10:30 AM	10:50 AM	Solutions Showcase	Essentials of Regulatory Digital Transformations	Hall B, 200 Aisle
10:30 AM	11:00 AM	MedTech Innovator Showcase	MedTech Innovator Showcase — Orthopaedics	Hall B, 500 Aisle
10:30 AM	11:00 AM	MedTech Exec Talk	Strengthening FDA's 510(k) Third Party Review Program: Streamlining the Process, Maximizing Patient Benefit	Hall B, 500 Aisle
10:45 AM	12:00 PM	Panel Session	Global Regulatory Convergence — Emerging Trends and Future Opportunities	Room 156 C
10:45 AM	12:00 PM	Panel Session	New Diagnostic Technologies Are Transforming Testing	Room 157 A
11:00 AM	11:20 AM	Solutions Showcase	Mitigating Human Factors Risk	Hall B, 200 Aisle
11:00 AM	11:30 AM	CEOs Unplugged	Insights from Executives Navigating High Growth Companies	Hall B, 300 Aisle
11:15 AM	11:45 AM	MedTech Exec Talk	The Changing Payer/Provider Landscape: Opportunities for Medtech	Hall B, 500 Aisle
11:15 AM	12:15 PM	Panel Session	What Do Hospital Administrators Really Want?	Room 157 B
11:30 AM	11:50 AM	Solutions Showcase	Phase Zero: How to Be Resource-Efficient with New Product Opportunities	Hall B, 200 Aisle
11:30 AM	12:00 PM	Meetup	Digital & Connected Health Meetup	Meetup Zone, East Registration
11:35 AM	12:20 PM	CEOs Unplugged	Lessons from a Legend	Hall B, 300 Aisle
12:30 PM	2:00 PM	Plenary Session	Plenary Lunch	Hall B, Plenary Theater
2:15 PM	4:00 PM	Super Session	CDRH Town Hall	Room 156 AB



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# TRUE TO PATIENT CARE



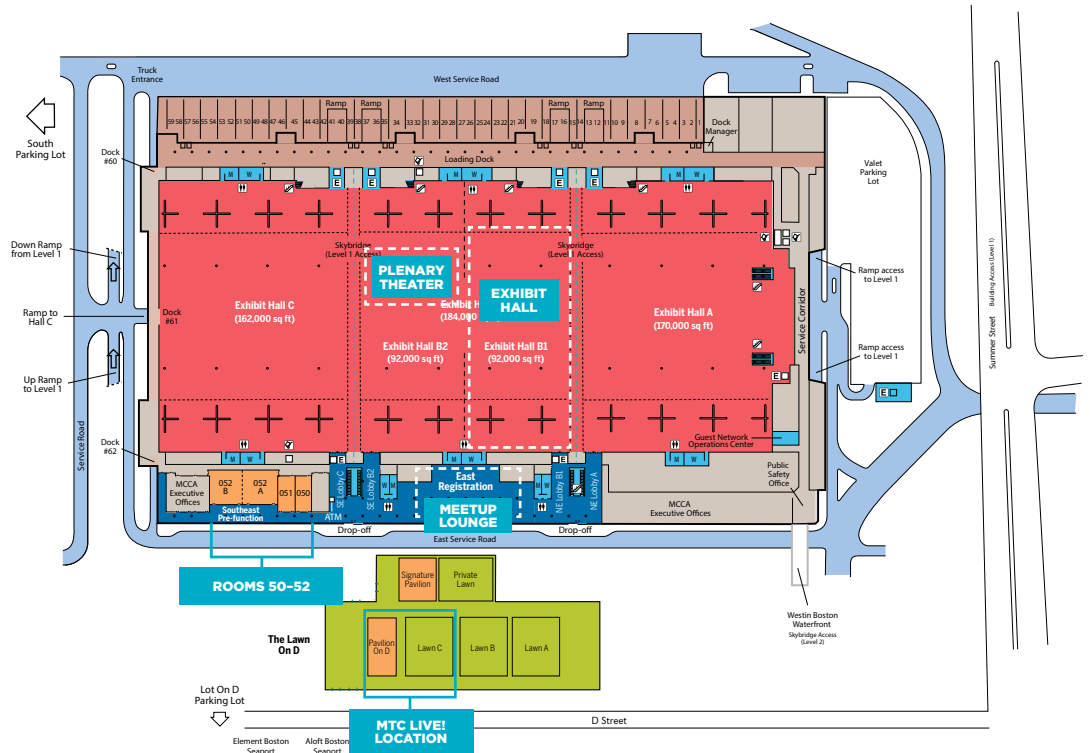
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# FLOOR Maps

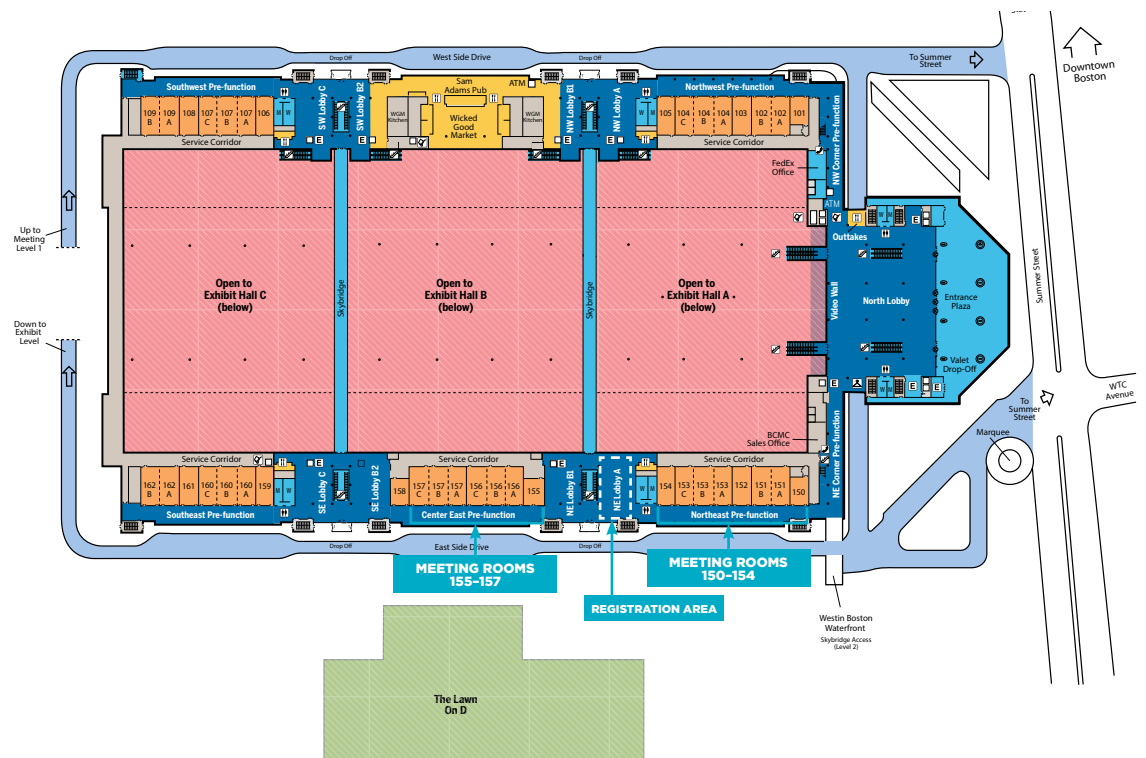
## EXHIBIT HALL LEVEL

- Special Program Room: 052
- Meetup Zone: East Registration
- Hall B: Plenary Theater
- Hall B: MedTech Connect Zone
- Hall B: Exhibits
- MTC Live!: Lawn on D

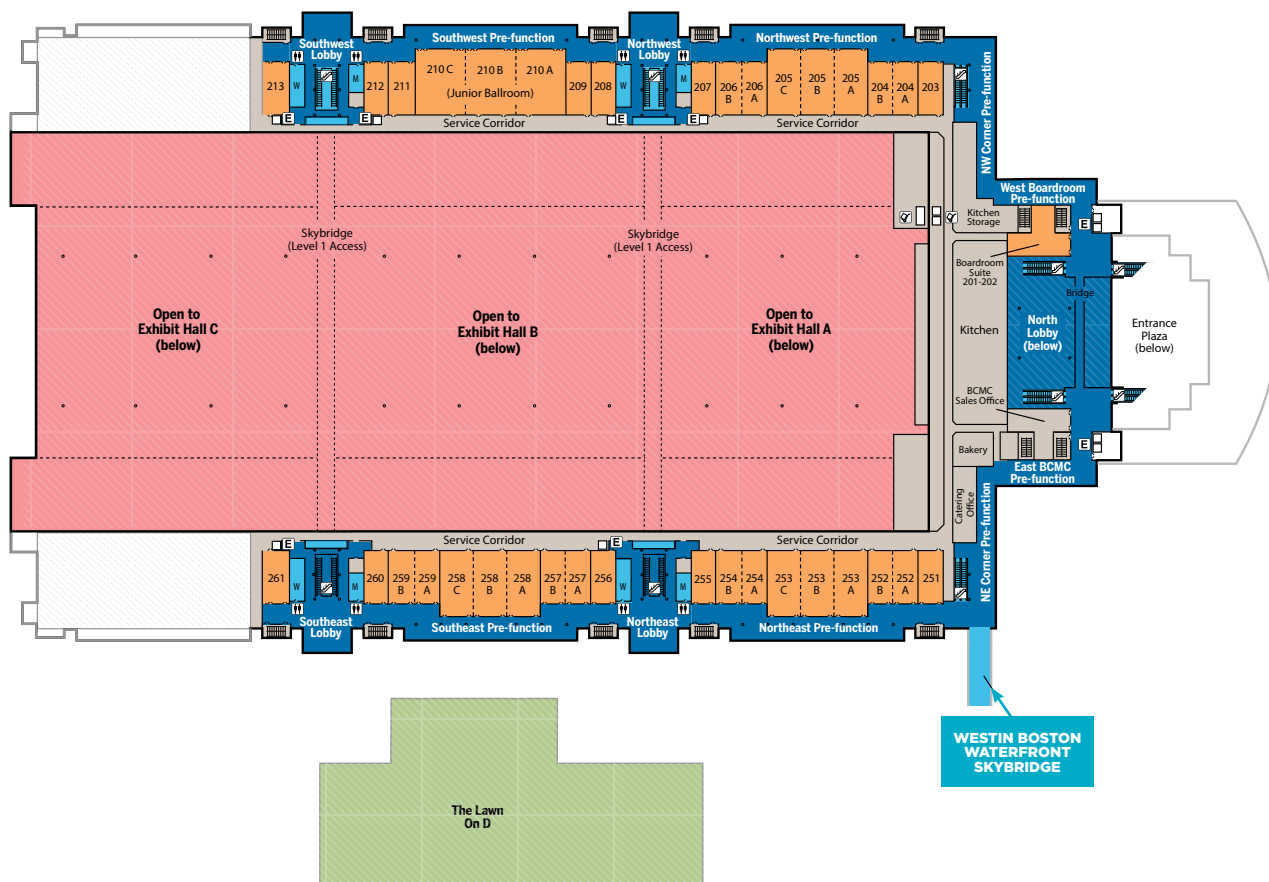


## LEVEL 1

- Registration: NE Lobby A
- Speaker Ready Room: 150
- Coat Check: 158
- Session Rooms: 156 C – 157 C
- Super Session Room: 156 AB



## LEVEL 2



## Key

Special Program Room.....	052	Exhibit Space.....		Elevator.....	E
Meetup Zone.....	East Registration	Meeting Rooms .....		Freight Elevator .....	☑
Plenary Theater .....	Hall B	Ballroom .....		Escalator .....	☑
MedTech Connect Zone .....	Hall B	The Lawn on D.....		Restrooms.....	♂ ♀
Exhibits.....	Hall B	Lobby & Pre-function .....		Permanent Concessions.....	☑
MTC Live!.....	Lawn on D	Public Use.....		Pay Phone.....	☑
Registration.....	NE Lobby A	Ring Road.....		Stairs .....	☑
Speaker Ready Room.....	150	Non-Public Access.....			
Coat Check.....	158	Loading Dock Pre-Feb Area & Covered Truck Access .....			
Session Rooms.....	156 C – 157 C	Food Services .....			
Super Session Room .....	156 AB				

# Networking EVENTS

## INTERNATIONAL RECEPTION

**Sunday, September 22 | 5:30 PM – 7:30 PM**

**Legal Seafood Harborside, 270 Northern Ave., Boston, MA 02210**

Meet attendees from across the globe, enjoy iconic Boston fare and take in beautiful harbor views at our pre-conference reception. All attendees are encouraged to attend.

Sponsored by **Québec** 

## WELCOME LUNCH

**Monday, September 23 | 12:00 PM – 1:30 PM**

**East Registration**

Make time to network and refuel in between sessions.

## WELCOME RECEPTION

**Monday, September 23 | 5:00 PM – 6:30 PM**

Join us in toasting to the first day of the conference at the lively Welcome Reception, held right in the Exhibit Hall.

Sponsored by **NYPRO**  
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## LGBTQIA+ RECEPTION

**Monday, September 23 | 6:00 PM – 7:00 PM**

**Committee Bar, 50 Northern Ave., Boston, MA 02210**

Join LGBTQIA+ medtech professionals at Committee Bar for drinks, light hors d'oeuvres and networking. The need for equality and representation for our community is ongoing, and there are steps we can take, beginning with driving positive change in our offices, companies and industry. Join us as we look to foster new platforms for discussion of medtech and LGBTQIA+ issues.



## NETWORKING BREAKFAST

**MedTechColor** Hosted by **MedTech Color**

**Tuesday, September 24 | 7:30 AM – 9:00 AM**

**Room 052**

This event will bring together key stakeholders and medtech professionals of color from across the ecosystem to hear from thought leaders in the industry. The host, MedTech Color, has three objectives: (1) build and support a community of stakeholders and medtech professionals; (2) increase professional and leadership opportunities for medtech professionals of color; and (3) add value to the medtech industry through thought leadership, programs, education and professional development.

Sponsored by



**AdvaMed Advance**  
Advancing Inclusion & Diversity  
in the MedTech Industry

## ADVAMED ADVANCE RECEPTION

**Powered by Women's Executive Network**

**Tuesday, September 24 | 5:00 PM – 5:45 PM**

**AdvaMed booth (#229)**

Join us for a powerful networking experience in the AdvaMed Booth and learn more about our newest initiative, AdvaMed Advance — Advancing Inclusion and Diversity for the Medical Device Industry. Form valuable connections with leaders from national and regional initiatives highlighting women leaders including AdvaMed's Women's Executive Network, MedExec Women, MedTech Women and Medical Alley.

» **AdvaMed Women's Executive Network** 

WEN is an international organization that elevates women in medtech by amplifying and connecting regional organizations to benefit patients, employees and industry. WEN and its partner organizations will be onsite to facilitate conversations that bring together diverse perspectives in pursuit of a better health care ecosystem.

» **To learn more about WEN and its partners, please visit [advamed.org/WEN](http://advamed.org/WEN).**

## CHAIRMEN'S NETWORKING RECEPTION

**Tuesday, September 24 | 5:00 PM – 6:30 PM**

Join us in the Exhibit Hall for an ice-cold pint of Guinness or a local craft beer and check out the latest from our medtech exhibitors.

Sponsored by  **IDA**  
**Ireland**



## MTC LIVE!

**Tuesday, September 24 | 8:30 PM – 10:00 PM**

**The Lawn on D, Boston Convention & Exhibition Center**

Make time to unwind at the best after party in town — MTC Live! Enjoy food, games and live music at the Lawn on D, a unique venue conveniently located just outside the Convention Center. Featuring Swing Time — an engaging set of solar-powered LED swings — the Lawn on D promises a relaxing and entertaining evening for all attendees.

Sponsored by  **AliraHealth**  **BD**  **novasys health**  
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## NETWORKING BREAKFAST WITH EXHIBITORS

**Wednesday, September 25 | 8:00 AM – 9:00 AM**

**Hall B**

Take advantage of the last day of the conference to meet with exhibitors at our networking breakfast in the Exhibit Hall.

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# PLENARY Sessions

Monday, September 23 | 3:30 PM – 5:00 PM



AdvaMed President and CEO Scott Whitaker will provide a compelling overview of how the medical technology industry is not only a beneficiary of the accelerating “knowledge-doubling curve,” but also a primary driver of it. The discussion will include the unveiling of a new AdvaMed advocacy tool that will champion patients, the innovation ecosystem and the life-changing power of medtech.

## FORECASTING THE INFLUENCE AND IMPACT OF THE NEXT WAVE OF TECHNOLOGIES ON MEDICAL DEVICE INNOVATION



**MODERATOR: John Carlson**, President, Health Solutions, Flex



**C. Michael Gibson, MD**, CEO, Baim Clinical Research Institute



**Dr. Jeffrey Karp; Eng. PhD**, Professor of Medicine, Brigham and Women's Hospital



**J. Craig Venter, PhD**, Founder, Chairman and Chief Executive Officer, J. Craig Venter Institute

Tuesday, September 24 | 12:30 PM – 2:00 PM



**Governor Charles Baker Jr.**  
(Massachusetts)

## A CANDID CONVERSATION WITH INFLUENTIAL STAKEHOLDERS



**MODERATOR: Michael R. Minogue**, CEO, President & Chairman of the Board, Abiomed



**Jessica Hopfield, PhD**, Health Care Strategist and MedTech Investor



**Dorothy E. Puhly**, Former Executive Vice President, Chief Operating Officer and Assistant Treasurer, Dana-Farber Cancer Institute

## INSIGHTS FROM INDUSTRY TITANS ON THE TRENDS DRIVING THE MEDTECH INNOVATION ECOSYSTEM IN THE 21ST CENTURY



**MODERATOR: Scott Whitaker**, President and CEO, AdvaMed



**Omar Ishrak**, Chairman and Chief Executive Officer, Medtronic



**Kevin Lobo**, Chairman and Chief Executive Officer, Stryker

**Tuesday, September 24 | 3:45 PM – 5:00 PM**



## MEDTECH INNOVATOR FINALS

The MedTech Conference is excited to welcome MedTech Innovator back to the plenary stage on the afternoon of Tuesday, September 24. Four finalist companies from the MedTech Innovator competition will present to a panel of industry-leading judges and compete for the audience vote to win \$500,000 in prizes and the award of MedTech Innovator 2019!

MedTech Innovator is the industry's non-profit global competition and accelerator for medical device, digital health and diagnostic companies. Its mission is to improve the lives of patients by accelerating growth of companies that are transforming the health care system. In 2019, MedTech Innovator, with the support of its partners and sponsors, will give out \$500,000 in cash prizes, scholarships and in-kind awards.

**HOST: Paul Grand**, CEO, MedTech Innovator



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are proud to partner with MedTech Innovator for the fifth consecutive year.

## MEDTECH INNOVATOR *Judges:*



**SEAN COYER**

*Leader, Digital Health  
Innovations and Ventures  
Gore Innovation Center*



**JENNIFER KOZAK**

*Vice President, New  
Business Development  
Johnson & Johnson*



**CHRISTOS  
MONOVOUKAS**

*VP, Global M&A Leader/  
Business Development  
Olympus*



**HEATHER WALSH**

*Director  
External Innovation  
Baxter International*

# PLENARY Sessions

Wednesday, September 25 | 12:30 PM – 2:00 PM

## LIFETIME ACHIEVEMENT AWARD

Presented by  IQVIA™  
MEDTECH



**Catherine M. Burzik**

Wednesday, September 25 | 12:30 PM

## GLOBAL HEALTH INNOVATOR AWARD

TEAMFund was launched with the vision that the entire medtech sector might come together to find ways to connect the people most in need of care with the innovations and technologies that can save and transform their lives. This year's \$50,000 award will be the third that TEAMFund has sponsored and presented at The MedTech Conference in recognition of an early-stage medtech company that has a novel, appropriate and sustainable medical device for the world's low-resource and resource-constrained populations.

Looking ahead to 2020 and beyond, TEAMFund seeks to fulfill the essential work of:

- » Research into disease burden and community-specific needs in low-resource settings;
  - » Provision of advisory support of medtech innovators attempting to serve low-resource communities;
  - » Development and implementation of impact measurement tools to assess the efficacy of medtech innovations;
  - » Programmatic research tied to innovation;
  - » Catalyze others to invest;
  - » Provide grant support to foster a broader ecosystem of medtech innovations and private sector investment; and
  - » Demonstrate the power of the medtech community in meeting UN SDG goals 3, 8 and 17.
- » **For more information, please visit [teamfundhealth.org](http://teamfundhealth.org).**

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## A CHAMPION'S MEDTECH STORY



**Rolf Benirschke**, Chief Patient Officer,  
Legacy Health Strategies



**Bill Walton**, Naismith Memorial  
Basketball Hall of Fame Member

## MEDICARE'S ROLE IN THE INNOVATION ECOSYSTEM



**MODERATOR: Scott Whitaker**, President  
and CEO, AdvaMed



**Seema Verma**, Administrator, Centers for  
Medicare & Medicaid Services



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# LIFETIME ACHIEVEMENT *Award*

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**AdvaMed is honored to present Catherine M. Burzik, former CEO of KCI,  
with the 2019 Lifetime Achievement Award.**

**The Lifetime Achievement Award will be presented during the  
Wednesday Plenary Lunch. Please join us in recognizing Cathy for  
all her contributions to our industry.**

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# MEDTECH Innovator

**The MedTech Conference and Advamed Accel are proud to partner with MedTech Innovator for the fifth consecutive year.**

MedTech Innovator is a 501(c)(3) non-profit organization dedicated to improving the lives of patients by accelerating the growth of companies transforming the health care system. Each year, outstanding early and mid-stage medical device, diagnostic and digital health companies are selected to participate in the program and compete for non-dilutive cash prizes. Since 2013, MedTech Innovator has awarded \$1.9 million to past participants. Alumni have gone on to raise over \$1 billion in follow-on equity funding.

This year's competition began in November 2018 with over 800 applications submitted. From March through April, the highest-scoring applicants from online reviews were invited to pitch at six events across the U.S. and internationally. Over

250 industry representatives, including investors, business development executives and subject matter experts, joined the MedTech Innovator team to meet with and evaluate the companies. From there, 50 outstanding companies were selected to participate in the MedTech Innovator Showcase at The MedTech Conference. Each company receives one Full Access registration as well as access to exclusive programming and networking opportunities. Twenty-five of the MedTech Innovator Showcase companies participate in a four-month virtual accelerator, which provides companies with the opportunity to receive customized, in-depth mentorship from industry stakeholders. Four finalists go on to compete for the title of MedTech Innovator 2019.

» **To learn more, please visit [medtechinnovator.org](http://medtechinnovator.org).**

**800+**

Early to mid-stage medtech companies submitted applications



**50**

Showcase Companies



**25**

Accelerator Companies



**4**

Finalists



**GRAND PRIZE WINNER**







## MEDTECH INNOVATOR *Sponsors*



### *MedTech Innovator Finals*

#### **TUESDAY, SEPTEMBER 24**

Join us for the highly anticipated MedTech Innovator competition finals on Tuesday, September 24, during which four finalist companies present their technologies and compete for \$500,000 in prizes and awards — all based on a live audience vote!

### *MedTech Innovator Showcase*

#### **TUESDAY, SEPTEMBER 24 & WEDNESDAY, SEPTEMBER 25**

Also, be sure to catch the MedTech Innovator Showcase, which features the top 50 companies from the 2019 MedTech Innovator program in moderated, industry-themed panel sessions — right in the middle of all the action on the Exhibit Hall floor!

## MEET THE 2019 MEDTECH INNOVATOR SHOWCASE COMPANIES



### 2019 MEDTECH INNOVATOR ACCELERATOR PARTICIPANTS



See these top 50 companies featured on the MedTech Innovator Stage in the Exhibit Hall.



MEDTECH  
INNOVATOR

# Showcase Schedule

➤ Find these presentations on the MedTech Innovator Stage in the Exhibit Hall.

## TUESDAY, SEPTEMBER 24

### Cardiovascular

**MODERATOR:** Stephen Ralph, W.L. Gore

**9:15 AM – 9:45 AM**

Bardy Diagnostics  
HD Medical  
Moving Analytics  
Respirix  
Vectorious Medical Technologies

### Vascular Solutions

**MODERATOR:** Josh Magnuson, Fujikura

**9:50 AM – 10:20 AM**

Koya  
Protembis  
Soletics  
Venari Medical

### Oncology

**MODERATOR:** Jessica Richter, Experien Group

**10:30 AM – 11:00 AM**

Avelas Biosciences  
Embolx  
HEPTA Medical  
OncoRes Medical  
Subtle Medical

### Molecular Diagnostics

**MODERATOR:** Kevin Coker, Proxima Clinical

Research

**11:05 AM – 11:35 AM**

Altratech  
GNA Biosolutions  
Ischemia Care  
Nanomix  
Orbit Genomics

### Neurotechnology

**MODERATOR:** Avi Roop, RCT Ventures

**11:45 AM – 12:15 PM**

EPIC Neuro  
Forest Devices  
Halo Neuroscience  
Savonix  
ThermoPeutiX

### Chronic Disease Management

**MODERATOR:** Heather Walsh, Baxter

International

**2:15 PM – 2:45 PM**

Avisi Technologies  
Bigfoot Biomedical  
Evergaze  
PyrAmes  
toSense

### Precision & Personalized Medicine

**MODERATOR:** James Kaiser, HOYA Corporation

**2:50 PM – 3:20 PM**

American BioOptics  
Glycotest  
HealthReveal  
Onkos Surgical  
Previvo



## WEDNESDAY, SEPTEMBER 25

### Critical Care

**MODERATOR:** Kristin Simoens, Ximedica

**9:15 AM – 9:45 AM**

CloudCath  
CoapTech  
Flosonics Medical  
Patch'd  
Potrero Medical

### Surgical Advancements

**MODERATOR:** Ajay Khatri, Johnson & Johnson

**9:50 AM – 10:20 AM**

ClearCam  
EndObetes  
Medasense Biometrics  
Olfactomics  
Starling Surgical

### Orthopaedics

**MODERATOR:** Christos Monovoukas,

Olympus

**10:30 AM – 11:00 AM**

ATRO Medical  
Bone Health Technologies  
Pristine Surgical  
Surgivisio  
ZKR Orthopedics



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# PANELS AND *Super Sessions*

**Our sessions are categorized into six Program Pillars that encompass all of our programming. These Pillars help define the types of content that will be featured throughout The MedTech Conference.**

- **Getting to Yes from Regulators to Payers and Beyond — the Decision-Maker Gauntlet**
- **After Yes — Navigating the Rules of the Road in Today's Marketplace**
- **Industry Outlook and Insights**
- **MedTech (R)evolution**
- **Global Health Innovations**
- **Patient Perspectives**

## *Super Session*

### ➤ **MedTech as IT**

**Monday, September 23 | 8:30 AM – 9:00 AM**

**Room 156 AB**

#### INTERNATIONAL, BUSINESS STRATEGIES

Setting the stage for the conference program this year, Medtronic's Chief Information Officer Sean Lennon will open the program with a special presentation comparing and contrasting the attributes of MedTech, pharma and software organizations. Structurally, the MedTech sector has more in common with the IT sector, which carries important implications for government policy, reimbursement, regulatory and industry profiling initiatives around the world. This presentation will serve as a lead-in to the Super Session immediately following, "Revolutionizing the Silver Economy."

**Sean Lennon**, Chief Information Officer, Medtronic

society. Whether it is called the "Silver Tsunami," the "Longevity Economy" or the "Silver Economy," the realities, opportunities and risks are ever more present. Longevity is an all-encompassing megatrend with social, political, economic and security implications that will impact governments, nations, companies and health care.

The percentage of the world's population over 60 years of age will jump from 12% to 22% between 2000 and 2050, and for those over 80 it will quadruple. In the U.S. alone, 15.6% of the population is now over 65 and by 2030 this will increase to 20.6%. Japan, with nearly 100,000 citizens who have reached the age of 100 or older, and Finland are two of the fastest "graying" and "super graying" populations, with Europe not too far behind.

Health care systems are watching, acting and learning. With aging comes geriatric diseases, comorbidities and loneliness. The need to diagnose these disease states faster and more accurately is critical. Digital technologies have proven to be valuable assets, though more computational horsepower is needed to optimize them and address anticipated future needs. Physicians are also relying on AI-based automation fueled by automatic tracking of biometric information for certain tasks. AI is also helping patients and their families understand diseases and treatment options. But is the key AI or IA, intelligence augmentation, where machines extend human capabilities instead of replacing them? Human versus machine is a tricky subject. People need to feel comfortable for the technology to work and deliver impact. Referred to as the "uncanny valley," the balance between man and robot interaction still needs work.

A recent Smithsonian article states "The tension between what technology can now do and how much older people

## *Super Session*

### ➤ **Revolutionizing the Silver Economy**

**Monday, September 23 | 9:00 AM – 10:30 AM**

**Room 156 AB**

#### INTERNATIONAL, BUSINESS STRATEGIES

Aging has taken on a persona of its own. It is not just about people getting older, it represents a fundamental paradigm shift about how we live, work and achieve fulfilling lives. It also entails dramatic decreases in the size of the productive workforce, the number of qualified physicians and the availability of care givers across

actually use it is at the heart of what's become known as 'connected aging.'" Experts in aging, health care, policy and technology from Japan, Finland, Australia, the U.K. and U.S. will discuss this exciting opportunity and how their countries are leveraging digital platforms, AI and other cutting-edge technologies for elderly care and economic benefit.

**MODERATOR: Joseph Coughlin**, Director, MIT AgeLab

**Daniel Grant, PhD, MBA, MD & CEO**, MTPConnect

**Harriet Finne-Soveri, MD, PhD**, Senior Medical Officer, National Institute for Health and Welfare, Finland

**Lord Prior of Brampton**, Chair, NHS England

**Sayaka Tomihara**, Director, Medical and Assistive Device Industries, Ministry of Economy, Trade, and Industry, Japan

## »» The Business Value of Design: How Do the Best MedTech Design Performers Increase Their Revenues and Shareholder Returns at Nearly Twice the Rate of Their Industry Counterparts?

**Monday, September 23 | 9:30 AM – 10:45 AM**

**Room 157 A**

### BUSINESS STRATEGIES, EMERGING TRENDS

We all know examples of bad product and service design. The USB plug (always lucky on the third try). The experience of rushing to make your connecting flight at many airports. The exhaust port on the Death Star in "Star Wars." We also all know iconic designs, such as the Swiss Army Knife, the humble Google home page, or the Disneyland visitor experience. All of these are constant reminders of the way strong design can be at the heart of both disruptive and sustained commercial success in physical, service, and digital settings.

Despite the obvious commercial benefits of designing great products and services, consistently realizing this goal is notoriously hard — and getting harder. Only the very best designs now stand out from the crowd, given the rapid rise in consumer expectations driven by the likes of Amazon; instant access to global information and reviews; and the blurring of lines between hardware, software, and services.

Companies need stronger design capabilities than ever before. So how do companies deliver exceptional designs, launch after launch? What is design worth?

To answer these questions, we have conducted, and will explore in the session, what we believe to be the most extensive and rigorous research undertaken anywhere to study the design actions that leaders can make to unlock business value.

**MODERATOR: Stephanie Henze**, Associate Partner, McKinsey and Company

**Craig Loomis, MS, MBA**, General Manager, Diagnostic Cardiology Core Solutions, General Electric

**Paul Hermes**, Board of Directors, Cadence Inc., Former Entrepreneur in Residence, Medtronic

## »»» Articulating the Value of Diagnostics: Moving Toward Value Based Approaches

**Monday, September 23 | 9:30 AM – 10:45 AM**

**Room 156 C**

### DIAGNOSTICS

The term "value" in health care has been difficult to define, yet stakeholders — from diagnostic test developers, to payers, to hospitals and health systems — are constantly seeking high-value products and services that improve health outcomes for patients in clinical and cost-effective ways. However, the ability to define value is critical, particularly as the health care world moves toward more value based approaches to care delivery and reimbursement. This panel will present a range of perspectives on defining value, developing clinical evidence to support value claims and contemplating value based approaches for diagnostics.

**MODERATOR: Lena Chaihorsky**, Co-Founder & Vice President, Payer Innovation, Alva10

**Heather Brown**, Senior Vice President, Market Access and Reimbursement, HeartFlow

**Rochelle C. Fink, MD, JD, MBA**, Senior Health Science Specialist, U.S. Food and Drug Administration

**Matthew Tucker**, Head of Sales and Marketing, VITAL & Enterprise Strategy, Highmark Health

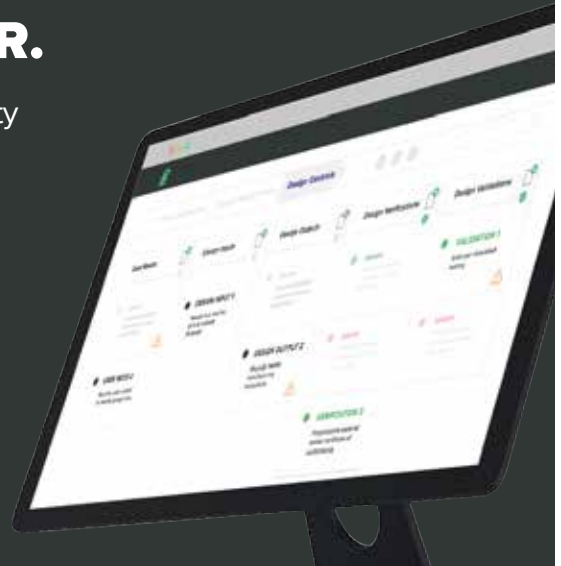
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# PANELS AND *Super Sessions*

## Pillars

- » Getting to Yes from Regulators to Payers and Beyond — the Decision-Maker Gauntlet
- » After Yes — Navigating the Rules of the Road in Today's Marketplace
- » Industry Outlook and Insights
- » MedTech (R)evolution
- » Global Health Innovations
- » Patient Perspectives

## » A Values-Based Approach to MedTech Business Integrity

**Monday, September 23 | 9:30 AM - 10:45 AM**

**Room 157 C**

### LEGAL AND HEALTH CARE COMPLIANCE, BUSINESS STRATEGIES

Ensuring ethical behavior is of critical importance to the MedTech industry. Experts agree that compliance systems based on values, rather than rules, have greater potential for long-term success, but such a transition can pose significant change-management challenges. This session will feature legal/compliance, behavioral change and communication experts who dissect challenges and opportunities for MedTech companies to enable business decision-making based on values. The panel will focus on three critical success factors for more quickly moving the commercial organization from a rules- to a values-based mindset:

1. Cognitive: considers what employees need to know to remain in compliance
2. Emotional: focuses on how employees feel about what they choose to do or how they act
3. Behavioral: helps employees act on information in a compliant way

The panel will define these inter-related components and provide examples from the MedTech space for how to address them. The cross-functional panel of experts will deliver practical, relevant and current advice.

Additionally, key success factors will be explored, including but not limited to:

- » Ensuring that employees can clearly articulate why ethical decision-making helps improve the lives of their customers and patients

- » Helping the organization characterize the behaviors/traits of the “model sales representative” in the context of ethical behavior

- » Avoiding training that creates confusion versus clarity

**MODERATOR: Ilyssa Levins**, Founder/President, Center for Communication Compliance

**Ann Ford, BSN, JD**, Partner, Hall Prangle & Schoonveld

**Michael Varadian, JD, MBA**, Founder, HealthSpan Advisors

**Denis Jacob**, VP, Deputy Chief Compliance Officer, Orthofix

## »»» Case for Quality

**Monday, September 23 | 9:30 AM - 10:45 AM**

**Room 157 B**

### REGULATORY, QUALITY AND GOOD MANUFACTURING PRACTICES

Case for Quality is a program developed under the auspices of the Medical Device Innovation Consortium (MDIC) where various stakeholders, including FDA and the medtech industry, have partnered to identify practices that lead to higher device quality. The program has been underway for several years and includes the CDRH Case for Quality Voluntary Improvement Program (CFQ VIP), 18 companies and 51 facilities that undergo periodic assessment focused on practices that advance quality and safety and lead to better outcomes for patients.

Hear from leaders in the Case for Quality, who will discuss current program activities as well as what the future holds for CfQ. Get an agency perspective, including the benefits to companies participating in the program. Topics include Qualifying to Participate in CfQ, Executive Engagement, the Voluntary Improvement Program, and others.

**MODERATOR: Joe Sapiente**, VP QA RA, Hologic Inc.

**Pamela Goldberg, MBA**, President and CEO, MDIC

**George Serafin**, National Managing Principal, Healthcare and Life Sciences, Grant Thornton

**Sara Sulfridge**, Director, Quality Strategic Program Office, Baxter

**Francisco Vicenty**, Program Manager, Case for Quality, USFDA/CDRH/Office of Compliance

## »» Efficiently Collect Real World Data: Industry, Policy, and Regulatory Perspectives

Monday, September 23 | 11:00 AM – 12:15 PM

Room 156 C

### REGULATORY, QUALITY AND GOOD MANUFACTURING PRACTICES

The demand for Real World Evidence (RWE) has increased dramatically, with the payers requiring more evidence to make their decisions and the global regulatory bodies looking to real world data for pre- and post-market decisions. Savvy medtech companies are using real world data sets to their competitive advantage. Historically a practice for disruptive products, today, RWE could be a critical component of successful go to market strategy. This session will look at how to make the collection of this data more efficient, accessible, and compliant. In a panel moderated by Seth Goldenberg, VP of Medical Device and Diagnostics for Veeva, the audience will hear the perspectives from Owen Faris, Clinical Trials Director – CDRH at US Food and Drug Administration, Rachel Rath, NESTcc Deputy Director, and Manish Bharara, Regulatory and Clinical Affairs, Siemens Healthineers, on the collection, application and challenges of RWE, ultimately resulting in better outcomes and safer and more efficient use of technology.

**MODERATOR: Seth Goldenberg, PhD**, Vice President, Vault Medical Device & Diagnostics, Veeva Systems

**Manish Bharara, PhD, MBA**, Sr. Manager, Global Clinical Affairs, Siemens Healthineers

**Owen Faris, PhD**, Director, Office of Clinical Evidence and Analysis, FDA/CDRH

**Rachel Rath**, Chief of Staff, National Evaluation System for health Technology Coordinating Center (NESTcc)

**Diane Wurzbarger**, Executive, Regulatory Affairs, Americas & Global Strategic Policy, GE Healthcare

## » SME Medtech Innovations That Are Transforming Health Care in the U.S. and Abroad

Monday, September 23 | 11:00 AM – 12:15 PM

Room 157 A

### GLOBAL HEALTH

Given the complexities of payment, policy, and care delivery ecosystems in low- and middle-income countries, it should come as no surprise that change agents in these regions are

developing innovations with the potential to transform health systems not only in their own communities but in countries of all sizes around the world. Fostering breakthroughs in health care delivery models, affordable technologies, and more, these organizations are creating new pathways to improving health care quality and access while challenging the paradigm of modern-day patient care.

**MODERATOR: Kaakpema Yelapaala**, Chief Executive Officer and Founder, access.mobile

**Lisa Bourget**, Senior Director, Strategy, Management and Partnerships, Duke Global Health Innovation Center, Innovations in Healthcare

**Chris Macek**, CEO, SystemOne

**Xavier Urtubey**, CEO & Co-Founder, AccuHealth

## » Value Based Arrangements: New Proposed Rules — Implications for Future Arrangements and Activities

Monday, September 23 | 11:00 AM – 12:15 PM

Room 157 C

### LEGAL AND HEALTH CARE COMPLIANCE, MARKET ACCESS, PAYMENT AND HEALTH CARE DELIVERY ISSUES

It is widely recognized that the U.S. health care system must transition from a fee-for-service/fee-for-product (volume-based) payment framework to a value-based paradigm to achieve better clinical outcomes, lower costs and improve the patient experience. Value-Based Arrangements (VBAs) condition or modify payment based upon the results achieved (clinical, cost, and/or patient experience outcomes). The current fraud and abuse laws deter broader and more comprehensive engagement in patient-centered value-based arrangements. This panel will examine relevant proposed rules, and in particular the new Anti-Kickback Statute Safe Harbor proposed rules and its implications for future arrangements and activities.

**MODERATOR: Andrew Furlow**, Counsel, Hogan Lovells US LLP

**Saliha Greff**, Vice President & General Counsel — Respiratory, Gastrointestinal and Informatics — MITG, Medtronic

**Thomas Conniff**, Assistant General Counsel, Johnson & Johnson



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# PANELS AND *Super Sessions*

## *Pillars*

- Getting to Yes from Regulators to Payers and Beyond — the Decision-Maker Gauntlet
- After Yes — Navigating the Rules of the Road in Today's Marketplace
- Industry Outlook and Insights
- MedTech (R)evolution
- Global Health Innovations
- Patient Perspectives

## ➤ Delivering Great Care and Technology Transformation in the World's Largest Integrated Health System

**Monday, September 23 | 11:00 AM – 12:15 PM**

**Room 157 B**

**INTERNATIONAL, GLOBAL HEALTH, MARKET ACCESS, PAYMENT AND HEALTH CARE DELIVERY ISSUES**

How do you deliver great care at population scale? Where do technology and industry fit in, and what are the forces shaping the evolution of the UK's National Health Service? Join us for a panel interview with three people driving big changes in NHS England, which serves a population of more than 55 million people: Lord David Prior, Chair of NHS England, Dr. Sam Roberts, Chief Executive of the Accelerated Access Collaborative, and Prof. Tara Donnelly, Chief Digital Officer at NHSX, a new unit moving forward the digital transformation of health and social care.

**MODERATOR: Ashley McEvoy**, Executive Vice President, Worldwide Chairman, Medical Devices, Johnson & Johnson

**Tara Donnelly**, Chief Digital Officer, NHSX

**Lord Prior of Brampton**, Chair, NHS England

**Roland Sinker**, Chief Executive, Cambridge University Hospitals NHS Foundation Trust

**Sam Roberts**, Chief Executive Officer Accelerated Access Collaborative, NHS England and NHS Improvement

## *Super Session*

### ➤ Health 2040: MedTech's Role in a Transformed Future

**Monday, September 23 | 12:15 PM – 1:30 PM**

**Room 156 AB**

**BUSINESS STRATEGIES, EMERGING TRENDS**

Twenty years from now, the health care system we know today will look completely different. There will be a fundamental shift from "health care" to "health." And while disease will never be completely eliminated, through science, data, and technology, we will be able to identify it earlier, intervene proactively, and better understand its progression. Greater data connectivity and interoperability, open, secure platforms, and increasing consumer engagement will lead to a future focused on wellness and managed by companies that assume new roles to create value. Ten stakeholder archetypes — grouped into three distinct, but interconnected, categories — are likely to emerge and replace and redefine traditional industry roles.

Today, no segment of the health care ecosystem is immune to these transformative changes. Industry leaders need to make choices now about which core capabilities they will need to lead on, and which they will need to partner with others on, over the next 5, 10 and 20 years. This session will challenge medtech executives to think differently about the future — both in the shorter-term and longer-term — and the business model choices they need to make to survive in this type of health ecosystem.

**MODERATOR: Pedro Arboleda, MBA**, Managing Director, Deloitte

**Michael Apkon, MD, PhD**, CEO, Tufts Medical Center

**Sheri Dodd**, Vice President/General Manager, Medtronic Care Management Service & Non-Intensive Diabetes Therapies

**Michael Minette**, VP of Strategy, Orthopedics Group, Zimmer Biomet

## » Value Based Care: Lessons and Learnings in LATAM Impacting MedTech Industry

Monday, September 23 | 12:30 PM – 1:45 PM

Room 157 B

### INTERNATIONAL, PAYMENT AND HEALTH CARE DELIVERY

Demonstrate how the industry could be a strategic agent to generate added value in the LATAM healthcare systems through VBC, promoting better clinical outcomes and being an ally to support and improve the healthcare system sustainability.

Moreover, it is important to promote an open dialogue between HCS agents: industry, hospitals and the public sector to identify gaps, perspectives, opportunities and introduce public policies that favor and allow the implementation of VBC models in LATAM.

It is important to mention, that these kinds of strategies between all the agents in the healthcare system allow us to generate better outcomes, identify opportunities and generate knowledge, which permit us to have better and robust healthcare systems.

**MODERATOR: Luly Castellanos de Samper**, International Vice-President, Johnson & Johnson Medical, LATAM

**Fabio Katayama**, Executive Director, Hospital Samaritano

**Adolfo Llinas**, Medical Director, Santa Fe Foundation of Bogotá

**Marcia Makdisse**, Co-founder & Chief Value Officer | CVO, CareCycle – Value Based Healthcare

## » U.S. - China Relationship: From Cooperation to Confrontation

Monday, September 23 | 12:30 PM – 1:45 PM

Room 157 C

### INTERNATIONAL

The U.S. - China relationship had been on a general cooperative trajectory for the almost 40 years — since Deng Xiaoping initiated “socialism with Chinese characteristics,” and U.S. policy looked for China to become a “responsible stakeholder.” Presidents Xi Jinping and Donald Trump have ushered a new era of confrontation — first with a trade war and then to investment restrictions and even military threats. James McGregor, author of two books on China, has witnessed first-hand much of this transition and can explain what this means for the global economy and the medical technology industry.

**James McGregor**, Chairman, Greater China, APCO Worldwide

## » Developing a Framework for Patient Input in Medical Device Clinical Trials

Monday, September 23 | 1:00 PM – 2:00 PM

Room 157 A

### PATIENT PERSPECTIVES

Industry, FDA and patient groups recognize the importance and value of patient input in the ideation, design, testing and approval of new medical device technologies, but often struggle to elicit and incorporate patient input in a meaningful way. Patients can identify outcomes that are meaningful, risks that they would be willing to tolerate, and practices that can decrease the burden of participation in clinical trials. Attendees at this session will learn about an MDIC collaboration that includes medical device industry, patients and regulators, to develop a suite of tools to help medical device companies solicit input from patients and patient groups on clinical trial design elements that are aligned with patients’ real-world priorities.

**MODERATOR: Jon Hunt**, Vice President, Clinical Science and Technology, MDIC

**Dean Bruhn-Ding, BS**, RAC, Vice President Regulatory Affairs & Quality Assurance, CVRx, Inc.

**Barry Liden, JD**, Vice President of Patient Engagement, Edwards Lifesciences

**Bray Patrick-Lake**, Director, Strategic Partnerships, Evidation Health

**Michelle Tarver, MD, PhD**, Director, Patient Science and Engagement Program, CDRH, FDA



# PANELS AND *Super Sessions*

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## ➤➤➤ Using Data and Analytics to Demonstrate the Value of Diagnostics

**Monday, September 23 | 1:00 PM – 2:00 PM**

**Room 156 C**

### DIAGNOSTICS

Applying sophisticated analytics to large clinical and claims databases can generate evidence demonstrating the value of diagnostics. This evidence can in turn be leveraged in market access, maximizing sales and marketing, manufacturing, research and clinical development. Building off of the AdvaMedDx Framework for Comprehensive Assessment of the Value of Diagnostic Tests to guide evidence development, this session will showcase two use cases — oncology and sepsis — generated through data analytics to reinforce the value of diagnostics for patient health and health care.

**MODERATOR: Barry Rosenberg, MD, MBA**, Managing Director and Senior Partner, Boston Consulting Group

**Joseph Bernardo**, Operating Partner, Linden Capital Partners

**Peer M. Schatz**, CEO, QIAGEN

**Alan Wright, MD**, CMO, Roche Diagnostics

## *Super Session*

### ➤➤ The New World of 510(k)

**Monday, September 23 | 2:00 PM – 3:15 PM**

**Room 156 AB**

### REGULATORY, QUALITY AND GOOD MANUFACTURING PRACTICES

For over 40 years, FDA's 510(k) process has provided a safe and efficient path to market for the vast majority of medical devices and diagnostics. Over that time, the process has continually evolved to adapt to the rapid pace of medtech innovation and new health care issues. The 510(k) process may be poised for another evolutionary leap as FDA has proposed a number of significant changes to this bedrock regulatory paradigm. Learn from senior FDA management what the future holds for 510(k) and what industry thinks of this new phase in regulation.

**MODERATOR: Phil Desjardins**, Vice President, Global Regulatory Policy & Intelligence, Johnson & Johnson

**Susan Alpert**, Principal, SFA Consulting

**Maureen L. Mulvihill, PhD**, President and CEO, Actuated Medical, Inc.

**Jeff Shuren, MD, JD**, Director, CDRH

**April Veoukas, JD**, Director, Regulatory Affairs, Abbott

## ➤➤ Chasing Value: Understanding How to Work with GPOs to Introduce New Health Care Innovation in the Supply Chain

**Monday, September 23 | 2:00 PM – 3:15 PM**

**Room 157 B**

### MARKET ACCESS, PAYMENT AND HEALTH CARE DELIVERY ISSUES

Come learn about how to successfully launch new and innovative technology with GPOs. Does a GPO work for your product and market implementation strategies? Hear from GPOs and suppliers who have worked with them on recent experience in medtech, industry trends, new innovation forums, diversity programs and value based initiatives to foster optimal, high quality health care.

This is an excellent opportunity to learn from experts across the supply chain how they have successfully worked together and launched new innovations with group purchasing organizations. Successful partnerships and best practices will be explored in this highly informative session.



\*\*Want to learn more and talk to representatives from Premier and Vizient directly? Join us for a meet-and-greet on Tuesday morning with GPO contracting, diversity and innovation program leaders from 10:30 AM to 12:30 PM. Come meet supply chain leaders who have been working with medtech innovators and learn about how your company can work with a GPO.\*\*

**MODERATOR: Khatereh Calleja JD**, President & CEO,  
Healthcare Supply Chain Association

**Kyle Chenet**, CEO, 410 Medica

**Becky Foret, RN, BSN, MBA**, Sr. Director, Sourcing  
Operations — Med/Surg, Vizient

**Larry Koesterer, RPh, CPSM**, Senior Category Leader, Intalere

**Chaun Powell, MBA**, Group Vice President, Strategic Supplier  
Engagement, Premier Inc.

**Phil Royston**, President, Access Scientific, LLC

## » AdvaMed's New Code of Ethics: Is Your Company Prepared to Comply?

**Monday, September 23 | 2:00 PM – 3:15 PM**

**Room 157 C**

### LEGAL AND HEALTH CARE COMPLIANCE BEST PRACTICES

AdvaMed recently released its updated Code of Ethics on Interactions with Health Care Professionals, which will take effect on January 1, 2020. The updated Code introduces four new topics critical for medical technology companies: Jointly Conducted Education and Marketing Programs, Communicating for the Safe and Effective Use of Medical Technology, Consigned Products, and Company Representatives Providing Technical Support in the Clinical Setting.

Will your company need to adopt new policies to reflect the Code's new sections, notably those relating to communications, technical support and joint programs? Are your company's industry codes in compliance? This discussion will feature industry experts who will offer practical tips to get into compliance with only a quarter of the year left to prepare.

**MODERATOR: Matt Wetzel**, Senior Counsel, Akin Gump  
Strauss Hauer & Feld LLP

**Jonathan Turner**, Vice President, Ethics and Compliance,  
Smith & Nephew

**Kristi Travers**, Assistant General Counsel, Johnson & Johnson

**Avi Spira**, Chief Compliance, Risk & Privacy Officer, FUJIFILM  
Holdings America Corporation

**Nancy S. Travis**, Vice President, International Compliance &  
Governance, AdvaMed

## »»» Establishing the Value of Your Medtech Innovation — It's Never Too Early

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**Monday, September 23 | 2:15 PM – 3:15 PM**

**Room 156 C**

### BUSINESS STRATEGIES

Before even building the first prototype, medtech innovators should be thinking about how their invention will deliver value to health care customers. The panel will discuss how innovators can define, demonstrate, quantify and communicate the value of their technologies at each stage of development and through early commercialization and scaled growth.

**MODERATOR: Amy Siegel**, Founder and Principal, S2N  
Health, LLC

**Aaron Sandoski**, Co-Founder and Managing Director, Norwich  
Ventures

**Scott Schorer**, President and CEO, GI Dynamics

**Martha Shadan**, President and CEO, Miach Orthopaedics



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# PANELS AND *Super Sessions*

## Pillars

- **Getting to Yes from Regulators to Payers and Beyond — the Decision-Maker Gauntlet**
- **After Yes — Navigating the Rules of the Road in Today's Marketplace**
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## ➤ **More Value for Patients and Society Through Data-Driven Health Care: U.S. and International Perspectives**

**Monday, September 23 | 2:15 PM – 3:15 PM**

**Room 157 A**

### PATIENT PERSPECTIVES, EMERGING TRENDS

Big Data is a term that has spurred hope and promises for drug discovery through optimizing patient treatment and care, all said to reduce cost, increase quality and effectiveness of care, and make patients and providers happier. Increasing and on-going efforts have been made in the areas of data collection from medical records, devices, wearables, claims, tests and sequencing. No matter what the source or type of data, the promises have been equally as wide. Yet, the progression from research to clinical value has not moved as fast or with the all the promised results.

There is no question that digitalization and datafication have become new health care engines. The on-going collection and compilation of health data now available to develop better care, and solutions for patients and health professionals is showing results. In this session, datafication in the health care and medtech industries will be discussed and explored from the solutions and platforms perspectives, including ethics, showing how under which conditions health data can be shared and utilized to protect individuals while delivering on the industry-wide promises of data. The session will be a benchmark on how to build advanced legislative and business environments for collecting and utilizing health data to create more value for patients, companies and governments alike. Special focus will be paid to the conditions for developing data-driven health care in the U.S. and in the Nordics. Finland's actual success in data integration and management has been used to build a revolutionary win-win situation for patients, companies and government. This session also serves as an invitation for the on-going dialogue

and collaboration between the different players from society, companies — startups though global corporations — government and academia to learn and move to the next step of actual value from data-driven health care.

**MODERATOR: Marja Liisa Niinikosk**, Chief Executive Officer, Helsinki Business Hub

**Jaqueline Corrigan-Curay**, Director of Medical Policy, FDA

**Visa Honkanen**, Director of Strategic Development, Helsinki-Uusimaa Health Care District

**Mitja Kurki, PhD**, Senior Computational Scientist, FINNGEN project analysis team leader, Broad Institute of MIT and Harvard, Finnish Institute of Molecular Medicine, Helsinki, Finland

**Stasha Ler**, Director Digital Health, Medtronic

**Pekka Kahri**, Technology Officer, HUS Helsinki University Hospital

**Tero Silvola**, CEO, BC Platforms

## ➤➤ **China Market Access Updates — Regulatory, Clinical, Reimbursement and IP**

**Tuesday, September 24 | 8:30 AM – 12:15 PM**

**Room 157 A**

**LEGAL AND HEALTH CARE COMPLIANCE BEST PRACTICES; MARKET ACCESS, PAYMENT AND HEALTH CARE DELIVERY ISSUES; REGULATORY, QUALITY AND GOOD MANUFACTURING PRACTICES; INTERNATIONAL**

**CHAIR BY Grace Palma, MBA**, CEO, China Med Device, LLC

**Opening Remarks on China Medical Device and Diagnostic Trends and Growth Areas**

**INTRODUCTIONS: Eric Rugo**, Vice President Government Affairs, Stryker

**Jiang Feng**, Chief Executive Officer, China Association of Medical Devices Industry

### **China NMPA (CFDA) Regulatory and IP Key Updates**

Recent Developments in China Medical and IVD Devices: MAH/ Legal Agents and the Implications in local manufacturing and product registration. China Post Market Compliance and the mandatory reporting. Innovation, companion diagnostic/ biomarker(CDx), combination device classification, Registration Guidelines Revision Plan.



UDI has implications on everyone. What is its status and implementation?

China is reforming its IP law. What is the status with IP protection for both domestic and overseas companies?

**MODERATOR: Grace Palma, MBA**, CEO, China Med Device, LLC

**Li Ding**, Vice Chief of Guangdong NMPA (CFDA) Bureau

**Jason Liang**, Director of Post Market Surveillance, China Med Device

**Lindsay Tao, MD**, Corporate Director, Global Health Policy, Johnson & Johnson

**Zhi Tao**, Guangdong Patent & IP Office

#### China NMPA (CFDA) Clinical Affairs Key Updates

Clinical updates to support regulatory registration and compliance: as the chairing country for the IMDRF clinical evaluation committee, what are the latest updates in the real world evidence, clinical trial/evaluation, international clinical data acceptance guideline? How do you know which path to take or combine to mitigate the clinical trial requirements?

Has the acceptance of overseas clinical data been successful in avoiding clinical trial or reducing clinical trial sample size? How to provide Chinese ethnic justification?

**MODERATOR: Grace Palma, MBA**, CEO, China Med Device, LLC

**LiJuan He**, ASPAC Regulatory Affairs Transformation Lead, Johnson & Johnson

**Lindsay Tao, MD**, Corporate Director, Global Health Policy, Johnson & Johnson

**Xing Zhou**, Principal Consultant, Siemens Healthcare Diagnostic

#### China Reimbursement Reform

China reimbursement frame work and concepts: high level key differences between China and US reimbursement systems, China provincial vs national reimbursement vs private payment system. US based executive practical perspectives on prioritizing China provincial reimbursements efforts, obtaining patient charge codes and reimbursements for new product and existing product codes and reimbursements. What are the lessons learned?

**MODERATOR: Eric Rugo**, Vice President Government Affairs, Stryker Corporation

**Jiang Feng**, Chief Executive Officer, China Association of Medical Devices Industry

**Deng Shao Ping**, President, Xichuan Provincial People's Hospital

**Jeff Potkul**, Global Director, Medtronic MITG

**Anita Wei**, Senior Director of Public Affairs & Communications, BD Greater China

**Elizabeth Woody**, Vice President, Public Affairs, BD

#### SPECIAL GUEST:

**Daisy Du**, Global Lead, Medtronic Neurovascular Health Economics and Reimbursement, Medtronic

## »»» FDA's New Approaches to Software Regulation: Pre-Certification and Artificial Intelligence

**Tuesday, September 24 | 9:15 AM – 10:30 AM**

**Room 156 C**

### REGULATORY, QUALITY AND GOOD MANUFACTURING PRACTICES

Advances in software and data technologies have forced the FDA to reimagine its approach to regulating these products. This panel will explore the Agency's current plan to restructure its software regulations through its pre-certification pilot program and the Agency's proposal to regulate artificial intelligence. Panelists will offer insights into how companies developing medical software are positioning themselves to take advantage of these proposals and other regulatory challenges they face.

**MODERATOR: Nathan A. Brown, JD**, Partner, Akin Gump LLP

**Diane Johnson**, Digital Health Policy Lead, Johnson & Johnson

**Bakul Patel, MSEE, MBA**, Sr Director Digital Health, FDA

**Venk Varadan, MBA**, Co-Founder and CEO, Nanowear

## »» The New World of Medtech M&A Valuation: Strategies to Adapt and Thrive

**Tuesday, September 24 | 9:45 AM – 11:00 AM**

**Room 157 B**

### BUSINESS STRATEGIES

Continued strong sector fundamentals, improving end markets and new product launches and healthy pipelines have led to a significant run up in valuations of private and public medtech assets. As a result, organizations have been forced to adopt new and more advanced valuation techniques to appropriately evaluate acquisition targets.

# PANELS AND *Super Sessions*

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Officials from some of the most successful medtech organizations will share insights and best practices for capturing and analyzing the most relevant aspects in designing a comprehensive valuation for M&A and what challenges remain, including the following:

- » How are companies succeeding in competitive situations for attractive targets?
- » What are the right analytical tools for evaluating complex economics globally, including payer dynamics and commercial risks?
- » What levels of strategic and operational diligence are required to properly value deal targets?
- » How is the capital markets environment — cheap credit, activist shareholders — affecting resource allocation for transformative M&A?

**MODERATOR: John Babitt**, Partner, EY

**Charlie Attlan**, SVP Business Development, Boston Scientific

**Chris Cleary**, SVP Business Development, Medtronic

**Susan Morano**, VP Business Development — Medical Devices, Johnson & Johnson

**J.P. Peltier**, Global Group Head, Healthcare Investment Banking, Piper Jaffray

## ➤ **Seeing Is Not Always Believing — Tackling Legal Advertising Disguised as Medical Alerts**

**Tuesday, September 24 | 9:45 AM – 11:00 AM**

**Room 157 C**

### LEGAL AND HEALTH CARE COMPLIANCE BEST PRACTICES

Widespread concern has been raised about the medical misinformation surrounding the safety of FDA-approved or

cleared medical devices and drugs. What is behind this medical misinformation? Often it is legal advertising — disguised to look like an FDA safety alert, recall or other critical medical warning, but actually intended to drum up patients to join class-action lawsuits. The ads may not be placed by the lawyers directly, but by “lead generators” who are paid to find plaintiffs across the U.S. for the law firms. This panel will discuss recent trends in attorney advertising, as well as the impact attorney advertising is having on the MedTech industry.

**MODERATOR: Becky Wood**, Partner, Sidley Austin LLP

**John F. Brenner, JD**, Chief Litigation Counsel, BD

**Raymond De Rise**, Vice President Global Legal & General Counsel, Sekisui Diagnostics, LLC

**Rusty Silverstein**, President and Founder, X Ante

**Aviva Wein**, Assistant General Counsel, Products Liability, Johnson & Johnson

## *Super Session*

### ➤➤➤ **It Takes a Village: How the Health Care Community Is Working Together to Tackle Cybersecurity**

**Tuesday, September 24 | 11:00 AM – 12:15 PM**

**Room 156 AB**

#### EMERGING TRENDS, REGULATORY, QUALITY AND GOOD MANUFACTURING PRACTICES

Managing cybersecurity in the health care community is a shared responsibility; all participants must proactively do their part. This panel will explore the various ways in which the health care space is jointly tackling these issues, including perspectives from FDA, medical device manufacturers and health care providers.

**MODERATOR: Zach Rothstein, Esq.**, Vice President, Technology & Regulatory Affairs, AdvaMed

**Denise Anderson, MBA**, President, H-ISAC

**Greg T. Garcia**, Executive Director, Health Sector Coordinating Council

**Suzanne Schwartz, MD, MBA**, Deputy Director, Office of Strategic Partnerships & Technology Innovation, Center for Devices & Radiological Health, FDA

**Chris Tyberg**, Divisional Vice President, Information Security, Abbott

**Jithesh Veetil, PhD**, Program Director, Medical Device Innovation Consortium (MDIC)

## »»»» Diverse Perspectives on Developing and Deploying Digital Technologies

**Tuesday, September 24 | 11:15 AM – 12:15 PM**

**Room 157 B**

### MARKET ACCESS, PAYMENT AND HEALTH CARE DELIVERY ISSUES

The advent of technologies that use digital platforms and artificial intelligence has the potential to significantly impact the health outcomes of patients and to change the way that health care is delivered. This session will explore the various considerations that should be factored into the development and use of these types of technologies. Experts will discuss the process for developing and positioning these devices, data protection and risk considerations, regulatory and legal compliance issues, market positioning, and payment.

**MODERATOR: Vernessa Pollard**, Partner and Co-Chair of FDA Practice, McDermott Will & Emery

**Afia Asamoah**, Senior Counsel and Trust and Compliance Officer, Verily Life Sciences

**Russell Jones**, Partner, Deloitte Risk and Financial Advisory, Deloitte Consulting

**Uday Kumar**, President and CEO, Element Science

**Leslie Wise**, Principal Consultant, Evidence Matters

## » Small Companies Selling Big Ideas to Huge Corporations

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**Tuesday, September 24 | 11:15 AM – 12:15 PM**

**Room 157 C**

### BUSINESS STRATEGIES, EMERGING TRENDS

What does it take for a startup to sell to corporate giants? The panel will examine ways for small-sized companies to pitch big ideas to hardly accessible clients. As commerce becomes more virtual and distances shrink, what are the new ways for small enterprises from the medtech and digital health industries to perform their larger peers?

Through the analysis of success stories and failures, the panelists will discuss what it takes to make it big when you're small.

**MODERATOR: Kathryn Zavala, PhD**, VP, Operations & Business Development, MedTech Innovator

**Steven Arless**, CEO, SoundBite Medical Solutions Inc.

**Nick Dougherty**, Program Director, PULSE@MassChallenge,

**Paul L'Archevêque**, Minister of Health and Social Services, Québec

**Adam Wollowick MD, MBA**, Sr. Director, Business Development, Stryker

## » Medtech, Look to Marketing for the Solution

**Tuesday, September 24 | 2:15 PM – 3:30 PM**

**Room 156 C**

### BUSINESS STRATEGIES, EMERGING TRENDS

Ninety percent of hospital execs who responded to a recent ZS survey believe that medtech manufacturers can't succeed with product innovation alone. Customers are demanding something different. A more empowered marketing capability can help medtech companies bring more personalized value to patients, providers and health care systems while improving the portfolio's relevance overall. In this panel, we will explore why the industry needs to evolve marketing's role, how to make it happen and what benefits leading companies, customers and patients can see as a result.

**MODERATOR: Matt Singer**, Principal, ZS Associates

**Robert Clark**, Chief Communications Officer, Medtronic

**Rajit Kamal**, Vice President, Global Franchise Leader, Johnson & Johnson

**George Parr**, EVP & Chief Marketing Officer, BD

**Randy Pritchard, MBA**, Sr. Vice President, U.S. Marketing, Roche Diagnostics Corporation



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## *Super Session*

### » Pulse of the Industry 2019

**Tuesday, September 24 | 2:15 PM – 3:30 PM**

**Room 156 AB**

#### BUSINESS STRATEGIES, EMERGING TRENDS

A decade since the financial crisis, the medtech industry has re-established steady growth rates and record levels of venture capital investment. However, medtech has yet to fully realize the potential of new digital technologies to transform the industry. Connected devices will capture and analyze data to deliver personalized care and improved outcomes, while presenting new challenges in customer engagement, data management and cybersecurity. EY's 13th annual *Pulse of the Industry Medical Technology Report* examines each of these topics and will be the foundation for the panel conversation where we'll explore how medtech companies can best seize the opportunities and avoid the dangers ahead.

**MODERATOR: James Welch**, Global Client Service Partner, EY

**John Liddicoat, MD**, Executive Vice President and President, Medtronic Americas Region

**Ashley McEvoy**, Executive Vice President, Worldwide Chairman, Medical Devices, Johnson & Johnson

### » Going Viral: Best Practices in Social Media

**Tuesday, September 24 | 2:15 PM – 3:30 PM**

**Room 157 A**

#### REGULATORY, QUALITY AND GOOD MANUFACTURING PRACTICES, LEGAL AND HEALTH CARE COMPLIANCE BEST PRACTICES

Twitter. Facebook. Instagram. Social media platforms have transformed how individuals and corporations are communicating and sharing information. These and other burgeoning social media tools can provide MedTech companies new opportunities to effectively interact with patients, physicians, employees and other stakeholders. However, as a highly-regulated industry, MedTech companies must consider this evolving media landscape in the context of FDA/FTC guidance and work to develop ways to maximize use of these new social media tools that don't run afoul of regulators.

In this session, participants will gain an overview of how FDA/FTC regulates MedTech company communications in the age of social media. Attendees will also learn about Advamed's recently updated Direct-to-Consumer Advertising Industry Principles and how they can help companies establish processes in compliance with current regulations. Finally, representatives from MedTech companies with active social media presences will provide case studies on how they have successfully utilized these new communications platforms. A Q&A session with all panel participants will conclude the session.

**MODERATOR: Sandra Cohen Kalter, JD**, Vice President and Chief Regulatory Counsel, Medtronic

**Richard Cleland**, Assistant Director, Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission

**Lisa Dwyer**, Partner, FDA and Life Sciences, King & Spalding

**Eric Boyles**, Senior Director, Global Digital and Social Media Team, Medtronic

**Jeanne Mell**, VP Corporate Communications, OraSure Technologies, Inc.

### » International Digital Health: Perspectives on Data, Partnerships and Scaling Internationally

**Tuesday, September 24 | 2:30 PM – 3:45 PM**

**Room 157 B**

#### INTERNATIONAL, EMERGING TRENDS

The digital transformation of health care will ensure the traditional medical device industry now has a digital strategy



at its core. The question of going digital will move from “if” to “how.” In an outcomes-based market where data will become a product’s value driver, manufacturers inevitably come to a fork in the road: invest in-house or partner? The panel will offer perspectives on both routes while sharing insights on the challenges and potential around data, partnerships and scaling internationally.

**MODERATOR: Ivan Houlihan**, VP, Life Sciences, IDA Ireland

**Shaun Braun**, Group Information Officer, MedSurg & Neurotechnology, Stryker

**Mick Farrell**, CEO, ResMed

**John O’Brien**, Executive Chairman, S3 Connected Health

**Toby Sainsbury, PhD**, Technologist, Industrial Technologies Group, IDA Ireland

## » Price Monitoring of Medical Devices in Brazil

**Tuesday, September 24 | 2:45 PM – 3:15 PM**

**Room 157 C**

### INTERNATIONAL

In this session, ANVISA will review its recent regulatory impact assessment regarding monitoring of medical device prices and the next steps related to public consultation and methodologies.

**Renato Porto**, Director — Third Division, National Sanitary Surveillance Agency — ANVISA

**Gabrielle Troncoso**, General Manager of Regulation and Good Regulatory Practices, ANVISA

## » ANVISA — The State of Regulatory Efficacy at 20 Years

**Tuesday, September 24 | 3:15 PM – 3:45 PM**

**Room 157 C**

### REGULATORY, QUALITY AND GOOD MANUFACTURING PRACTICES, BUSINESS STRATEGIES

This session will provide highlights of ANVISA’s state-of-the-art regulatory framework in its 20th anniversary year, showcasing its accomplishments and improvements. Director Porto will cover the revision of ANVISA’s rulemaking process to incorporate good regulatory practices including regulatory impact assessment, the alignment of this new model with the requirements of the OECD in support of Brazil’s accession to that body, ANVISA’s efforts toward international regulatory convergence, particularly for the

medical technology sector and its policy prioritization of the use of international standards and practices toward this objective.

**MODERATOR: Diane Wurzburger**, Executive, Regulatory Affairs Americas & Global Strategic Policy, GE Healthcare

**Renato Porto**, Director — Third Division, National Sanitary Surveillance Agency — ANVISA

## Super Session

### »» MDR/IVDR — What Now?

**Tuesday, September 24 | 3:45 PM – 5:00 PM**

**Room 156 AB**

### INTERNATIONAL, REGULATORY, QUALITY AND GOOD MANUFACTURING PRACTICES

Implementation of the MDR/IVDR remains problematic. Relevant and necessary implementing acts remain in limbo, notified body capacity does not appear sufficient to be able to do the necessary reviews in advance of the deadlines and many additional technical questions remain unresolved. This panel will address the fundamental issues in implementing the regulations, as well as attempt to offer perspective on potential mechanisms that could be utilized to reduce the review backlog and ensure products can remain on the market in the EU. The panel will have a wide representation from industry, regulators, consultants, and notified bodies. The session will provide a comprehensive update of the scenarios that are likely to unfold in the coming months and offer insight into how these may be addressed.

**MODERATOR: Angela Brown**, Director, Regulatory Affairs, ICON plc

**Oliver Bisazza**, Director, Regulations & Industrial Policy, MedTech Europe

**Michel Marboeuf, MBA**, Senior Director Regulatory Corporate, Stryker

**John Wilkinson, MBA**, Director of Devices, Medicines and Healthcare products Regulatory Agency (MHRA), U.K.

# PANELS AND *Super Sessions*

## Pillars

- » Getting to Yes from Regulators to Payers and Beyond — the Decision-Maker Gauntlet
- » After Yes — Navigating the Rules of the Road in Today's Marketplace
- » Industry Outlook and Insights
- » MedTech (R)evolution
- » Global Health Innovations
- » Patient Perspectives

## » EtO Sterilization of Medical Devices: The Impact of Evolving Regulatory Requirements

**Tuesday, September 24 | 3:45 PM – 5:00 PM**

**Room 157 A**

### REGULATORY, QUALITY AND GOOD MANUFACTURING PRACTICES

A panel of FDA and industry experts on sterilization processes, and environmental health and safety, will discuss the impact of emerging federal and state efforts to strengthen oversight of ethylene oxide (EtO) emissions that result from EtO use in medical device sterilization. Topics covered will include potential challenges MedTech companies could face in achieving and demonstrating compliance under evolving standards, and other potential impacts of changing EtO regulations on industry and public health.

**MODERATOR: Ellen Kondracki**, Vice President, Sustainability & EHS, BD

**Dan Carestio**, Chief Operating Officer, STERIS Corporation

**Phil Cogdill, MBA**, Sr. Director of Quality, Sterilization & Microbiology, Medtronic

**Joyce Hansen**, VP, J&J Sterility Assurance, Johnson & Johnson

**Suzanne Schwartz, MD, MBA**, Deputy Director (and Acting Director), Office of Strategic Partnerships & Technology Innovation, FDA

## » How Major New Players Are Challenging the Current Health Care Ecosystem

**Tuesday, September 24 | 4:00 PM – 5:00 PM**

**Room 157 C**

### BUSINESS STRATEGIES, EMERGING TRENDS

Major non-health care players such as Apple, Google, Best Buy, Amazon, Berkshire Hathaway and JPMorgan Chase are launching key initiatives in various health care segments, driving change aimed at improving the patient experience. Established players in the health care ecosystem are monitoring these activities and trying to assess the impact on their product and service innovations. Some of these new players are already changing the way health care is managed and delivered, and they are bringing a fresh perspective to a segment that has historically been inward-focused.

This session will discuss the landscape and impact of these new players, and will discuss:

- » What these players are hoping to achieve, and what strategies are they employing to meet their goals?
- » How can established MedTech players collaborate with these new entrants to evolve the dynamics of the ecosystem further?
- » How will these new entrants leverage the experience of life sciences-focused players?

**MODERATOR: Gabriele Brambilla**, Chief Executive Officer, Alira Health

**Luba Greenwood**, Strategic Business Development and Corporate Ventures, Verily, a Google company

**David Inns, MBA**, CEO, GreatCall Inc.

**Cindy Kent**, Board of Advisors, Best Buy



## » The Role of Diagnostics in Promoting the Health and Health Care of Women

Tuesday, September 24 | 4:00 PM – 5:00 PM

Room 157 B

### DIAGNOSTICS

Diagnostic testing is critical at every stage of a woman's life. From reproductive health to heart health, diagnostic tests give health care providers the ability and confidence to make appropriate health prevention, management and treatment decisions for women. This session will explore how diagnostic tests have enabled researchers to uncover the significant biological and physiological differences between men and women and the progress being made to address the range of conditions and diseases that exclusively, disproportionately or differently affect women.

**MODERATOR: Nicole Sweeney**, Associate Director, Payment Policy and Reimbursement, Diagnostic Systems, BD

**Margaret Eckenroad**, Vice President, Women's Health, Hologic

## » Value Based Health Care in Action: Enhancing Patient Outcomes and Managing Costs

Wednesday, September 25 | 8:30 AM – 9:30 AM

Room 157 B

### INTERNATIONAL, MARKET ACCESS, PAYMENT AND HEALTH CARE DELIVERY ISSUES

This panel will discuss practical implementation of Value Based Health Care (VBHC) programs, rather than only the theory behind it. What can you do to ensure you and your organization are aware of, and leveraging, this fundamental paradigm shift in health care delivery? Prioritizing the patient as the center of the health care equation is arguably the core reason VBHC is becoming the norm for improving health care systems. It involves measuring outcomes that matter to patients and total costs of delivering those outcomes. This panel will discuss case studies from the U.S. and Europe and examine these core principles from an international perspective. Key topics for discussion include:

- » Evidence requirements for VBHC implementation
- » Examples of where and why a detailed understanding of the patient pathway is crucial
- » Pragmatic examples of where VBHC has been implemented
- » Key challenges that arise when implementing VBHC
- » Suggestions for overcoming these challenges

**MODERATOR: Andrew Baker**, Senior Director, Health Economics & Payment Policy Reimbursement, Stryker

**MODERATOR: Richard Charter**, Director EMEA, Value Based Healthcare

**Signe Houghton**, Director of Marketing, Global Alliances, Neurovascular, Stryker Corp.

**Ansaar Rai, MD**, Professor and Vice Chair, Clinical Operations, J.W. Ruby Memorial Hospital, West Virginia University Medicine

**Thomas Vanda Castelee**, Co-Founder and CEO, Awell

## » Health Care Fraud: The Government View and the Compliance Perspective

Wednesday, September 25 | 8:30 AM – 9:30 AM

Room 157 C

### LEGAL AND HEALTH CARE COMPLIANCE

In the last several years, government scrutiny of the health care industry has significantly increased, with 2018 bringing the largest health care enforcement action in the Department of Justice's history. Medical device and pharmaceutical manufacturers, health care providers, insurers, and other players in the industry have been paying close attention and ramping up compliance efforts to ensure they are not the subject of the next big enforcement action.

This panel will bring together current and former prosecutors to discuss hot topics at the intersection of government enforcement and industry compliance. Speakers, including the chief of the nation's most active enforcement authority in health care cases, will cover the government's enforcement priorities in the health care industry — from drug pricing and reimbursement to opioid diversion.

Attendees will also hear the unique insights of former prosecutors who now handle compliance for health care organizations. They will discuss the issues keeping them up at night and how their organizations are responding, including providing practical advice that attendees can apply to their own compliance function.

**MODERATOR: Miranda Hooker, JD**, Partner, Pepper Hamilton LLP

**Lisa A. Schlatz, JD**, Senior Legal Counsel, Partners HealthCare

**Amanda Strachan**, Chief of Health Care Fraud Unit, United States Attorney's Office for the District of Massachusetts

**Maureen Ruane**, Health Care Consultant, Educator & Advisor; Former Chief, Health Care & Government Fraud Unit, United States Attorney's Office for the District of New Jersey

# PANELS AND *Super Sessions*

## *Pillars*

- Getting to Yes from Regulators to Payers and Beyond — the Decision-Maker Gauntlet
- After Yes — Navigating the Rules of the Road in Today's Marketplace
- Industry Outlook and Insights
- MedTech (R)evolution
- Global Health Innovations
- Patient Perspectives

## ➤ Inspections and MDSAP

Wednesday, September 25 | 9:15 AM – 10:30 AM

Room 156 C

### REGULATORY, QUALITY AND GOOD MANUFACTURING PRACTICES

This session provides up-to-date insight on regulatory inspections. Learn about the latest information on ORA re-alignment and improved collaboration between ORA and CDRH. What will this mean to your company, and how can you best prepare for future inspections? What are the current areas of focus for FDA? The session will also cover MDSAP inspections, which are becoming increasingly popular with companies as word spreads about the value in reducing redundant inspections from a variety of regulatory authorities. Hear from one of the MDSAP pioneering companies, sharing actual experiences as well and “dos” and “don’ts.”

**MODERATOR: Laila Gurney**, Senior Executive, Global Regulatory Affairs, GE Healthcare

**Mike Heyl**, Partner, Hogan Lovells

**Luann Pandy, PhD**, Senior Vice President, Global Quality, Medtronic

**Melissa Torres**, Associate Director for International Affairs, Center for Devices and Radiological Health, FDA

**Thomas Westrick**, Vice President and Chief Quality Officer, GE Healthcare

## ➤ The Democratization of Personalized Medicine — Bringing It Closer to the Community

Wednesday, September 25 | 9:15 AM – 10:30 AM

Room 157 A

### DIAGNOSTICS

Genomics-guided precision medicine has become more common practice for patient risk predisposition screening, disease diagnosis, patient stratification, targeted therapy treatment decision support, and prognostics in cancer and rare diseases. While there are emerging wet lab standards, there continues to be a lack of consistency in the analysis, interpretation and reporting of these types of genomic tests that is slowing their diffusion in broader clinical practice. Further, healthcare providers and the testing laboratories that serve them have made limited progress on integrating genomic testing results with patient clinical and outcomes data — which is critical to achieving real genomics-guided precision medicine.

This panel will discuss the current state of molecular diagnostic and genomics testing and how healthcare providers, laboratories, pharma, and payers can work more collaboratively together to establish improved protocols and methods of test interpretation and reporting for clinical decision support, integration of molecular and genomic results with patient clinical data, and the development of RWD-RWE evidence to accelerate the development of high-value diagnostics that apply genetic information, and democratize the benefits of genomics-guided precision medicine.

**MODERATOR: David Parker, PhD**, Senior Vice President, Diagnostics Solutions, Precision For Medicine

**Sheryl Elkin, PhD**, Chief Scientific Officer, N-of-One, Inc.

**Paul Gerrard**, Medical Director and MolDX Director of Clinical Science, Palmetto GBA

## ➤ Strategic Use of Postmarket Real-World Evidence and Data Regarding Quality and Value

Wednesday, September 25 | 9:45 AM – 11:00 AM

Room 157 C

### MARKET ACCESS, PAYMENT AND HEALTH CARE DELIVERY ISSUES

This expert panel will explore uses of real world evidence (RWE), with specific regard to application to quality measurement, value based payment and coverage. The panelists, who include



consultants with expertise in health care data analytics and innovative methods to generate and use RWE, will discuss issues of interest to attendees, such as the potential use of clinical trial and Food and Drug Administration (FDA)-mandated surveillance data to demonstrate value for payment and coverage

**MODERATOR: Tom Valuck, MD, JD**, Partner, Discern Health

**Maggie Alston**, Senior Healthcare Analytics Consultant, Milliman, Inc.

**David Wierz, PhD**, Senior Principal, The OCI Group, LLC

**Tracy Dodenhoff, MBA, MID**, Vice President, Strategic Development, Archimedic

## » Solving the Addiction Crisis with Devices, and Mobile Health and Digital Therapeutics

**Wednesday, September 15 | 9:45 AM – 11:00 AM**

**Room 157 B**

### BUSINESS STRATEGIES, EMERGING TRENDS

The addiction crisis results in 142,000 preventable deaths in the U.S. annually with an associated cost of \$340 billion. Of the 21.7 million Americans who should have received treatment in 2017, only 2.5 million went to treatment. Approximately 75% of those who do receive treatment, do not complete it. Recidivism rates are about 70%. Managing the supply of illegal drugs historically is not impactful, and the majority of deaths are due to legal access (19,000 annual deaths are due to prescription opioids and 88,000 deaths are due to alcohol.) Addiction represents one of the largest categories of preventable deaths. The panel explores how mobile health and medical devices may have a unique role to both improve access to treatment and avoid unnecessary deaths.

**MODERATOR: Jamie Wolszon**, Vice President, Technology & Regulatory Affairs, AdvaMed

**Christian Haller**, CEO and Founder, LifeLine Medical

**Rebecca Baker**, Director, HEAL (Helping to End Addiction Long-term) Initiative, National Institutes of Health, Office of the Director

**David Curd**, Vice President, Global Clinical Affairs, Avanos Medical

## »» Global Regulatory Convergence — Emerging Trends and Future Opportunities

**Wednesday, September 25 | 10:45 AM – 12:00 PM**

**Room 156 C**

### REGULATORY, QUALITY AND GOOD MANUFACTURING PRACTICES, INTERNATIONAL

The complexity of the global medical device regulatory landscape continues to increase. This session will discuss recent information shared at the September International Medical Devices Regulatory Forum (IMDRF) meeting and will include panelist reflections on these timely updates. Focus will include IMDRF activities and a deep dive look at initiatives designed as building blocks for the development of a Medical Device Single Review Program (MDSRP) to ultimately enable a single regulatory pre-market review to satisfy multiple regulatory jurisdictions.

**MODERATOR: Nicole Taylor Smith**, Vice President, Global Regulatory Policy, Medtronic

**Augusto Geyer**, Deputy General Manager of the Medical Devices Office, National Sanitary Surveillance Agency — ANVISA

**Jeff Shuren, MD, JD**, Director, CDRH

**Melissa Torres**, Associate Director for International Affairs, Center for Devices and Radiological Health, FDA

**John B. Wilkinson, MBA**, Director of Devices, Medicines and Healthcare products Regulatory Agency (MHRA), U.K.

## »» New Diagnostic Technologies Are Transforming Testing

**Wednesday, September 25 | 10:45 AM – 12:00 PM**

**Room 157 A**

### DIAGNOSTICS, EMERGING TRENDS

Emerging and innovative new technologies in diagnostics are advancing at a tremendous pace — transforming how providers and patients manage health. The session will examine and showcase new diagnostic technologies that are creating opportunities for clinical laboratories and physicians to make faster, more accurate diagnoses.

**MODERATOR: Gregory Stutman, MBA**, Director, Global Solutions, IQVIA

**Rahul Dhandu**, Co-founder, CEO & President, Sherlock Biosciences

**Ariel Beery**, CEO, MobileODT

**Ketan Paranjape**, Vice President, Diagnostics Information Solutions, Roche

**Jonathan Romanowsky**, Co-Founder and COO, Inflammatrix

# PANELS AND *Super Sessions*

## *Pillars*

- » Getting to Yes from Regulators to Payers and Beyond — the Decision-Maker Gauntlet
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- » Global Health Innovations
- » Patient Perspectives

## » What Do Hospital Administrators Really Want?

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**Wednesday, September 25 | 11:15 AM – 12:15 PM**

**Room 157 B**

### BUSINESS STRATEGIES, MARKET ACCESS, PAYMENT AND HEALTH CARE DELIVERY ISSUES

Hospital mergers and acquisitions, group purchasing organizations (GPOs), integrated delivery networks (IDNs), accountable care organizations (ACOs) and Value-Added Committees (VACs) are all hospital administrators (HA) whose skill sets are growing in sophistication. The impact on traditional medical device/diagnostic sales and marketing strategies is profound, and keeping up with HA learning curves and expectations can be difficult. What are the most recent trends in HA decision-making processes and how can we integrate those into our own sales, marketing and product development programs? How can medical device companies appeal to the economic buyer and:

- » Create meaningful value propositions for disruptive medtech products?
- » Integrate advances in technology and analytics and leapfrog the competition?
- » Identify buyer segments that will respond to a strong clinical value proposition?
- » Arm a clinical champion with the tools needed to grow HA interest?

**MODERATOR: Maria Shepherd, MBA**, President & CEO, Medi-Vantage

**Shannon Kane**, Director of ACO Analytics, Value Care Alliance

**Susan Martin**, Chief Financial Officer & Vice President, Middlesex Health

**Jeanne O'Brien**, CEO, Value Care Alliance

## *Super Session*

### »»» CDRH Town Hall

**Wednesday, September 25 | 2:15 PM – 4:00 PM**

**Room 156 AB**

### REGULATORY, QUALITY AND GOOD MANUFACTURING PRACTICES

Join us for an exclusive peek into FDA's Center for Devices and Radiological Health (CDRH) during our Wednesday afternoon CDRH Town Hall. This is a rare opportunity to interact directly with Dr. Jeffrey Shuren and other senior office leaders from CDRH. After Dr. Shuren provides an update on CDRH priorities, panelists will answer specific questions from the audience. Take advantage of this session and get answers to all of your burning questions directly from CDRH.

**MODERATOR: Janet Trunzo**, Senior Advisor to the President and Senior Executive Vice President, Technology & Regulatory Affairs, AdvaMed

**William H. Maisel, MD, MPH**, Director, Office of Product Evaluation and Quality and CDRH Chief Medical Officer, U.S. Food and Drug Administration

**Suzanne Schwartz, MD, MBA**, Deputy Director, Office of Strategic Partnerships & Technology Innovation, Center for Devices & Radiological Health, FDA

**Jeff Shuren, MD, JD**, Director, CDRH

**Katie O'Callaghan**, Deputy Director, Office of Strategic Partnerships and Technology Innovation, FDA

**CAPT Raquel Peat, PhD, MPH**, Director of the Office of Health Technology 6 (Office of Orthopedic Devices), Office of Product Evaluation and Quality, FDA



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# CEOs Unplugged

**THE POPULAR CEOs UNPLUGGED SERIES RETURNS WITH SESSIONS FEATURING UNCENSORED COMMENTARY, INSIGHTS AND EXPERTISE FROM TOP MEDTECH INDUSTRY LEADERS AND INFLUENCERS.**

**>> Hall B, 300 Aisle**

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## Improving Lives by Adding to the Quality of Life

**Monday, September 23 | 2:15 PM – 2:45 PM**

While medical technology is often the difference between life and death, it is far more often a decisive factor in determining a patient's quality of life. QOL products deliver healthier, safer and more functional lifestyles and play a critical role in returning patients to contributing active and vibrant lives. These are the products that often allow a neighbor, son/daughter, or parent to resume their valued place as contributors to our society. Frequently challenged to attract investment capital and/or receive favorable reimbursement, these products drive the innovative medical technology industry and are essential to maintain the desired quality of life. This panel will explore the challenges impacting quality of life enhancing products.

**MODERATOR: Bruce Japsen**, Senior Contributor, Forbes  
**Richard Paxman**, Managing Director, Paxman Coolers Limited

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## Culture, Leadership and Perseverance

**Monday, September 23 | 2:55 PM – 3:25 PM**

Culture, leadership and perseverance are just three of the common traits often found amongst the leaders of the medical technology space. What does it take to bring a new product to market? How do you build and sustain a culture of success that can weather the market downturns and other challenges? How do you recruit and retain top talent that will persevere, adapt and overcome unexpected challenges and be committed for the long haul? This panel will discuss these topics in an entertaining interactive and frank manner.

**MODERATOR: Maria Fagan**, President and Co-Founder, Regulatory and Quality Solutions LLC (R&Q)

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## Transformational Innovation: Delivering Outcomes, Fueling the Future

**Tuesday, September 24 | 9:15 AM – 10:00 AM**

With the shift to outcomes-based models and advances in digital technologies, many executives are taking a fresh look at their investment and innovation strategies.

Deloitte's R&D Survey (<https://www2.deloitte.com/insights/us/en/industry/life-sciences/medtech-research-and-development-innovation.html>) found that to build differentiated products, many companies are shifting investments away from core products and line extensions toward transformational innovation: innovation that creates and delivers customer value through novel products, solutions, and business models that address unmet market needs. Companies expect to increase the proportion of R&D budgets they spend on transformational innovation by five percentage points in the next two years.

Hear from CEOs who are leading the charge in transformational innovation. Learn how digital capabilities and the shift to value-based care have fueled their investment and innovation strategies, shifted priorities, and set the stage for the future.

**MODERATOR: Glenn Snyder**, Medtech Segment Leader, Deloitte Consulting LLP

**Lisa Earnhardt**, Executive Vice President, Medical Devices, Abbott

**Antoinette Gawin**, President & Chief Executive Officer, Terumo BCT

**David Pacitti**, President and CEO, Americas, Siemens Healthineers

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## Realizing Organizational and Global Value with Sustainable Business Actions

**Tuesday, September 24 | 10:10 AM – 10:50 AM**

Stakeholder expectations and market demands are increasingly requiring businesses to address community health, climate change and sustainable operations. Strategically aligning environmental and business objectives is critical. Gain an understanding of how top-performing organizations are achieving impactful results for customers, employees, the communities in which they operate and the global environment. Hear from medtech companies who understand the business case for meeting local employee/community needs, environmentally conscious strategies and sustainable manufacturing processes.

**MODERATOR: Greg Crist**, Chief Advocacy Officer and Head of External Affairs, AdvaMed

**Caroll H. Neubauer**, Chairman and Chief Executive Officer, B. Braun Medical Inc.

**Walt Rosebrough**, President and CEO, STERIS Corporation

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## How Data Will Transform Patient Outcomes, Medtech and Practice of Health, Why It Hasn't Happened

**Tuesday, September 24 | 11:00 AM – 11:45 AM**

How can medtech firms take a cue from big tech companies that are tapping data to transform products, capabilities, business models and entire markets? Collected from sources like devices, EMRs and patient surveys, data can provide valuable feedback to improve surgical practice, speed regulatory approval, improve reimbursement and definitively prove value. It can improve medical technology, help patients avoid institutions, reduce medication dependence and improve safety. It can extend medtech's relationship with patients well outside the realm of one-time interventions. This panel will focus on how medtech uses data — the barriers, the success stories and the future to come.

**MODERATOR: Brian Chapman**, Partner and Leader of ZS's Medtech Practice, ZS Associates

**Yvonne Bokelman, MBA, FACHE**, President & General Manager Strategic and Value-based Solutions, Zimmer Biomet

**Richard Loomis**, Chief Informatics Officer, Clinical Solutions, Elsevier

**Cindy Perettie**, CEO, Foundation Medicine

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## Future of Surgery

**Tuesday, September 24 | 11:55 AM – 12:25 PM**

Perhaps no place is technology having a greater impact on health care delivery than in the operating room and in particular in how surgery is performed. From robotics, VR, remote access and other advances in equipment are empowering physicians to be more precise, less invasive and more successful. The companies represented on this panel are having a major impact on surgery and the quality of patients' lives.

**MODERATOR: Monish Rajpal**, Managing Director and Partner, L.E.K. Consulting

**Joseph M. DeVivo**, Chief Executive Officer, InTouch Health

**Namal Nawana**, Chief Executive Officer, Smith & Nephew

**Todd Pope**, President and CEO, TransEnterix, Inc

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## Leadership Views on Diagnostics

**Tuesday, September 24 | 2:15 PM – 2:55 PM**

CEOs of leading diagnostics companies from the AdvaMedDx Board of Directors share perspectives on the opportunities they see for future innovation and growth in the field and the policy and market changes that must be altered or embraced to ensure advancement.

**MODERATOR: Joseph Bernardo**, Operating Partner, Linden Capital Partners

**Ramon Benet, MBA**, Chief Executive Officer, Instrumentation Laboratory (IL)

**Dave Hickey**, President, BD Diagnostic Systems, Becton Dickinson

**Peer Schatz**, CEO, QIAGEN

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## Advancing Inclusion and Diversity

**Tuesday, September 24 | 3:05 PM – 3:45 PM**

CEOs serving on AdvaMed's inclusion and diversity board committee will discuss how inclusive and diverse corporate cultures link to competitive advantages in talent, innovation and investment. They will also discuss how the industry working together to advance inclusion and diversity will be the best outcome to attract and retain top talent as well as serve the evolving needs of the patients who benefit from our life-saving technology.

**MODERATOR: Cathi Rittelmann**, Senior Client Partner, Leadership Development, Diversity & Inclusion Practices, Korn/Ferry

**Mary Anne Heino**, President and CEO, Lantheus Medical Imaging, Inc.

**Martha Shadan**, President & CEO, Miach Orthopaedics and Chairwoman, AdvaMed Accel Board of Directors

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## What's on the Top of Your Mind?

**Wednesday, September 25 | 8:15 AM – 9:00 AM**

Moderated dialogue among respected and experienced executives discussing their current priorities, goals and objectives. This panel will discuss their current business strategies and what are they expecting and planning for in the short and long term. Questions will range from geopolitical affairs, access to capital and capital markets, stakeholder interests, talent recruitment and succession planning and other interesting and commonly shared areas of interest.

# CEOs Unplugged

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## Buyers, Sellers and Facilitators: An M&A Discussion

**Wednesday, September 25 | 9:15 AM – 10:00 AM**

Always timely and relevant, M&A is a fact of life in medtech. Yet again this year, some exciting mergers and acquisitions have impacted our health care delivery landscape. Join us for a lively discussion with a knowledgeable and experienced panel of companies and facilitators on both sides of the deal. This discussion will include trends in valuation, deal structure, and other interesting discussion points.

**MODERATOR: Keith A. Pagnani**, Partner, Sullivan & Cromwell

**Carin Fradin**, Managing Director, JMP Securities

**Dev Kurdikar**, Former President and Chief Executive Officer, Cardiac Science Corporation, now part of ZOLL Medical

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## Massachusetts — The Who, What and Why of This Medtech Miracle Metropolis

**Wednesday, September 25 | 10:10 AM – 10:50 AM**

Massachusetts is home to the world's largest concentration of medical technology innovation. The products of more than 420 medical technology companies in close proximity to each other, medical devices are the number 1 export from Massachusetts as a percentage of the state's total exports (21% of Massachusetts total exports). Only California has more medical technology companies, employment, 510(k) approvals, venture capital, medical device patents or PMA approvals, and yet Massachusetts is 20 times smaller and has less than 1/6th the population of California. Mighty Massachusetts produces 15% of the total U.S. medical device exports while comprising only 1/4 of 1% of the total U.S. land mass and 2% of its total population. Why is there such a heavy concentration of medical technology companies in and around Massachusetts? It may be the proximity to research hospitals like Mass General, Brigham & Women's, Harvard Medical School, Boston Children's, UMass, Tufts, Dana-Farber, as well as access to investors, top human capital/talent, the long history of commercial success or the abundance of experienced consultants and service providers. Join us for a lively discussion about our dynamic and unique host city, state and region.

**Randall S. Barko**, Executive Director, Ximedica

**Marie O'Malley**, Senior Director, Supplier Outreach, Medtronic

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## Insights from Executives Navigating High Growth Companies

**Wednesday, September 25 | 11:00 AM – 11:30 AM**

AdvaMed's CEOs Unplugged Stage often features executives from the largest companies in the industry. While their experiences and insights are extremely valuable, it's also critically important to hear from executives running companies that might not yet be global, may not include multiple products and may not include easy access to capital and markets. High growth companies have their own set of challenges, and we expect this session to be of particular interest to early and mid-stage growth companies.

**MODERATOR: Pat Shafer**, Managing Director — Regulatory Risk and Quality Effectiveness, Grant Thornton LLP

**Tracy MacNeal**, President and CEO, Materna Medical

**Todd Usen**, Chief Executive Officer, Activ Surgical

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## Lessons from a Legend

**Wednesday, September 25 | 11:35 AM – 12:20 PM**

The recipient of this year's Lifetime Achievement Award had a long and distinguished career and made a significant impact on our industry and health care in general. Join her and several of her protégés for an hour-long fireside chat about the making of a truly legendary career and the lessons learned from it.

**MODERATOR: Larry Ferrere**, Senior Director, Strategy & Marketing, IQVIA MedTech

**Cathy Burzik**, 2019 Lifetime Achievement Award Winner

**Vince Forlenza**, Chairman of the Board and Chief Executive Officer, BD

**Todd Fruchterman, MD, PhD**, President and General Manager, 3M Health Care Business Group, Medical Solutions Division

**Chris Simon**, President and Chief Executive Officer, Haemonetics



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[val.kratzman@businessfinland.fi](mailto:val.kratzman@businessfinland.fi)

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**>> Hall B, 500 Aisle**

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## **Bridging Commercial and Military Market Needs to Advance Medical Device Development**

**Tuesday, September 24 | 9:25 AM – 9:55 AM**

In any economy, R&D executives must maximize their resources in order to advance next-generation medical technologies and product lines. The U.S. Department of Defense (DoD) annually funds development of specialized medical technologies to meet specific military needs in particular use environments. These programs can provide medical device manufacturers non-dilutive resources to advance technologies that are planned or already in development, or that may be too expensive or too risky to self-fund. However, many companies do not take advantage of these opportunities because they perceive the government contracting process as daunting and resource-intensive, believe the military market is limited, and are unsure how to leverage these efforts into products for the civilian market to ensure productive revenue streams. This session will explore a business model that successfully bridges industry's need to develop commercially viable devices and desire to achieve this using augmented resources, with the DoD's need for dependable sources of innovative, military-ready medical technology.

**MODERATOR: Joe Berger, MBA**, Senior Vice President,  
Commercial Business, Battelle

**Jason Opdyke, PhD**, Joint Product Lead, Department of  
Defense; Joint Program Executive Office for Chemical  
Biological and Nuclear Defense

**Joseph Turk**, EVP, Fresenius Medical Care North America

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## **Connected Ecosystems for Smarter Decisions**

**Tuesday, September 24 | 10:30 AM – 11:00 AM**

The emergence of the Internet of Things (IoT) — where physical devices are instrumented to capture and transmit data covering everything from environmental conditions to usage patterns and user behaviors — is arguably the next wave of digital advancement. The “things” in IoT can refer to a wide variety of devices such as subcutaneous drug delivery units, continuous glucose monitors and vitals monitoring equipment. The expanded sensing and communication capabilities of these “things” is a harbinger of new business possibilities. Not surprisingly, IoT is making inroads in the medical devices industry. Medical devices and diagnostic companies are transforming themselves from not only devices/consumables providers but also disease/care management organizations to achieve better health outcomes. In the hospital, manufacturers are connecting devices to enable health care professionals to make the smarter decisions on care delivery and treatments. And with increasing outpatient and at-home treatment, connected devices enable remote patient monitoring to ensure safety, accuracy and timeliness of treatment.

IoT promises to transform how medical device companies operate — from product design and development, to manufacturing, sales, performance monitoring and service. The IoT's global network of sensors and touchpoints is already raising the bar across health care — allowing device manufacturers, labs, health care providers and patients to reap more benefits from the increasingly digital, closely connected and highly competitive medical device market.

This session will explore the latest on IoT and connected devices and how to realize the three key benefits of a differentiated user experience, streamlined operations and lower cost and instant feedback.



**MODERATOR: Vidya Viswanathan, MBA**, Digital Solution Architect, Digital Therapeutics Product Owner, Cognizant

**Arnaub Chatterjee**, Senior Vice President, Product and Ecosystem, Acorn AI, Medidata Solutions

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## When Data-Driven Training, Marketing and Sales Came Together to Turn a Product Around: A Powerful Case Study

**Tuesday, September 24 | 11:15 AM – 11:45 AM**

How does a global medical device company go from having a product underperform for two years to exceeding sales results in back-to-back quarters in just 3 months? Come learn about how Teleflex consolidated three systems into one and digitally transformed their field teams to engage legacy reps, implement a new sales methodology and gather field learning data that drove commercial outcomes.

**MODERATOR: Kapil Kalra**, Chief Customer Officer, ACTO

**Jacqueline Cronin**, Senior Marketing/Training Manager, Teleflex Incorporated

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## Everyone Knows Health Care Is DOJ's Favorite Target; What Does That Mean for MedTech Executives?

**Tuesday, September 24 | 11:55 AM – 12:25 PM**

Unfortunately, it's become abundantly clear that health care has become DOJ's favorite target. Recent policy pronouncements and enforcement trends indicate an important shift to the ways in which companies, their management, and their board members need to handle investigations and compliance. This panel will explore very recent DOJ enforcement rulings, trends and policy pronouncements with the goal of providing valuable take-away lessons/information that addresses best practices for companies, executives and board member intent on avoiding, if not surviving, a DOJ investigation.

**MODERATOR: Ralph J. Caccia**, Partner, Wiley Rein LLP

**Chris White, Esq.**, Chief Operating Officer, General Counsel and Secretary, AdvaMed

**Daniel Gerhan**, Chief Litigation Officer, Employment & Civil Litigation/Investigations, Boston Scientific

**Blaine Dart**, Vice President, Global Trade Compliance & Risk Management, Zimmer Biomet

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## Emerging Issues Regarding the HCPCS Coding Process for Medical Devices

**Tuesday, September 24 | 2:10 PM – 2:50 PM**

In the midst of first-of-its kind litigation challenging a Health Care Common Procedure Coding System (HCPCS) coding decision, the Centers for Medicare & Medicaid Services (CMS) recently announced a number of changes to the coding process for 2019. This session will address these changes, the litigation and the implications of these recent developments for companies.

**MODERATOR: Stephanie Webster**, Partner, Akin Gump Strauss Hauer & Feld LLP

**DeChane Dorsey**, VP Payment and Health Care Delivery Policy, AdvaMed

**William Scheinler**, Chief Legal and Compliance Officer and Secretary, Alcresta Therapeutics, Inc.

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## Innovation, Regulation and Adaptation: Emerging Legal Issues in Digital Health

**Wednesday, September 25 | 8:15 AM – 8:45 AM**

Digital health — the convergence of digital and health care technologies to promote efficient health care and personalized medical treatment — is everywhere. Assistive technologies like robotics enable surgeons to perform less invasive surgeries while reducing the risk of human error; the same technologies also permit people with disabilities to live more independent lives. Virtual reality and video games supply new forms of patient rehabilitation and education. Artificial intelligence, other computational simulations and modeling aid decisions by clinicians, and the prospect of “precision medicine” — unique care designed for one individual — is on the horizon. Mobile health and telemedicine are making the provision of care more efficient and are increasing the availability of care to limited mobility patients or those in remote locales.

As these advancements and breakthroughs continue to be adopted, the companies that make them possible will be subject to significant and evolving legal issues. The goal of this session will be to review the most current and pressing of those issues, including, without limitation:

- » How the existing regulatory framework, from FDA and other governmental actors, will govern digital health technologies

# MEDTECH *Exec Talks*

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- » The legal risks to digital health companies and the ways that courts are adapting with traditional defenses and doctrines

The purpose of the session will be to alert stakeholder companies to the issues they need to address now in order to avoid legal threats later.

**Daniel Smulian, JD**, Shareholder, Greenberg Traurig, LLP

**Kate Black**, Shareholder, Data, Privacy & Cybersecurity Group, Greenberg Traurig, LLP

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## Beyond Silos: Fusing Digital Across the Enterprise

**Wednesday, September 25 | 9:00 AM – 9:30 AM**

Medical device and diagnostics companies are actively embracing digital initiatives to address evolving provider and consumer demand for convenience and outcomes validation. However, most digital initiatives are consumer/customer or “front office” facing with “back office” functions operating in more traditional forms. This dichotomy of a digital front office and traditional back office presents operational and financial risk as well as consumer/customer disappointment. While clinical differentiation is essential, commercial success will increasingly depend on a manufacturer’s ability to create a cohesive and fused approach to digital transformation.

Recently, commission research by Cognizant, along with a survey of over 500 business and technology decision makers in the U.S. and U.K., revealed significant benefits for companies that can seamlessly connect front- and back-office processes. Digital transformation is not about pilots or commercial launch of discrete apps, but transforming the enterprise to support agile management decision making to consumer/customer demands for visibility, reliability and satisfaction. Cognizant research found:

- » Digital transformation maturity is driven by four key areas: process, organization, technology, and data insights
- » Less than 40% of companies have aligned internal teams to put the customer at the forefront of their activities

- » Back-end process teams (e.g., supply chain, finance) are the least likely to have a decision-making role in digital transformation

However, companies with higher digital maturity are 2.5 times more likely to report double-digit revenue growth.

This session will share the findings of the research along with case studies and practical steps companies can take.

**Brian Williams**, Vice President, Chief Digital Officer & Global Life Sciences Consulting Leader, Cognizant

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## Digital Transformation of the Medical Technology Market – The Disruptor or Enabler?

**Wednesday, September 25 | 9:45 AM – 10:15 AM**

The four main pillars of digital transformation of the medical technology industry are internal operations digitization, care delivery digitization, connected devices and connected patients. The key questions this presentation would answer:

- » What are the future trends of digital transformation in the industry?
- » What role can digital technology play in the ongoing transformation of the medtech industry?
- » What are the key growth opportunities in each area of transformation for the medtech industry?
- » What are the predictions for the digital ecosystem in the medtech industry in 2020?

**Sowmya Rajagopalan**, Global Program Director, Frost & Sullivan

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## Strengthening FDA's 510(k) Third Party Review Program: Streamlining the Process, Maximizing Patient Benefit

Wednesday, September 25 | 10:30 AM – 11:00 AM

FDA is taking steps to make it flexible and efficient for developers of lower-risk devices to get their products to market swiftly. To accomplish this, FDA sees the 510(k) Third Party Review Program playing a crucial role. FDA is enhancing the program with the goal of obtaining FDA-equivalent review results from third party review organizations while reducing the amount of time FDA spends re-reviewing applications that have already been reviewed by third party organizations. This frees FDA resources to focus on those higher-risk devices that require more rigorous review. In the first year of MDUFA IV, FDA has already made considerable headway to strengthen the program, including sharing a plan to enhance the program, releasing a draft guidance, developing training for third party reviewers and undertaking process improvement activities. In this session, FDA will take a deep dive into the progress made to strengthen the program. Strengthening the 510(k) Third Party Review Program will make the third party review process what it was meant to be: a means of streamlining the regulatory process while maximizing patient benefit. FDA believes this approach will lessen burden on 510(k) applicants and FDA reviewers while ensuring that medical devices continue to meet high standards for safety and effectiveness.

**Gregory Pishko, PhD**, Third Party Team Lead, Acting Supervisor Third Party Policy and Operations, CDRH, FDA

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## The Changing Payer/Provider Landscape: Opportunities for Medtech

Wednesday, September 25 | 11:15 AM – 11:45 AM

Transitioning to value based care models poses transformational and financial challenges for the medtech industry. One of the biggest shifts companies have to address is the development of relationships and creation of partnerships among the providers, health plans and life sciences companies. The session will address issues such as program structure, financial considerations, reporting and patient engagement in the context of developing these partnerships. Additionally, the session will discuss how, when done well, collaboration between these three parties can lead to a patient experience that is a competitive and strategic differentiator.

Participants in this session will hear presenters discuss:

- » The value based care “triangle” and inter-connections of payers, providers and life sciences companies
- » Examples of value created from medical device and diagnostics partnerships
- » Best practices in implementing value based care processes

**MODERATOR: David Gregory, MPA, FACHE**, Principal and Healthcare/Life Sciences Consulting Leader, Baker Tilly

**Alan Lieber**, Vice President, Atlantic Health System

**Carlotta Rinke, MD, FACP, MBA**, Sr. Medical Director, Accountable Care Solutions



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» Hall B, 200 Aisle

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## Preparing for Medical Device Cybersecurity in 2020

**Tuesday, September 24 | 10:00 AM – 10:20 AM**

Over the last decade, technology has played a central role in advancing quality of care, creating new delivery mediums and changing access for patients, in large part due to the development of new medical devices. Device cybersecurity is a shared responsibility between device vendors, HDOs and others. Recent medical device regulatory guidance confirms the need to prepare for anticipated changes. This session will explore the evolution of cybersecurity as a HIPAA compliance mitigation into a patient safety enabler. It will delve into cybersecurity processes and functions that are expected to be performed and tools available to support.

**medcrypt** Mike Kijewski, CEO, MedCrypt

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## From Data to Data Science

**Tuesday, September 24 | 10:30 AM – 10:50 AM**

Data generated from devices is becoming more useful for device manufacturers, patients and healthcare providers. At the same time, the deluge of data and the associated security and compliance requirements are daunting challenges. In this session, we will discuss how Virtusa assists medical device companies to capture this data, manage security and compliance, provide interoperability with EMR or claims systems and generate valuable insights. In addition, we would like to demonstrate how AI and ML models can provide predictive models for reliability of devices or instruments or forecasting sales and targeting geographies.

Virtusa has created a data and innovation platform for our customers where, in a secure sandbox, we collaborate on device data model development, predictive analytics and visualizations.

**Santanu Sen**, VP Life Sciences, Virtusa

**virtusa** Manu Swami, Vice President – Data, AI & Analytics, Virtusa

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## Device Connectivity Platform as a Service: Build vs. Buy, Accelerate Time to Market

**Tuesday, September 24 | 11:30 AM – 11:50 AM**

Medical device connectivity: OEMs have different strategies to build their connected platform for their device. Some of the OEMs are currently building their platforms utilizing key components from partners such as PTC (Thingworx) or Microsoft, while some OEMs are building the whole platform grounds up. Another interesting trend is certain medical OEMs offering their connected platform as a service for other medical device companies, which helps speed up go-to-market strategy. The idea of the discussion is to analyze and debate the pros and cons of such strategies.



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**Krishna Padmanabhan**, AVP & Territory

Head – Medical, L&T Technology Services Limited

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## Evolving Commercial Models in the New Health Care Ecosystem

**Wednesday, September 25 | 10:00 AM – 10:20 AM**

With the industry changing rapidly, it isn't about the device, prescription or IT system. It's about the health care ecosystem focusing on improving patient outcomes while reducing costs. The health care industry is now a seller-beware world of super-informed, highly connected and data-driven buyers. From precision medicine, connected platforms and apps to artificial intelligence, data and media, the future of health care is transforming,



and commercial strategies must evolve to keep up. Join us for an in-depth look at top trends and key commercial strategies for managing these new types of buyers. We will be looking at the three drivers of change impacting commercial models: innovative technologies, changing job market and new buyer expectations. Audience takeaways include practical insights that can be applied within your own organization, frameworks and tools to uncover potential opportunities and gaps in your commercial model, and highlights from the latest research on commercial strategy and industry trends.



**Craig Ackerman**, Principal, The Alexander Group

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## Essentials of Regulatory Digital Transformations

**Wednesday, September 25 | 10:30 AM – 10:50 AM**

The increasing scope, complexity, and integration needs of global regulatory requirements are placing new demands on regulatory leaders and organizations. Regulatory data, processes and systems are straining to evolve to meet these demands. Yet the digital transformation occurring in other areas has been relatively slow to take hold in regulatory. Companies that are able to initiate and advance regulatory data digital strategies will enjoy significant advantages not only in compliance, but also in efficiency and growth.

Business partners don't always understand the importance of the regulatory function in driving growth for medical device firms: it's not just about compliance, it's also about enabling growth, quality and efficiency. Regulatory leaders understand that a strategic approach can yield both compliance and reduced time-to-market, quality improvements in post-commercial market surveillance and cost efficiency for the regulatory function. Yet the fragmented nature of regulatory data and systems does not lend itself to driving these outcomes.

In this session we will discuss how to create, articulate, "market" to senior leadership, and execute a regulatory data digital strategy that will unlock the power of full life-cycle, end-to-end data to meet emerging regulatory market needs and enable organizations to be more strategic and high-performing.



**Christopher Knerr**, Chief Executive Officer,  
Mareana

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## Mitigating Human Factors Risk

**Wednesday, September 25 | 11:00 AM – 11:20 AM**

Human Factor Risk is as crucial as clinical and cybersecurity risks. By not mitigating all risk, there remains a chance that the safety of patients, doctors, nurses and technicians can be jeopardized. All of the time and effort making sure a device works as intended could be lost if the device is not used as intended.

Typically, improper use of a device is neither malicious nor is it intended. Improper use can stem from a device not being intuitive, being unpleasant to use, or being bothersome, among other contributing factors. The lack of user adoption is one negative outcome from this situation. If the device is the only option for the task at hand, and non-use is not an option, a user may look for an easier way to use the device than what has been prescribed; a "hack around." The result? Human Factors Risk is substantially increased.

The focus needs to shift away from what a developer wants a technology to do and toward what the user and the patient need it to do.

During this session learn what technical solutions are available to help implement a UX (User Experience)-centric design process to develop the most user adoptable medtech product.



**Roger Mazzella**, Senior Product Manager, The Qt Company

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## Phase Zero: How to Be Resource-Efficient with New Product Opportunities

**Wednesday, September 25 | 11:30 AM – 11:50 AM**

New products can change the outlook for companies and the right product can create a new market segment. But even in the regulated device space, a comprehensive development process can be too burdensome for many early opportunities. Learn how to identify the need for a Phase Zero effort, rationalize the approach to collaborators and scope the necessary activities. Scott Thielman will share how a design firm thinks about targeted projects to reduce risk in the domains of technical functionality and product vision.



**Scott C. Thielman, PhD**, Chief Technology Officer,  
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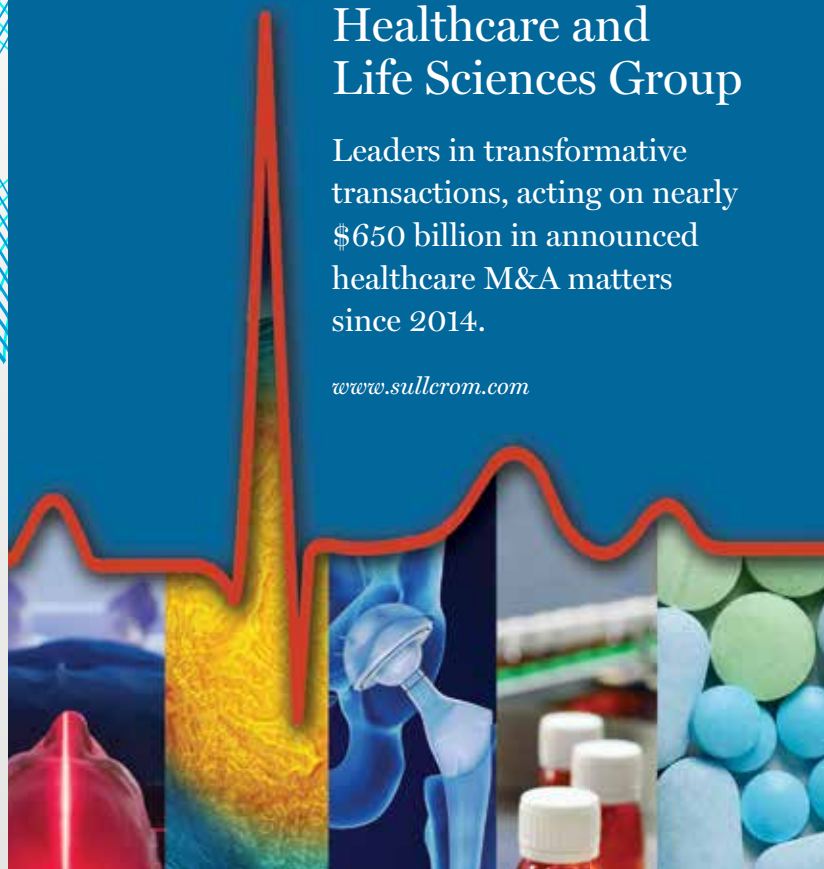
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➤ Exhibit Hall B, Booth 441

## INNOVATION PAVILION Participants



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#### Investor Trends in Medtech

**Tuesday, September 24 | 9:45 AM – 10:15 AM**

The number of innovations taking place at the intersection of medical devices and technology is growing at a rapid pace. Join JJDC's Kadir Kadhiresan and MedTech Strategist's David Cassak for a discussion on medtech trends and investment considerations in technologies leveraging AI, data science, virtualization and robotics.

**David Cassak**, Co-Editor-in-Chief and Managing Partner, MedTech Strategist

**Kadir Kadhiresan**, VP Venture Investments MD&D, JJDC

#### Successful Elevator Pitches and Investor Interactions

**Tuesday, September 24 | 11:15 AM – 11:45 AM**

It can be tricky to communicate the full potential of your discoveries without spilling the secret sauce. Join us for an in-depth panel on navigating relations with investors. In this panel, experts of the craft will share practical tips on becoming more effective in communicating your story to angel investors and VCs, increasing your chances of successful fundraising, expertise and call upon our key technology partners to provide unique insights on consumer, payer and provider pain points and the solutions they are seeking.

**Ajay Khatri**, Director, Venture Investments, JJDC

**Michal Preminger**, Head, Johnson & Johnson Innovation ENA

**Darshana Zaveri**, Managing Partner, Catalyst Health Ventures



## Perfecting Partnership

Tuesday, September 24 | 2:15 PM – 2:45 PM

When building a medtech company, investments and partnerships are a key element to your startup success. In today's ever-changing regulatory and financing environment, it is becoming increasingly important to engage early in the process. How can you adapt your business strategy to ensure you're setting your company up for fruitful partnerships? How are investors adapting their financing strategies and business models to accommodate new realities and positioning themselves for long-term success? Join a panel of medtech investors and business development professionals as they discuss their approaches to partnering in medtech.

**Ibraheem Badejo**, Sr. Director Scout/New Venture, Johnson & Johnson Innovation

**Kadir Kadhiresan**, VP Venture Investments MD&D, JJDC

**Jennifer Kozak**, VP New Business Development Med Device, Johnson & Johnson

**Nick Pachuda**, Global Vice President, External Innovation and Enabling Technologies, Johnson & Johnson

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» **VIVAQUANT**

**Presentations will be held on Tuesday, September 24, 10:30 AM – 11:00 AM and 3:00 PM – 3:30 PM.**

# ACADEMIC/ *Technology Transfer*

## Best Practices for Optimizing Relationships Between Medical Device Companies and Academic Institutions

Wednesday, September 25 | 10:00 AM – 11:30 AM  
Room 153 C

This session will continue efforts to cultivate the relationships formed from the AdvaMed Accel University Technology Transfer Initiative and the University Technology Transfer Best Practices Guide, which was launched in February 2019. This 90-minute program provides an excellent opportunity for academic and industry members to connect and build relationships within the medical technology industry. Participating academic representatives and industry executives will

have an opportunity to meet and engage with each other around available technologies and share insight on items to consider when engaging companies. A meetup will immediately follow the panel discussion.

**MODERATOR: Vinit Nijhawan**, Interim Executive Director, The Massachusetts Technology Transfer Center

**Eric Agdeppa**, Executive Director, Innovation and General Manager, Hill-Rom

**Daniel Castro**, Managing Director, Licensing at Partners HealthCare Innovation

**Heather Walsh**, Director, External Innovation, Baxter International

Thank you to **HOYA** for supporting The MedTech Conference's academic program and activities.

# PATIENT Pavilion

Sponsored by  **ABIOMED**  **BD**  **Edwards**

» Exhibit Hall B, Booth 128

See new and innovative products on display and hear dramatic stories from patients and senior medtech executives.

## PARTICIPATING Companies

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DIAGNOSTICS, DEVICES AND DIGITAL HEALTH

## Presentation Schedule:

### MONDAY, SEPTEMBER 23

2:30 PM – 2:45 PM Abiomed  
3:00 PM – 3:30 PM Edwards Lifesciences  
5:15 PM – 5:30 PM TBC  
5:45 PM – 6:00 PM TBC

### TUESDAY, SEPTEMBER 24

9:30 AM – 9:45 AM Insulet  
10:00 AM – 10:15 AM Medtronic  
10:30 AM – 10:45 AM Olympus  
11:30 AM – 11:45 AM Johnson & Johnson  
12:00 PM – 12:15 PM RTI Surgical  
  
2:30 PM – 2:45 PM B. Braun Medical Inc.  
3:00 PM – 3:15 PM Stryker  
3:30 PM – 3:45 PM Paxman Scalp Cooling  
5:30 PM – 5:45 PM TBC

### WEDNESDAY, SEPTEMBER 25

8:30 AM – 8:45 AM TBC  
9:30 AM – 9:45 AM TBC  
10:30 AM – 10:45 AM Zimmer Biomet  
11:30 AM – 11:45 AM TBC



Download the AdvaMed Events app for an up-to-date schedule of events. Just search for “AdvaMed Events” in the App Store or Google Play.





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# MEDTECH *Meetups*

## EMERGING LEADERS MEETUP

**Monday, September 23 | 1:15 PM – 2:00 PM**

**Boston Convention & Exhibition Center, East Registration**

Connect with fellow rising MedTech professionals at the MedTech Emerging Leaders Meetup, an opportunity to share experiences and exchange ideas with peers about leadership in the industry. Hear from a prominent voice in the MedTech industry about defining moments on their journey into leadership.

## GLOBAL HEALTH MEETUP

**Monday, September 23 | 2:45 PM – 3:15 PM**

**Boston Convention & Exhibition Center, East Registration**

Network with your peers engaged in global health initiatives and hear from leaders at Duke University's Global Health Innovation Center (GHIC). GHIC is spearheading a comprehensive study funded by the Bill & Melinda Gates Foundation focused on the challenges and opportunities associated with technology development, launch, and scale-up for under-resourced populations. Preliminary findings will be shared.

## GPOs MEETUP

**Tuesday, September 24 | 10:30 AM – 12:30 PM**

**Boston Convention & Exhibition Center, East Registration**

Join us for a meet and greet with Group Purchasing Organization (GPO) contracting, diversity and innovation program leaders, including representatives from Premier, Vizient, 410 Medical, Access Scientific, and Intelere! Meet supply chain leaders who have been working with medtech innovators and learn about how your company can work with a GPO.

## DIGITAL AND CONNECTED HEALTH MEETUP

**Wednesday, September 25 | 11:30 AM – 12:00 PM**

**Boston Convention & Exhibition Center, East Registration**

Join your peers engaged in digital and connected health for this exciting networking opportunity. The event will kick off with brief remarks from AdvaMed and MHealth Israel. Come meet the Israeli delegation and many other highly advanced digital health companies and entrepreneurs.







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For medical device and diagnostic companies, the digital revolution offers a powerful prescription for transforming the healthcare continuum from enhancing the customer experience to improving the connected health ecosystem and coordination of care.

At Cognizant, we partner with leading medtech companies to help drive better health outcomes by:

- **Transforming the customer experience** by combining human science, design thinking, user experience and technology to bring consumer insights.
- **Connecting the health ecosystem** to better coordinate care across the patient journey to provide a seamless customer experience.
- **Empowering patients with data-driven processes, platforms and intelligent devices** to facilitate engagement and decision-making.

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# SPECIAL Programs

\*Separate registration required



## 7th Annual Pediatric Device Innovation Symposium\*

**Sunday, September 22 | 8:00 AM – 5:00 PM**

**Room 052**

### Pediatric Device Clinical Trials — Forging a Better Path

Join stakeholders from the industry, government, academia and patient groups for the nation's leading pediatric innovation symposium where we will focus on unique challenges and opportunities related to pediatric device trials. Now in its seventh year, the one-day symposium, hosted by Children's National Health System, brings together key leaders in the device space to stimulate pediatric device innovation and bring solutions to market faster for the benefit of children everywhere. Another highlight is the \$200K "Make Your Medical Device Pitch for Kids" competition. It's a results-driven day that attendees at The MedTech Conference won't want to miss.

» Learn more at [pediatric-device-symposium.org](http://pediatric-device-symposium.org).

## AdvaMed Events

### U.S. Market Access Seminar

**Sunday, September 22 | 12:30 PM – 5:00 PM**

**Room 156 C**

The U.S. Market Access Seminar is a pre-program for international delegates attending The MedTech Conference. It will address key issues for non-U.S. medtech companies seeking to launch products in the U.S. market. Instructors will cover regulatory and reimbursement pathways, as well as perspectives about the changing landscapes in each of these areas in the U.S.

Sponsored by  **McDermott  
Will & Emery**

### Pediatric Devices: Update on a Framework for Pediatric Innovation

**Monday, September 23 | 9:30 AM – 11:00 AM**

**Room 153 B**

Key pediatric device stakeholders including the FDA, device industry CEOs, industry trade groups, and clinicians and representatives from the FDA-sponsored Pediatric Device Consortia will provide an update on a proposed ecosystem to facilitate the development and approval of pediatric medical devices. Join this important session to share your ideas and perspectives and to help brainstorm on the key attributes that will be required to develop a successful innovation framework.

## AdvaMed Event



### AdvaMed Accel and MedTech Innovator Partnering Forum

**Monday, September 23 | 2:00 PM – 4:00 PM**

*(invite-only)*

This forum will gather a limited group of start-ups, small and mid-size companies for presentations and networking with investors, strategists, accelerators and incubators, and other funders and subject matter experts.



### Medtech Insight Awards\*

**Monday, September 23 | 6:00 PM – 10:00 PM**

**State Room, 60 State Street, Boston, MA 02190**

Held in partnership with and during The MedTech Conference in Boston, the Medtech Insight Awards will honor and applaud those who, through their passion and unwavering commitment, are driven to cure, inform, minimize treatment burden, and make human lives better. Categories recognize achievements across the device and diagnostics industries, from technological innovations and partnerships, to emerging markets, to the more personal accomplishments of teams and individuals.

» For more information, please visit [pharmaintelligence.informa.com/events/awards/medtech-insight-awards-2019](http://pharmaintelligence.informa.com/events/awards/medtech-insight-awards-2019).

### One Year In: What We've Learned from Creating 100s of MEDDEV 2.7/1 Rev. 4 and EU MDR Compliant CERs (It's Harder Than You Think)

**Wednesday, September 25 | 8:45 AM – 9:45 AM**

**Room 052**

It's now September 2019 and MEDDEV 2.7/1 Rev. 4 is mandatory and EU MDR is right around the corner. Notified bodies are scrutinizing clinical data more than ever and giving companies significant findings for their CERs and, in some cases, refusing to certify products with gaps in clinical evidence, incomplete PMCF, and poorly written CERs. Attendees will come away with an understanding of the latest developments in CERs based on real-life stories. These are case studies you'll want to hear.

This session will feature medical device manufacturers and device consultants who have created Rev. 4 and MDR compliant CERs for products in a wide range of clinical specialties — being submitted to a variety of notified bodies. Our panel has seen it

# SPECIAL Programs

*\*Separate registration required*

all and will share the most impactful lessons learned from every aspect of the CER process.

Our speakers have encountered plenty of obstacles...and found solutions. In this session, learn how other manufacturers and experts have addressed closing their CER gaps and achieving compliance. Attendees can take these lessons back to your companies to gather the support needed to get your CERs ready.

Industry leaders will discuss lessons learned and case studies featuring a multitude of challenges. For example:

- » What is the difference between a Rev. 4 and MDR compliant CER?
- » Notified bodies will review your submission as if it is the first time; what does that mean?
- » What are your options if you have a low-risk device with no clinical data?
- » How are notified bodies reviewing CERs? What questions are they asking and what are they looking for in the clinical data?
- » When do you need to propose pro-active PMS or PMCF?

**Ibim Tariah, PhD, BSI**

**Jon Gimbel, PhD, R&Q**

**Joe Sapiente, Hologic (invited)**

## Clarifying Impact: Determining and Driving Quality and Technical Documentation Compliance

**Wednesday, September 25 | 10:00 AM - 11:00 AM**

**Room 052**

**Pat Shafer**, Managing Director — Regulatory Risk and Quality Effectiveness, Grant Thornton

**Martin E. Zuzulo**, Director — Compliance Risk, Health Care/ Life Sciences, Grant Thornton

## MDR Readiness Seven Months from Date of Application

**Wednesday, September 25 | 11:15 AM - 12:15 PM**

**Room 052**

26 May 2020, the date of application of the Medical Devices Regulation (MDR), is seven months away at the date of this seminar. Yet, the MDR regulatory system is still not finished as implementing acts, harmonized standards and guidance have not been issued, essential infrastructure is still not on line (Eudamed) and conformity assessment capacity (notified bodies) is lacking. Industry and even several non-EU countries are more and more concerned about what the effect will be on the EU medical devices market. And then there is Brexit, to complicate matters even more.

This hands-on practical workshop will take stock of where we are with the roll-out of the MDR, what we know and what we do not know yet, what to expect and how to develop scenarios for the coming months that may make the difference between staying on the market or seeing cash flow collapse. Topics include the state of play of EU level implementation, the economic operator regime and its influence on the company's supply chain as well as what medical devices companies still can do and should be doing in light of the 26 May 2020 date of application in order to minimize disruption of market access.

**Erik Vollebregt**, Partner, Axon Lawyers

## ICPD's Scientist Mentoring & Diversity Program

In conjunction with The MedTech Conference 2019, AdvaMed member companies will sponsor a training session for the Scientist Mentoring & Diversity Program for Medical Technology (SMDP MedTech), September 21–25, 2019, in Boston, MA. The year-long mentoring program benefits baccalaureate and graduate students from racial and ethnic groups underrepresented in the medtech industry, including Hispanic Americans, Pacific Islanders, African Americans and Native Americans. Attending students are interested in careers in the medical technology industry. Scholars are paired with industry mentors who are executives at medical device, medical technology and consumer health care companies. Scholars learn about career opportunities in industry and receive career development coaching and also attend The MedTech Conference.

- » **For more information about SMDP MedTech, please contact Scott May at [smay@icpdprograms.org](mailto:smay@icpdprograms.org) or visit [icpdprograms.org](http://icpdprograms.org).**



MVPvets will convene industry mentors for an intensive workshop focused on critical recareering topics and networking opportunities at the conference. The mission of MVPvets is to assist, and prepare, transitioning military veterans for meaningful employment in life science companies. With new health applications, and innovative consumer products being discovered and created daily, opportunities to support the science, technology, engineering, mathematics or business functions of life science organizations are vast. MVPvets brings veterans, mentors and employers together, through job matching, one-on-one mentoring, online learning and on-the-ground career-building endeavors.

- » **For more information, please visit [mvpvets.org](http://mvpvets.org).**



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# AdvaMed Accel Leadership SEMINAR & LUNCH

**Monday, September 23, 2019 | 8:00 AM – 1:00 PM**

**Boston Convention & Exhibition Center, Room 052**

Seminar Sponsor




Lunch Sponsor



The AdvaMed Accel Leadership Seminar provides insights to early and emerging-growth medical technology company executives as they bring innovations to market. Leading medtech CEOs share lessons on managing innovation and preparing businesses for long-term growth and commercialization. The program also features a preview of the MedTech Innovator competition, with start-up companies vying for the audience vote, and the Virginia Shimer Rybski Memorial Award, presented to the winning company during a networking lunch.

7:30 AM	<b>Registration and Coffee</b>
8:00 AM	<b>Welcome Remarks</b> <b>Martha Shadan</b> , President and CEO, Miach Orthopaedics & Chairwoman, AdvaMed Accel Board of Directors
8:15 AM	<b>De-Risking MedTech Innovation by Investing in the Process Before the Product</b> <p>Too many medtech start-ups fail due to a lack of seed or bridge funding, which results in fewer devices with high value potential entering clinical care and saving lives. Before investing in the product, innovators and the companies and investors that support them need to invest in a capital efficient development process and the people to drive it. During this session, attendees will learn from a panel of experienced company executives and advisors, who will discuss elements of medtech design and development models that de-risk medtech innovation to fail fast and help ensure investments are made in products with a higher likelihood of successful, capital efficient commercialization. Through an interactive audience discussion, panelists will also share their knowledge of successful commercialization approaches.</p> <p><b>MODERATOR: Paul Snyder</b>, Vice President Healthcare, Write2Market  <b>Benjamin Glenn</b>, Partner, Shay Glenn LLP  <b>Dev Kurdikar</b>, Former President and Chief Executive Officer, Cardiac Science Corporation, now part of ZOLL Medical  <b>Shar Matin</b>, Chief Operating Officer, ViewRay, Inc.  <b>Tiffany Wilson</b>, CEO, Global Center for MedTech Innovation (GCMI)</p>
9:15 AM	<b>Networking Break</b>

9:30 AM	<p><b>Integrating Health Economics and Outcome Research into the Product Development Cycle</b></p> <p>The probability of reimbursement is a key factor in determining whether to proceed with a product during its development. Medical device companies have often outsourced this work in the past, waiting until after the clinical results for regulatory purposes before they invest in HEOR and market access internally. In this session, we will discuss why this later-stage approach can undermine the success of a product launch, and how early stage companies are finding value by beginning HEOR and market access planning much earlier in the R&amp;D cycle.</p> <p><b>MODERATOR: Deepak Sahu</b>, Manager, Alira Health  <b>Matt Benessere</b>, Director, Global Market Access, Insulet  <b>Arthi Chandran</b>, Vice President and Head of WW Health Economics and Outcomes Research, BD  <b>Martin Gold</b>, Senior Director, Health Economics and Market Development, Integra LifeSciences  <b>Maria Stewart</b>, Global Vice President, Health Economics and Market Access, Boston Scientific</p>
10:30 AM	<p><b>Networking Break</b></p>
10:45 AM	<p><b>MedTech Innovator: Preliminary Competition and Execution Award</b></p> <p>A select group of MedTech Innovator Semi-Finalist companies will compete for the audience vote and the MedTech Innovator 2019 Execution Award, presented to the company in the Accelerator Program that demonstrates the strongest execution plan and potential.</p>  <p><b>HOST: Paul Grand</b>, Chief Executive Officer, MedTech Innovator</p> <p><b>JUDGING PANEL:</b>  <b>TBC</b></p> <p><b>PRESENTING COMPANIES:</b>  <b>TBC</b></p>
11:45 AM	<p><b>Networking Luncheon</b> <i>Sponsored by</i> </p>
12:30 PM	<p><b>Lessons in Leadership: An Interview with Mike Minogue, CEO, President &amp; Chairman of the Board, Abiomed</b></p> <p><b>MODERATED BY: David Cassak</b>, Co-Editor-in-Chief and Managing Partner, MedTech Strategist</p>
12:50 PM	<p><b>MedTech Innovator Execution Award &amp; Virginia Shimer Rybski Memorial Award Ceremony</b></p> <p><b>PRESENTED BY: Paul Grand</b>, Chief Executive Officer, MedTech Innovator, and  <b>George Ayd</b>, Assistant Vice President, Business Development and Marketing, Medmarc</p> <p>The winner of the Execution Award will also receive the Virginia Shimer Rybski Memorial Award. As a scientist and serial entrepreneur, Virginia Shimer Rybski worked for and founded several companies before becoming the President and CEO of Regenesys Biomedical, Inc. In the spirit of this dynamic woman, this award was created by AdvaMed Accel in 2013 to encourage the enthusiastic pursuit of business excellence in the medical technology industry and recognize the potential of a promising entrepreneurial company.</p>
1:00 PM	<p><b>Adjourn</b></p>

# International PROGRAMMING

**THE MEDTECH CONFERENCE WELCOMES INTERNATIONAL DELEGATIONS FROM OVER 30 COUNTRIES. PROGRAMMING FEATURES INCLUDE SESSIONS FOR THE GLOBALLY MINDED, SEMINARS FOR THOSE INTERESTED IN DOING BUSINESS IN THE U.S., NETWORKING EVENTS TO HELP YOU EXPAND YOUR CONTACT BASE AND MORE. HERE'S YOUR GLOBAL AGENDA:**

## SUNDAY, SEPTEMBER 22

### U.S. MARKET ACCESS SEMINAR

**12:30 PM – 5:00 PM**

**Room 156 C**

Sponsored by  **McDermott Will & Emery**

**Please be aware that lunch will not be served. This event is closed to the press.**

The U.S. Market Access Seminar is a pre-program for international delegates attending The MedTech Conference. It will address key issues for non-U.S. medtech companies seeking to launch products in the U.S. market. Instructors will cover regulatory and reimbursement pathways as well as perspectives about the changing landscapes in each of these areas in the U.S.

#### AGENDA

**12:30 PM – 12:35 PM** Welcome (**Angus McQuilken**, McDermott Will & Emery LLP)

**12:35 PM – 1:05 PM** U.S. Market Overview (**Steve Miller**, SelectUSA)

**1:05 PM – 1:50 PM** Establishing a Company in USA: Ramp-Up to Dealmaking and Operations

**SPEAKERS:** **Jennifer Bock** and **Albert Sokol**, McDermott Will & Emery LLP

» Taxation, immigration, other issues

**1:50 PM – 2:50 PM** Establishing a Company in the U.S.: Economic Development Support

**MODERATOR:** **Christine Sarkisian**

- » Massachusetts (**Mark Sullivan**, MOITI)
- » South Carolina (**Mike Graney**, Charleston Regional Development Alliance)
- » California (**Kwame Ulmer**, Ulmer Ventures)

**2:50 PM – 3:00 PM** Break

**3:00 PM – 5:00 PM** Combining Your FDA and Reimbursement Pathways: How to Find Your Fastest Way to Market

This discussion will focus on the benefits of a combined FDA and reimbursement pathway, helping participants understand the fastest path to market for new and novel technologies. International companies looking to sell products in the U.S. will benefit from being part of this interactive session led by thought leaders in the commercialization of new devices, diagnostics and digital health technologies.

**Anisa Mohanty**, Associate, McDermott Will & Emery LLP  
**Vernessa Pollard**, Partner, McDermott Will & Emery LLP  
**Michael Ryan**, Partner, McDermott Will & Emery LLP

### INTERNATIONAL RECEPTION

**5:30 PM – 7:30 PM**

**Legal Seafood Harborside, 270 Northern Ave., Boston, MA 02210**

Following the U.S. Market Access Seminar, delegates are invited to proceed to Boston landmark Legal Seafood Harborside to mix and mingle with key members of the local medtech community. Open to all conference registrants.

Sponsored by **Québec** 



## TUESDAY, SEPTEMBER 24

### GLOBAL MARKETS: WHERE TO INVEST?

**2:15 PM – 3:45 PM**

#### **Exhibition Hall, Solutions Showcase Stage**

Deciding where to invest regionally requires understanding a variety of factors, depending on the type of investment and new market opportunities you want to establish for your company. Regional markets all have competitive advantages that you might not know about. During this program, you will hear a series of 15-minute power presentations outlining the investment incentives available in various regions of the world. Oh, the places you'll go!

#### **SCHEDULE**

**2:15 PM** Developments in Latin America

**2:30 PM** Costa Rica

**2:45 PM** Finland

**3:00 PM** India

**3:15 PM** Guangzhou



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## INNOVATIONS IN GLOBAL HEALTH



AdvaMed is proud to partner with TeamFund and Duke University's Innovations in Health program to produce a series of presentations highlighting health technologies designed for under-resourced populations. Join us for these programs that put patients' needs first:

### SME MEDTECH INNOVATIONS THAT ARE TRANSFORMING HEALTH CARE IN THE U.S. AND ABROAD

**Monday, September 23, 11:00 AM – 12:15 PM**

**Room 157 A**

Given the complexities of payment, policy, and care delivery ecosystems in low- and middle-income countries, it should come as no surprise that change agents in these regions are developing innovations with the potential to transform health systems not only in their own communities but in countries of all sizes around the world. Fostering breakthroughs in health care delivery models, affordable technologies, and more, these organizations are creating new pathways to improving health care quality and access while challenging the paradigm of modern-day patient care.

### GLOBAL HEALTH MEETUP

**Monday, September 23, 2:45 PM – 3:15 PM**

#### **Meetup Zone**

Network with your peers engaged in global health initiatives and hear from leaders at Duke University's Global Health Innovation Center (GHIC). GHIC is spearheading a comprehensive study funded by the Bill & Melinda Gates Foundation focused on the challenges and opportunities associated with technology development, launch, and scale-up for under-resourced populations. Preliminary findings will be shared.

# International PROGRAMMING

## GLOBAL HEALTH INNOVATOR AWARD

**Wednesday, September 25, Plenary Lunch Presentation**

TEAMFund was launched with the vision that the entire medtech sector might come together to find ways to connect the people most in need of care with the innovations and technologies that can save and transform their lives. This year's \$50,000 award will be the third that TEAMFund has sponsored and presented at The MedTech Conference in recognition of an early-stage medtech company that has a novel, appropriate and sustainable medical device for the world's low-resource and resource-constrained populations. Looking ahead to 2020 and beyond, TEAMFund seeks to fulfill the essential work of:

- » Research into disease burden and community-specific needs in low-resource settings;
- » Provision of advisory support of medtech innovators attempting to serve low-resource communities;
- » Development and implementation of impact measurement tools to assess the efficacy of medtech innovations;
- » Programmatic research tied to innovation;
- » Catalyze others to invest; and
- » Provide grant support to foster a broader ecosystem of medtech innovations and private sector investment.

For more information, please visit [teamfundhealth.org](http://teamfundhealth.org).

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As of August 26, 2019

## 3DMedlab

### Booth #123

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Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 103,000 colleagues serve people in more than 160 countries.

## Abiomed, Inc.

### Patient Pavilion, Booth #128

Abiomed (NASDAQ: ABMD) is a pioneer and global leader in healthcare technology and innovation, with a mission of RECOVERING HEARTS AND SAVING LIVES. CEO, Chairman and President Michael R. Minogue has focused the company's efforts on developing ground-breaking technologies designed to assist or replace the life-sustaining pumping function of the failing heart. The company's portfolio of products and services offer healthcare professionals an array of choices across a broad clinical spectrum.

## ACTO

### Booth #222

## Actuated Medical

### Innovation Pavilion, Booth #441

## AdvaMed

### Booth #229

The Advanced Medical Technology Association (AdvaMed) is a trade association that leads the effort to advance medical technology in order to achieve healthier lives and healthier economies around the world. AdvaMed's membership has reached nearly 300 members and more than 80 employees with a global presence in countries including Europe, India, China, Brazil and Japan.

## Akin Gump Strauss Hauer & Feld LLP

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Akin Gump is a global law firm with extensive experience in the critical legal, regulatory, and strategic issues confronting digital health services and technologies.

## Alcon, Inc.

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Alcon, the global leader in eye care, works in over 70 countries and serves patients in over 140 countries. We are the largest eye care device company in the world — with businesses in surgical and vision care. We are committed to research and development to meet customer and patient needs.

## Alira Health

### Booth #329

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## Aon Risk Services

### Sponsor

Aon plc (NYSE:AON) is a leading global professional services firm providing a broad range of risk, retirement and health solutions. Our 50,000 colleagues in 120 countries empower results for clients by using proprietary data and analytics to deliver insights that reduce volatility and improve performance.

## Apttus

### Booth #247

Apttus is the pioneer of the Middle Office platform, which empowers enterprises to automate and optimize critical revenue-generating processes across sales channels. The analyst community ranks Apttus as the global gold standard for Quote-to-Cash (QTC), CPQ and Contract Lifecycle Management (CLM).

## Archimedic

### Booth #119

Archimedic is a full-service medical device developer, helping innovators who face technical, regulatory, or manufacturing challenges accelerate new products along the path to market. Our clients span established device manufacturers, top-tier academic hospitals, and venture-backed startups.

## Avanos Medical

### Booth #207

Avanos is a medical device company focused on delivering clinically superior breakthrough solutions that will help



patients get back to the things that matter. Headquartered in Alpharetta, Georgia, Avanos is committed to creating the next generation of innovative healthcare solutions which will address our most important healthcare needs, such as reducing the use of opioids while helping patients move from surgery to recovery.

## **B. Braun Medical**

### **Booth #455**

B. Braun Medical Inc., a leader in infusion therapy and pain management, develops, manufactures, and markets innovative medical products and services to the healthcare industry. Other key product areas include nutrition, pharmacy admixture, compounding, dialysis, ostomy, and wound care. The company is committed to eliminating preventable treatment errors and enhancing patient, clinician, and environmental safety. For more information, visit us at [www.BBraunUSA.com](http://www.BBraunUSA.com).

## **Baker Tilly Virchow Krause, LLP**

### **Booth #510**

Baker Tilly, a leading advisory, tax and assurance firm, serves life sciences companies ranging from start-ups to multi-billion dollar companies. We understand a company's business, financial and operational needs in all phases of the lifecycle and help companies address each phase's unique needs.

## **Bank of America Merrill Lynch**

*Sponsor*

## **Baxter International**

### **Booth #112**

Baxter provides a broad portfolio of products, including home, acute and in-center dialysis; IV solutions; infusion systems and devices; parenteral nutrition; biosurgery products; and pharmacy automation.

## **BD**

### **Patient Pavilion, Booth #128**

BD is a global medical technology company that benefits countless lives worldwide. Our 45,000 associates help advance health by improving the ways that discovery, diagnostics and delivery of care are conducted — enhancing outcomes, better managing healthcare delivery costs, increasing efficiencies, improving healthcare safety, and expanding patient access. Our product portfolio, leadership and partnerships help make a difference for global healthcare.

## **BIO El Paso-Juarez**

### **Booth #254**

BIO El Paso-Juarez is the cluster organization representing more than 30 medical device manufacturers and suppliers in the El Paso, TX and Juarez, Mexico region. Companies produce Class I, II, and III devices and have a vast array of manufacturing and product development capabilities.

## **BlackHagen Design**

### **Booth #312**

## **Boston Engineering**

### **Booth #116**

Boston Engineering provides product development consulting from concept design through commercialization and IoT connectivity. Certified to ISO 13485, Boston Engineering advances innovative medical devices, diagnostics, and therapeutic treatments. Learn more about our results at [boston-engineering.com/medical-devices](http://boston-engineering.com/medical-devices).

## **BSI Group America Inc.**

### **Booth #448**

BSI Medical Device's mission is to ensure patient safety while supporting timely access to global medical device technology. We strive to set the global standard in thorough, responsive, robust conformity assessments, evaluations, and certifications.

## **Business Finland**

### **Booth #449**

Business Finland is Finland's innovation, investment, funding, and trade agency focusing on the commercialization of new technologies, the internationalization of companies, and assisting companies investing in Finland. Finland and Helsinki Business Hub are seeking strategic partnerships in the medtech field. All services are free of charge.

## **California Life Sciences Association**

### **Booth #108**

California Life Sciences Association (CLSA) is the public policy and business association for CA life sciences. We work with industry, government, academia and stakeholders to shape public policy and drive innovation and business results for biotech, pharmaceutical, med device, diagnostics, academia, research, investors, and professional services.

## **Carbon**

### **Booth #442**

Carbon's mission is to reinvent how polymer products are designed, engineered, manufactured, and delivered towards a digital and sustainable future. Based in Silicon Valley, Carbon brings together innovations in software, hardware, and molecular science to deliver industry-leading digital manufacturing solutions. The Carbon Platform allows customers to build uniquely differentiated products while reducing waste and speeding time to market. To learn more, visit [www.Carbon3d.com](http://www.Carbon3d.com).

## **CBSET, Inc.**

### **Booth #420**

# EXHIBITOR & SPONSOR *Listing*

## Celestica

### Booth #248

A \$6.6B global provider of product lifecycle solutions, Celestica enables the world's leading healthcare companies — from design and manufacturing to after-market support. We specialize in solutions for high-reliability applications, including advanced solutions for surgical instruments, in-vitro diagnostics, and imaging/patient monitoring. Through our certified Healthtech Centers of Excellence network, we ensure flawless execution in compliance with the most rigorous quality standards.

## China Med Device, LLC

### Booth #346

China Med Device provides regulatory and commercialization turnkey solutions for medical devices, IVD and CDx in China. Regulatory services include strategy, registration, testing, CRO and PMS. Commercialization services include market research, reimbursement, partnership and distribution qualification.

## CINDE

### Booth #550

CINDE, the Costa Rican Investment Promotion Agency (CINDE) is a private, non-profit, apolitical organization aimed to attract FDI in the country. From helping discover Costa Rica's potential to installation and business development; we support companies all the way. Our services are free of charge.

## City of Cape Coral

### Booth #413

## ClearCam Inc.

### Innovation Pavilion, Booth #441

ClearCam is dedicated to providing clinicians with innovative tools and technologies that maximize their vision and skill in the operating room. We accomplish this through our core values of intellectual honesty, speed of light execution, direct communication, and simple, elegant design.

It is our mission to create products that improve today and tomorrow's surgical visualization platforms; platforms that employ cutting-edge technology and open doors to new and exciting surgical procedures that provide better patient outcomes.

## Cognizant

### Booth #419

Cognizant is one of the world's leading professional services companies, transforming clients' business, operating and technology models for the digital era. Headquartered in the U.S., Cognizant is ranked 193 on the Fortune 500 and is consistently listed among the most admired companies in the world. Learn more at [www.cognizant.com/life-sciences](http://www.cognizant.com/life-sciences).

## Consulate General of Belgium — Flanders Investment & Trade

### Booth #351

Flanders Investment & Trade (FIT) promotes international enterprise in Flanders. We facilitate investment projects and support export companies through:

- Free advice
- A global network of experts
- Setting up business in FL
- Facilitating export from FL
- Matching companies worldwide
- FL expertise.

## Deloitte

### Partnering Suite 1

Deloitte helps medtech companies develop and implement innovative and practical solutions to stay ahead in a digital-driven, outcomes-based world. Our work across the global health care industry enables us to deliver value at every step, from insight to strategy to action. And our focus on innovation helps medtech companies uncover opportunities to reshape the entire health care industry and the future of health. [www.deloitte.com/us/medtech](http://www.deloitte.com/us/medtech)

## Delve

### Booth #424

## DJO Global

### Booth #100

DJO provides solutions for musculoskeletal and vascular health, rehabilitation, and pain management, as well as joint reconstruction. Our products help prevent injury, rehabilitate after injury or surgery, and manage progression of degenerative disease, helping patients to keep moving and return to a healthier lifestyle. Visit [www.DJOglobal.com](http://www.DJOglobal.com).

## DSM Biomedical

### Booth #435

DSM is the world's leading biomedical partner with over 30 years of experience, offering the broadest portfolio of advanced healing solutions and expertise. From concept to commercialization, DSM is a full-service partner, turning ideas into high-quality solutions from biomedical materials to finished devices. In 50 countries and six continents, benefitting 31.5M+ patients annually, the breadth of DSM's global network is unmatched.

## Economic Development Department in the City of Brampton

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### Booth #149

Brampton, Ontario, is the second fastest growing city in Canada and is located in North America's third largest biotechnology cluster. Brampton's young, diverse population with over 230 different cultures creates a microcosm of the world for R&D and clinical trials. Brampton is home to over 2,300 health and life sciences companies and is a leader in preventative healthcare. [investbrampton.ca](http://investbrampton.ca)

## Edwards Life Sciences

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### Patient Pavilion, Booth #128

Edwards Lifesciences, based in Irvine, California, is the global leader in patient-focused medical innovations for structural heart disease, as well as critical care and surgical monitoring. Driven by a passion to help patients, the company collaborates with the world's leading clinicians and researchers to address unmet healthcare needs, working to improve patient outcomes and enhance lives. For more information, visit [Edwards.com](http://Edwards.com) and follow us on Twitter @EdwardsLifesci.

## Emphysys

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### Booth #319

## Epitel

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### Innovation Pavilion, Booth #441

Epitel is revolutionizing the way we monitor brain health with Epilog, our hardware-enabled data analytics platform that takes medical-grade EEG monitoring out of the hospital and into the home for the first time. Epilog provides long-term brain health monitoring where you are, when you need it.

## Esker

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### Booth #350

As a worldwide leader in AI-driven process automation software, Esker helps financial and customer service departments digitally transform their order-to-cash and purchase-to-pay cycles. The company has global headquarters in Lyon, France, and U.S. headquarters in Madison, Wisconsin.

## EY Global Services Limited

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### Sponsor

The EY Health Sciences and Wellness architecture brings together a worldwide network of more than 20,000 professionals to build data-centric approaches to customer engagement and improved outcomes. We help our clients deliver on their strategic goals; design optimized operating models; and form the right partnerships so they may thrive today and succeed in the health systems of tomorrow. We work across the ecosystem to understand the implications of today's trends, proactively finding solutions to business issues and to seize the upside of disruption in this transformative age.

## Fang Consulting

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### Booth #106

Fang Consulting is headquartered in Minnesota's Medical Alley; we specialize in providing completely customizable onsite and remote regulatory and quality consulting services for medical device companies. Our team of experts ensure that our clients obtain the clearance to place new products and keep existing products on any global market.

## FedEx

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### Booth #241

FedEx HealthCare Solutions is committed to offering specialty services to the healthcare industry. In addition to core shipping services, FedEx also offers customized solutions including temperature-controlled ground and air transport, a high degree of visibility and compliance with 24-hour monitoring, and end-to-end solutions to handle storage, fulfillment and distribution of inventory.

## Fibralign Corp.

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### Innovation Pavilion, Booth #441

Fibralign Corporation is a Stanford University spin-out biotech company that produces novel therapeutic medical devices to address major unmet medical needs. The company is in commercial sales in the U.S. with its first product, the BioBridge® Collagen Matrix.

BioBridge's first target is treatment and prevention of Secondary Lymphedema, a global chronic disease that currently has no cure. Clinical benefit has already been demonstrated and a Stanford-led multi-site clinical study is currently underway for breast cancer-related lymphedema (funded by an NCI SBIR bridge grant).

## FirstWord Group

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### Booth #417

FirstWord MedTech offers fast, free and reliable updates on commercial and R&D developments shaping the global medical device, diagnostics and digital health sectors. Its premium MedTech PLUS service provides further analysis into key market-disrupting events and insights into emerging industry trends.

## Fitango

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### Booth #152

## Flex

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### Booth #516

Flex provides Sketch-to-Scale solutions for the medtech industry. With over 200,000 employees and 2,500 engineers across 30 countries, Flex accelerates time to market and optimizes resource allocation for efficient, cost-effective solutions throughout the product life cycle. With FDA-registered and ISO 13485 compliant facilities and a world-class quality system, Flex offers innovative design, new product introduction, resource reallocation, or transformation. Leveraging real-time supply chain insight and advanced platform technologies across multiple industries, Flex provides unmatched opportunity for profitable business growth.

# EXHIBITOR & SPONSOR *Listing*

## Food and Drug Administration

### Booth #554

The 510(k) Third Party Review Program improves public health by helping to yield more rapid 510(k) decisions and allowing the FDA to focus its resources on higher risk devices, while still maintaining oversight of the review of lower risk devices. Visit our booth to learn more.

## Forest Devices

### Innovation Pavilion, Booth #441

Forest Devices develops tools for early stroke detection. The company's first product, AlphaStroke, is used in the pre-hospital environment by EMTs and paramedics to rapidly identify ischemic stroke and gauge severity. Using AlphaStroke, pre-hospital providers can triage stroke patients to the right treatment faster. Save time, save brain.

## Frost & Sullivan

### Booth #213

Through content and collaboration, Frost & Sullivan's Transformational Health industry analysts, consultants, and futurists help organizations across the globe understand the voice of the customer, and identify new business models and areas of greatest disruption. Our unbiased insight assists with strategic planning, new market entry, investment and growth opportunities.

## Gals Bio

### Booth #152

## GNA Biosolutions GmbH

### Innovation Pavilion, Booth #441

GNA Biosolutions is a molecular diagnostics company located in Germany. Our disruptive Pulse Controlled Amplification (PCA) technology captures

and amplifies nucleic acids from complex clinical samples, enabling ultrafast and cost-effective molecular diagnostic assays. PCA assays are being developed for a number of therapeutic areas, including infectious diseases and biothreats.

## Goddard Inc.

### Booth #317

Goddard creates remarkable medical devices. We are a full-service product development and mechanical engineering firm specializing in med device, biotech, and combination products. We work from concept creation through manufacturing hand-off. Explore more: [goddardtech.com](http://goddardtech.com). What are you working on?

## Gore & Associates

### Sponsor

Gore Medical Products Division engineers devices that treat a range of cardiovascular, bariatric, hernia and other health conditions. Gore builds on its legacy of improving patient outcomes through research, education, and quality initiatives.

## Government of Canada

### Booth #145

## Government of Ontario

### Booth #147

## Grant Thornton

### Booth #252

The rapidly evolving healthcare needs of today's patient population and technology disruption present both opportunities and challenges for life sciences organizations. Grant Thornton's advisory consulting, audit, and tax professionals provide innovative business and technology solutions and services that can help you achieve a competitive advantage, now and into the future.

## Greenberg Traurig

### Booth #433

Greenberg Traurig, LLP, has approximately 2,100 attorneys in 41 locations in the United States, Latin America, Europe, Asia, and the Middle East. GT is consistently among the largest firms in the U.S. on the Law360 400 and among the Top 20 on the Am Law Global 100. [www.gtlaw.com](http://www.gtlaw.com)

## Greenlight Guru

### Booth #500

Greenlight Guru is the only quality management software platform built exclusively for the medical device industry. Device makers across the globe are replacing their outdated paper-based and general purpose legacy quality systems with Greenlight Guru.

## Guangzhou Liaison Office In Boston

### Booth #416

## Haemonetics

### Patient Pavilion, Booth #128

## Harmac

### Sponsor

## Health-ISAC

### Booth #450

Health-ISAC is a trusted community of critical infrastructure owners and operators within the global healthcare sector. Members share timely, actionable, relevant information including intelligence on threats, best practices and mitigation strategies. The health sector becomes more resilient worldwide by working together.



## Healthlink Europe

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### Booth #343

Our mission is be the number one choice for life science manufacturers looking to outsource their logistics and back office services. We specialize in warehousing, logistics and fulfillment, value added services, reverse logistics, multilingual customer services, VAT processing and deferment, and finance and administration.

## Hemex Health

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### Innovation Pavilion, Booth #441

Hemex Health offers medical diagnostics for at-risk populations. Our Gazelle™ Diagnostic Device is an easy-to-use platform that supports two tests: an affordable, one-minute malaria test — more accurate than existing diagnostics — and the first affordable hemoglobin variant test to identify and quantify hemoglobin types (such as sickle cell).

## Hemotek

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### Innovation Pavilion, Booth #441

Hemotek Medical Inc. is dedicated to providing patients with safer hemodialysis. Our patented device will reduce deaths and adverse events from Venous Needle Dislodgement. There are ~57M needle-based hemodialysis sessions per year in the US and 250M worldwide. The US market opportunity is \$20M per year and \$100M worldwide.

## Hinge Clinica Inc.

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### Booth #120

## Hogan Lovells

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### Sponsor

With more than 500 life sciences and health care lawyers across the globe, we work closely with you and each other to tackle tough issues and difficult-to-enter markets. From budding startups to multinational enterprises, we've been there before and know how to position you for success.

## Hollister Incorporated

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### Sponsor

## Hologic, Inc.

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### Sponsor

At Hologic, we're an innovative medical technology company that enables healthier lives everywhere, every day. We are also a company that prospers and grows, which is why we've been able to expand our offerings to empower even more people and champion women's health.

## HOYA

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### Partnering Suite 9

Founded in 1941 in Tokyo, Japan, Hoya is a global med-tech company, and a leading supplier of innovative high-tech and medical products. Hoya is active in the fields of healthcare and information technology providing eyeglasses, medical endoscopes, intraocular lenses and optical lenses, as well as key components for semiconductor devices, LCD panels and HDDs. With sales of \$5.3B in 2019, HOYA has over 150 offices and subsidiaries worldwide, and employs a multinational workforce of 37,000 people.

## HS Design, Inc.

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### Booth #405

## ICON

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### Booth #206

ICON plc, a global provider of outsourced development and commercialization services to pharmaceutical, biotechnology, medical device, and government and public health orgs, specializes in the strategic development, management and analysis of programs that support clinical development. Visit [ICONplc.com](http://ICONplc.com).

## IDA Ireland

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### Booth #322

IDA Ireland is Ireland's economic development agency, responsible for promoting Ireland as the European location for investment. This year, we proudly mark our 70th anniversary in working with multinationals as they establish and grow their Irish presence. Ireland continues to be a top destination

for medical technology innovation, and home to 300+ companies that employ over 25,000 people. Stop by booth 322 to learn more and make sure to catch our annual Chairmen's Networking Reception!

## Indegene

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### Booth #160

Indegene Omnipresence is the next-generation customer experience platform for med-device manufacturers that offers both Omnichannel and CRM capabilities through a single, unified platform. As a result of the strategic alliance with Microsoft, Omnipresence brings together and contextualizes the power of Microsoft Dynamics, LinkedIn, Azure, and Office for life sciences.

## Insulet

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### Patient Pavilion, Booth #128

## Integra LifeSciences

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### Sponsor

Integra LifeSciences is a global leader in regenerative technologies, neurosurgical and extremity orthopedic solutions dedicated to limiting uncertainty for clinicians, so they can focus on providing the best patient care. Integra offers a comprehensive portfolio of high-quality, leadership brands. For the latest news and information about Integra and its brands, please visit [www.integralife.com](http://www.integralife.com).

## Integrated Computer Solutions

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### Booth #422

## Intertek

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### Booth #406

Intertek partners with medical device manufacturers to deliver assurance, testing, inspection and certification services to help them meet global regulatory requirements. Our experts understand the latest technologies and requirements, and can provide solutions for safety, EMC, performance, chemical, environmental, cyber security, and more.

# EXHIBITOR & SPONSOR Listing

## InTouch Health

### Booth #218

InTouch Health, ranked 2019 Best in KLAS for Virtual Care Platforms, is a telehealth services company that offers healthcare providers solutions to efficiently deliver virtual care for a broad array of use cases and healthcare environments. InTouch Health provides a reliable, dedicated cloud-based network and virtual care solutions designed to ensure connectivity for health systems, providers, and patients at all times.

## Invest Lithuania

### Booth #224

## IQVIA Medtech

### Booth #333

IQVIA™ MedTech, part of IQVIA (NYSE: IQV), is dedicated to supporting the orchestration of the “concept to market” business needs of the medical device and in vitro diagnostics industry. IQVIA is a leading global provider of information, innovative technology solutions, and contract research services. Learn more at [iqviamedtech.com](http://iqviamedtech.com).

## itracHEALTH Corp.

### Innovation Pavilion, Booth #441

itracHEALTH Corp is a developer of fully integrated, broadly-capable, best-in-class chronic care management solutions with an initial focus on addressing the home-health needs of frail and/or at-risk seniors, thereby enabling them to age in place without compromising the need to manage the complexity of their medical conditions.

## Johnson & Johnson

### Booth #530

As the world’s most comprehensive medical devices business, we are building on a century of experience, merging science and technology, to shape the future of health and benefit even more people around the world. With our unparalleled breadth, depth and reach across surgery, orthopaedics, vision and interventional solutions, we’re working to profoundly change the way care is delivered. We are in this for life.

## KCI USA Inc.

### Sponsor

## Korn Ferry

### Sponsor

Korn Ferry is a global organizational consulting firm. We help clients synchronize strategy and talent to drive superior performance. We work with organizations to design their structures, roles, and responsibilities. We help them hire the right people to bring their strategy to life. And we advise them on how to reward, develop, and motivate their people.

## L&T Technology Services Limited

### Booth #461

L&T Technology Services (LTS) is a leading global ER&D services company, serving 51 of the world’s top ER&D spenders in areas such as product development, imaging, analytics, regulatory affairs and IoT. With over 399 patents filed, we employ over 15,000+ professionals in 48 locations globally.

## L.E.K. Consulting

### Sponsor

L.E.K. Consulting is a global management consulting firm that uses industry expertise and analytical rigor to help solve clients’ most critical business problems.

## Larta Institute

### Booth #249

## Leavitt Risk Partners

### Booth #310

Leavitt Risk Partners developed a methodology that accurately quantifies financial risk around healthcare outcomes. The BLISCare Outcome-Based Performance Guarantee enables medtech and device companies to differentiate themselves by taking accountability for the outcomes of their products.

## Linden Capital Partners

### Booth #200

Linden Capital Partners is a Chicago-based private equity firm focused exclusively on the healthcare industry. Linden’s strategy is based upon three elements: (i) healthcare specialization, (ii) integrated private equity and operating expertise, and (iii) strategic relationships with large corporations. Linden invests in middle market platforms in the medical products, specialty distribution, pharmaceutical, and services segments of healthcare.

## MAG Optics

### Innovation Pavilion, Booth #441

MAG Optics is a clinical stage ophthalmic company, developing the first patient-centric corneal shape-changing platform. The intra-corneal implant is used to treat Keratoconus, a progressive, degenerative eye disease that causes severe visual impairment, as well as Presbyopia (loss of near vision as you age) and Astigmatism.

## Mareana

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### Booth #216

Mareana is a big data and advanced analytics company. Its proprietary technology platform, qSuite, helps companies make better use of unstructured data, improve overall data interoperability, and create value from data through advanced modeling and analytics. qSuite is tailored to organizations that deal with large data sets spread across multiple systems. Our customers represent the life sciences, chemical, and general industrial manufacturing industries.

## Marwood Group

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### Booth #210

The Marwood Group is a leading healthcare-focused advisory firm that assists MedTech companies in developing market access strategies for their pipeline and portfolio. In addition to the value of Marwood's strategic guidance, Marwood's research can be leveraged in discussions with commercial payers, providers, and CMS as well as prospective investors and acquirers.

## Massachusetts Life Sciences Center

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### Booth #301

The Massachusetts Life Sciences Center is an economic development and investment agency dedicated to supporting the growth and development of the life sciences in Massachusetts, home to the most verdant and productive life sciences ecosystem in the world. Through public-private funding initiatives, the MLSC supports innovation, research and development, commercialization, and manufacturing activities in the fields of biopharma, medical device, diagnostics, and digital health.

## MassBio

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### Booth #301

MassBio's mission is to advance Massachusetts' leadership in the life sciences to grow the industry, add value to the healthcare system and improve patient

lives. Representing 1,200+ biotechnology companies, academic institutions, disease foundations and other organizations involved in life sciences and healthcare, MassBio leverages its unparalleled network of innovative companies and industry thought leaders to advance policy and promote education, while providing member programs, events, industry information, and services. Learn more at [www.MassBio.org](http://www.MassBio.org).

## MassMEDIC

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### Booth #301

## McDermott Will & Emery

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### Sponsor

Composed of top lawyers with demonstrated strength across intellectual property, regulatory, transactional, employment and litigation law, McDermott's global life sciences team, in concert with our #1 ranked Health Advisory practice, serves as counsel for many of the world's leading medical device, diagnostic and digital health companies and investors.

## McKinsey

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### Sponsor

McKinsey & Company is a global management consulting firm helping institutions in the private, public, and social sectors. With consultants in 133 cities in 66 countries, across industries and functions, we work closely with teams at all levels of an organization to shape winning strategies, mobilize for change, build capabilities, and drive successful execution.

## MDG Boston

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### Booth #118

## MedAcuity

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### Booth #327

MedAcuity is an ISO 13485:2016 certified software engineering firm that provides medtech companies support for the software development of Class I, II, III, and PMA medical devices. We do this by

offering a full spectrum of services, all led by engineers who are experts in medical device software development.

## Medcrypt

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### Booth #202

MedCrypt. Proactive Healthcare Security — In a Few Lines of Code. Medical device vendors used to be able to ship a device, hope that there were no cybersecurity issues, and address problems over time. Today, leading vendors build security features into devices, and win market share as a result.

## Medec

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### Booth #246

Medtech Canada is the national association representing the medical technology industry in Canada. Our association advocates for achieving patient access to leading edge, innovative technology solutions that provide valuable outcomes. Our members are committed to providing safe and innovative medical technologies that enhance the quality of patient care, improve patient access to health care, and help enable the sustainability of our health care system. The medical technology industry in Canada employs over 35,000 Canadians in approximately 1,500 facilities across the country.

## Medical Device Innovation Consortium

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### Booth #440

The Medical Device Innovation Consortium (MDIC) is the first public-private partnership created with the sole objective of advancing medical device regulatory science throughout the total product life cycle. MDIC's mission is to promote public health through science and technology and to enhance trust and confidence among stakeholders. Our initiatives improve product safety and

# EXHIBITOR & SPONSOR *Listing*

patient access to cutting-edge medical technology while reducing cost and time to market.

## Medidee

### Booth #225

Medidee is the leading Medical Device expertise and consultancy partner for RA, Clinical and QA. Based in Switzerland with branch offices all over Europe and the US, we are a reliable partner for Medical Device manufacturers, competent authorities and public organizations for addressing legal and regulatory requirements. With over 40 medical device experts & engineers we help managing product V&V, GCP and GMP compliance with MDR, IVDR, applicable standards, Meddevs and MDSAP. [www.medidee.com](http://www.medidee.com).

## Medmarc

### Booth #324

Created in 1979 by 31 members of Advamed, Medmarc's mission is to be the superior provider of liability insurance and related risk management solutions. We support the development, testing, and delivery of medical products that save lives and improve the quality of life. Contact us to discuss the cost of insurance coverage and what coverages are needed for your business plan. (703) 652-1360

## Medpoint

### Booth #407

## MedSec LLC

### Booth #260

MedSec is the only cybersecurity company dedicated exclusively to medical devices. MedSec leverages its unique understanding of the medical device space to offer a wide range of cybersecurity services, partnering with medical device

manufacturers on the design, architecture, verification, cybersecurity risk assessment, regulatory compliance, and maintenance of legacy systems.

## Medsix, Inc.

### Innovation Pavilion, Booth #441

MITHackingMedicine winner. JLABS@M2D2 resident. Creating solutions to improve post operative recovery management.

## MedTech Innovator

### Booth #612

## MedTech Strategist

### Booth #548

MedTech Strategist is a leading information provider and investment conferences organizer focused exclusively on the rapidly evolving global medical device industry. Our two publications: MedTech Strategist, and Market Pathways: Global Medical Device Regulatory, Reimbursement & Policy Review.

## Medtronic plc

### Patient Pavilion, Booth #128

As a global leader in medical technology, services and solutions, Medtronic improves the lives and health of millions of people each year. We use our deep clinical, therapeutic and economic expertise to address the complex challenges faced by healthcare systems today. Let's take healthcare Further, Together. Learn more at [Medtronic.com](http://Medtronic.com).

## mHealth Israel

### Booths #152, 153

## MIDI Medical Product Development Corporation

### Booth #341

MIDI is an Expert in Medical Device Innovation: MIDI is an award-winning strategic medical device development consulting firm with over 45 years of experience servicing domestic and international clientele representing medical, life sciences, drug delivery and home healthcare markets. Our prime goal is total satisfaction for the clients we serve.

## Minnetronix Medical

### Booth #212

Minnetronix Medical is a privately held medical technology company focused on bringing therapies to market that solve unmet needs. Since 1996, we have been a valued development, manufacturing and technology partner for medical device companies across the globe. We specialize in RF energy, fluid and gas management, optical systems and stim and wearable devices. Today, we are expanding what we do and are developing a portfolio of proprietary solutions for the neuro ICU.

## Model N

### Booth #251

Model N is a leading provider of cloud revenue management solutions for life sciences and high-tech companies. Driving mission-critical business processes such as pricing, quoting, contracting, regulatory compliance, rebates and incentives, our software helps companies know and grow their true top line and maximize every revenue moment at speed and scale.



## MTEC

### Booth #650

#### MTPConnect

##### Booth #517

MTPConnect is an independent, not-for-profit organization formed as part of the Australian Government's Industry Growth Centres Initiative. Its objective is to accelerate the rate of growth of Australia's medical technology, biotechnology and pharmaceutical sector. MTPConnect has offices in Melbourne, Sydney, Brisbane and Perth.

#### National Research Council

##### Booth #244

NRC, Canada's largest federal research and development organization provides customized research and technology solutions using platform technologies, state-of-the-art equipment and proprietary knowledge to help develop next-generation lab-on-a-chip and point-of-care systems, digital health and simulation platforms as well as implantable materials.

#### NeuroSigma, Inc.

##### Innovation Pavilion, Booth #441

NeuroSigma is a California-based life sciences company commercializing Trigeminal Nerve Stimulation (TNS) therapies for treating neurologic and neuropsychiatric disorders. In April 2019, NeuroSigma's non-invasive Monarch® external Trigeminal Nerve Stimulation (eTNS®) System became the first-ever medical device to receive FDA clearance for treating pediatric ADHD.

#### Novasys, an IQVIA Company

##### Booth #333

Novasys Health, an IQVIA company, partners with medical device and diagnostic manufacturers, offering tech-enabled, outsourced commercial service teams. Technology is wrapped around all of the offerings, and program success is tracked and measured with our real-time business intelligence analytics.

## NOVO

### Booth #506

NOVO — Digital and Physical Product Design. For our global clients in the medical industry, we deliver best-in-class product design and development strategy. We've supported a range of medical products including cardiovascular devices, digital health systems, ophthalmology tools, optics, respiratory and patient-monitoring systems. Our Health Canada and FDA/compliance support, all driven by solid engineering processes, helps companies achieve higher product quality and accelerate time to market.

#### NSF International

##### Booth #107

NSF International offers consulting, training and testing services to assist medical device companies in navigating U.S. and international regulatory hurdles throughout the total product lifecycle. We have combined regulatory and industry expertise across all therapeutic areas.

#### Nypro

##### Sponsor

Nypro, a Jabil Company, provides design, digital manufacturing, and intelligent supply chain solutions for leading brands of medical devices, diagnostics, consumer health and pharmaceutical delivery systems.

#### Olympus

##### Booth #306, Partnering Suite 6

Olympus is a global technology leader, crafting innovative optical and digital solutions in medical technologies, life sciences, industrial solutions, and cameras and audio products. Throughout our 100-year history, Olympus has focused on being true to society and making people's lives healthier, safer and more fulfilling. Visit [olympusamerica.com](http://olympusamerica.com) and [truetolife.com](http://truetolife.com).

#### Oxitone

##### Booth #152

## Pacific Bridge Medical

### Booth #452

Pacific Bridge Medical (PBM) is a consulting firm dedicated to assisting international medical companies with business development and regulatory affairs in Asia. We have helped hundreds of companies achieve success in the Asian medical markets since our founding in 1988. Our consultants are experts in regulatory strategy, product registration, distributor search, quality compliance, and more. We have offices in China, Japan, Singapore, and Hong Kong, and partners throughout Asia.

#### Paxman

##### Patient Pavilion, Booth #128

#### Pepper Hamilton LLP

##### Booth #110

Pepper Hamilton LLP is a multipractice law firm with more than 425 lawyers nationally. Its Health Sciences Department, a team of 110 attorneys, collaborates across disciplines to solve complex legal challenges confronting clients throughout the health sciences spectrum, including innovative biotech, pharmaceutical and medical device developers and manufacturers.

#### Pharma Intelligence

##### Booth #211

Informa's Pharma Intelligence is the trusted partner of the top 50 global pharmaceutical companies and the top 20 medical device companies. From drug and device discovery and development to regulatory approval, drug reimbursement to lifecycle management — we provide the global intelligence and insight to advance our partners' initiatives.

#### Physcient Inc.

##### Innovation Pavilion, Booth #441

Physcient makes surgical dissection faster, easier, and safer by removing the risk of accidental cuts and burns and simplifying the development of natural tissue planes. Our Model DD1 for open surgery is producing excellent results in vascular and colorectal surgery. Versions for laparoscopic and endoscopic surgery will follow soon.

# EXHIBITOR & SPONSOR *Listing*

## Prapela, Inc.

### Innovation Pavilion, Booth #441

Prapela, Inc., is introducing medical and consumer products based on its patented Stochastic Vibrotactile Stimulation (SVS) technology. SVS is a gentle, random vibration that boosts healthy, rhythmic breathing and heart rates, helping babies relax. SVS is non-habit forming and does not interrupt sleep cycles. Please visit [www.prapela.com](http://www.prapela.com).

## PRIA Healthcare Management

### Booth #313

PRIA drives market adoption and payer coverage of innovative medical devices and procedures. Combining patient and clinical data, as well as evidence of patient demand, we build patient access programs that accelerate the commercialization of your innovative procedure or treatment.

## PRIDCO

### Partnering Suite 13

The Puerto Rico Industrial Development Company (PRIDCO) is a government-owned corporation dedicated to promoting the island as an investment destination for companies and industries worldwide. Puerto Rico is the most exciting destination with skilled workforce, innovative entrepreneurial ecosystems and competitive tax incentives, among other advantages. Learn more at [businessinpuertorico.com](http://businessinpuertorico.com)

## Pristine Surgical

### Innovation Pavilion, Booth #441

Pristine Surgical has completely re-thought and re-designed the most fundamental of minimally invasive surgical tools, the rod lens scope, with a single-use digital imaging platform.

Pristine has developed a revolutionary new digital arthroscope and redesigned the entire surgical imaging system with the overall goal to improve the surgical episode.

## Product Creation Studio

### Booth #549

We are an integrated team of engineers and designers. We help forward-thinking companies realize new products that enhance people's lives. Services: electrical engineering, design, firmware, UX, mechanical engineering, quality assurance, project management. Industries: medical, consumer.

## Propel

### Booth #323

## Proven Process Medical Devices Inc.

### Booth #408

## Quebec Government

### Booths #141, 143, 240, 242

The mission of Québec's Ministère de l'Économie et de l'Innovation is to support business growth, entrepreneurship, innovation, export trade and investment. Québec has undeniable strengths in many life sciences fields. It is among the industries and the research facilities that Québec can count on to build its future and ensure its prosperity.

## Quidel

### Patient Pavilion, Booth #128

## Racer Technologies

### Booth #249

## RAMED Biosciences, LLC

### Booth #140

## RBC Medical Innovations

### Booth #150

## Reed Tech

### Booth #111

Reed Tech offers medical device data management and submission solutions for FDA and other regulatory authorities' Unique Device Identifier Databases. We apply a decade of experience to help device manufacturers fulfill UDI submission requirements. Our solution provides timely, accurate submission and maintenance of GUDID records and will support future global UDID submissions.

## Regulatory & Quality Solutions (R&Q)

### Booth #347

Regulatory & Quality Solutions (R&Q) is an industry-leading regulatory and quality consulting firm that helps medical device and combination product companies bring safe and effective products to market . . . and keep them there. R&Q's team of 200+ consultants have served over 300 companies around the globe. Learn more at [RQTeam.com](http://RQTeam.com).

## RMDY

### Booth #152

## Roundtable Healthcare Partners

### Sponsor

RoundTable Healthcare Partners is an operating-oriented private equity firm focused exclusively on the healthcare industry. Roundtable creates value by partnering with healthcare companies that can benefit from our extensive industry relationships and proven operating and transaction expertise. RoundTable was founded in 2001 and is based in Lake Forest, Illinois.

## RSIP Vision

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### Booth #152

## RTI Surgical

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### Patient Pavilion, Booth #128

## Russell Reynolds

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### Sponsor

Russell Reynolds Associates is a global leadership advisory and search firm. Our 425+ consultants in 46 offices work with public, private and nonprofit organizations across all industries and regions. We help our clients build teams of transformational leaders who can meet today's challenges and anticipate the digital, economic and political trends that are reshaping the global business environment. From helping boards with their structure, culture and effectiveness to identifying, assessing and defining the best leadership for organizations, our teams bring their decades of expertise to help clients solve their most complex leadership issues. [www.russellreynolds.com](http://www.russellreynolds.com).

## Sagentia

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### Booth #426

Sagentia is a global science, product and technology development company. Our mission is to help companies maximize the value of their investments in R&D. We partner with clients in the consumer, industrial, medical, and oil and gas sectors to help them understand the technology and market landscape, decide their future strategy, solve the complex science and technology challenges and deliver commercially successful products.

## Salesforce

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### Partnering Suite 8

Salesforce helps the most innovative medical device companies deliver amazing customer experiences and support across all of the channels customers use and is driving a new era of connected, personalized medicine for the changing relationships between life science companies, providers and patients.

## SalesForce4Hire

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### Booth #556

SalesForce4Hire is a leading commercialization company that has helped medtech companies achieve dramatic results for nearly 20 years.

## SDL plc

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### Booth #117

SDL is the global leader in content creation, translation, and delivery. For over 25 years, we've helped life science companies deliver transformative business results by enabling experiences that engage researchers, members, and consumers across multiple touchpoints worldwide.

## Securisyn Medical

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### Innovation Pavilion, Booth #441

Securisyn Medical is actively solving the complications associated with airway management in ventilated patients. Our most-market ready device, the SolidAIRity™ III Airway Stabilization System, addresses unplanned extubation, the unintentional dislodgement of a patient's life-sustaining breathing tube, which costs \$4.9B and claims more than 33,000 lives each year in U.S. ICUs alone.

## Sidley Austin LLP

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### Sponsor

Sidley Austin LLP is a premier international law firm. Our food, drug and medical device regulatory, compliance and enforcement lawyers represent major pharmaceutical, biotechnology, medical device, food, dietary supplement, tobacco product and cosmetic companies in the U.S., the EU and Asia. Sidley has the only life sciences practice with a top-tier ranking across these three geographic areas. At the LMG Life Sciences Awards in 2017, Sidley won "Regulatory Firm of the Year" for the fifth year in a row.

## Siemens Health

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### Sponsor

At Siemens Healthineers, our purpose is to enable healthcare providers to increase value by empowering them on their journey toward expanding precision medicine, transforming care delivery, and improving patient experience, all made possible by digitalizing healthcare.

## Silicon Valley Bank

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### Sponsor

For more than 35 years, Silicon Valley Bank (SVB) has helped innovative companies and their investors move bold ideas forward, fast. SVB provides targeted financial services and expertise through its offices in innovation centers around the world. With commercial, international and private banking services, SVB helps address the unique needs of innovators. Learn more at [svb.com](http://svb.com).

## Simon-Kucher & Partners

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### Booth #309

Simon-Kucher's medtech practice is focused on supporting our clients with strategy, marketing, pricing, and sales topics. While we are proud to support 40 of the top 50 medtech and diagnostics companies, we also work with small- and mid-sized companies, including OEM suppliers and service companies for the healthcare industry.

## Smith & Nephew, Inc.

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### Booth #311

Smith+Nephew is a portfolio medical technology business that exists to restore people's bodies and their self-belief by helping them live their "Life Unlimited." Our employees deliver this mission every day through the excellence of our product portfolio, and the invention and application of new technologies across our global franchises of Orthopaedics, Advanced Wound Management and Sports Medicine/ENT.

## Softimize

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### Booth #152

# EXHIBITOR & SPONSOR Listing

## Soletics

### Innovation Pavilion, Booth #441

Soletics has developed thin temperature-regulating gloves to provide increased quality of life for sufferers of circulatory and connective tissue disorders. When a change in temperature is detected, the gloves automatically send out low levels of heat to the areas where needed in order to maintain a stable climate for the user.

## Starfish Medical

### Booth #262

## STERIS

### Booth #348

STERIS is a leading provider of infection prevention and other procedural products and services. Our MISSION IS TO HELP OUR CUSTOMERS CREATE A HEALTHIER AND SAFER WORLD by providing innovative healthcare and life science product and service solutions around the globe.

## Stryker

### Booth #217

Stryker is one of the world's leading medical technology companies and, together with our customers, is driven to make healthcare better. We offer innovative products and services in Orthopaedics, Medical and Surgical, and Neurotechnology and Spine that help improve patient and hospital outcomes.

## Sullivan & Cromwell LLP

### Sponsor

Sullivan & Cromwell LLP provides the highest quality legal advice to clients globally. The results the firm achieves have set it apart for 140 years and have become a model for the modern practice

of law. Today, S&C is a leader in each of its core practice areas and geographic markets.

## Sunrise Labs, Inc.

### Booth #446

At Sunrise Labs, our goal is your success. Employing optimized ISO-13485:2016 certified work processes, we deliver "best in class" medical device design and engineering expertise for all stages of product development. Our experts are passionate about applying technology to improve patient lives.

## Taiwan Tech Arena

### Booth #555

## TASK Micro-Electronics

### Booth #411

## TDK Corporation

### Booth #349

Sensors are a key growth area for TDK. TDK's sensor portfolio covers various applications such as consumer, industrial and medical imaging. TDK's picoTesla grade bio-magnetic sensors are based on a magnetoresistive (MR) element, derived from TDK's market-leading spintronics used in hard disc drives (HDD).

## Temple Health and Bioscience District

### Booth #109

The Temple Health and Bioscience District (THBD) is a city-supported, not-for-profit bioscience incubator located in Temple, Texas. THBD provides premier office and laboratory space for early-stage biotech companies that are taking health-related products from conception to manufacturing.

## Terumo BCT

### Sponsor

Terumo BCT is a mission-driven biomedical company focused on unlocking the potential of blood and cell-based therapies. The medical device company strives to advance patient care, broaden treatment options and improve patient outcomes through its technologies within the sectors of blood banking, transfusion medicine and regenerative medicine.

## Terumo Medical

### Sponsor

## The Alexander Group

### Booth #352

The Alexander Group has decades of experience aligning resources to grow revenue for global companies. For more than 30 years, The Alexander Group has provided management consulting services to the world's leading sales and marketing organizations. When clients need to grow revenue, they look to The Alexander Group for benchmarking, data-driven insights, actionable recommendations and, most importantly, results. The Alexander Group works with many of the largest healthcare companies to help them evolve their commercial lens in an ever-changing healthcare environment. The Alexander Group has a highly sophisticated set of best practices to grow revenue and a rich repository of industry data that informs our insights and recommendations. The Alexander Group's expertise ranges from strategy to execution and can help maximize sales coverage and sales training investments. To learn more about The Alexander Group's Healthcare practice and services, visit [www.alexandergroup.com](http://www.alexandergroup.com).



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## The Qt Company

### Booth #307

Qt software enables companies to create modern UI/UX on any platform including desktops, mobile, embedded, and wearables. Qt is the platform of choice for medical devices and is built into FDA and EU cleared devices sold today. Qt Safe Render is certified to IEC 62304:2006. To learn more, visit [qt.io](http://qt.io).

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## Theranica

### Booth #152

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## TikaMobile

### Booth #125

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## Toxikon

### Booth #325

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## Travelers

### Sponsor

Innovation can cause gaps in understanding, leading to gaps in protection. At Travelers, we've put years of experience with life sciences companies to good use, tailoring insurance products for this innovative industry. To learn more, contact Patty Nichols, life sciences practice leader, [pnichols@travelers.com](mailto:pnichols@travelers.com) or your independent insurance agent or broker.

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## University of Massachusetts

### Booth #410

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## University of Pittsburgh

### Booth #512

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## Vanderbilt University Center for Technology Transfer and Commercialization

### Booth #256

Vanderbilt University's Center for Technology Transfer and Commercialization (CTTC) manages, markets, and out-licenses intellectual property developed in the course of performing research and caring for patients at Vanderbilt University and the Vanderbilt University Medical Center.

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## Varian

### Patient Pavilion, Booth #128

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## Vectorious Medical Technologies

### Innovation Pavilion, Booth #441

Vectorious' V-LAP, the world's first in-heart microcomputer, provides accurate measurements of left atrial pressure (LAP), allowing physicians to manage heart failure on a non-emergency basis, improving quality of life while minimizing hospitalizations.

Using cutting-edge technology, the V-LAP sensory implant is the first digital, wireless, battery-free device that communicates from deep within the body. This allows physicians to make informed decisions and to provide heart failure patients with better treatment based on real-time clinical data and powerful AI algorithms.

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## Veeva Systems

### Booth #101

Veeva Systems Inc. is the leader in cloud-based software for the global life sciences industry. Committed to innovation, product excellence, and customer success, Veeva serves more than 750 customers, ranging from the world's largest pharmaceutical and medical device companies to emerging biotechs.

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## Velentium

### Booth #209

Velentium is a contract design and development engineering firm specializing in active implantables and their accessories. World-class expertise in systems design, embedded cybersecurity, electrical and mechanical development, firmware, software, mobile apps, cloud-based applications, test systems, prototyping and manufacturing (FDA manufacturer of record). We've implemented an ISO 13485 certified quality management system to create safe, effective, and compliant technical solutions.

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## Virtusa

### Booth #428

Virtusa Corporation (NASDAQ GS: VRTU) is a global provider of digital business transformation, digital engineering, and information technology (IT) outsourcing services that accelerate our clients' journey to their digital future. Virtusa serves Global 2000 companies in the banking, financial services, insurance, healthcare, telecommunications, media, entertainment, travel, manufacturing, and technology industries. © 2018 Virtusa Corporation. All rights reserved.

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## VivaQuant, Inc.

### Innovation Pavilion, Booth #441

VivaQuant is a digital health company providing remote cardiac arrhythmia monitoring services to clinics and hospitals. Key to our unique capabilities is our FDA-cleared wearable device that includes proprietary noise cancelling and artificial intelligence algorithms that result in high-clarity ECGs and reliable identification of arrhythmias.

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## Vonco Products LLC | Ligualoc

### Booth #648

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## Water Street Healthcare Partners

### Sponsor

Water Street is a strategic investor focused exclusively on healthcare. Its team specializes in collaborating with companies to accelerate growth and create greater long-term value. Over the past ten years, Water Street has built more than 30 market-leading companies. It is actively pursuing opportunities to invest in and grow medical technology companies.

# EXHIBITOR & SPONSOR *Listing*

## Wells Fargo

### Sponsor

Wells Fargo's Healthcare Corporate & Investment Banking team delivers a comprehensive suite of financial solutions to the healthcare industry. We have a dedicated team of experienced healthcare bankers that provide strategic advice, debt and equity underwriting, and corporate banking services to healthcare companies around the world. Visit [wellsfargo.com/healthcarebanking](http://wellsfargo.com/healthcarebanking) to learn more.

## Westwood & Wilshire

### Sponsor

Westwood & Wilshire is the premier executive firm for innovative growth medtech and digital health companies operating at the forefront of science, medicine and technology.

## Wiley Rein

### Sponsor

Wiley Rein is a dominant presence in Washington, DC, with more than 240 attorneys and public policy advisors. The firm has earned international prominence by representing clients in complex, high-stakes regulatory, litigation, and transactional matters.

## William Blair

### Sponsor

William Blair is the premier global boutique with expertise in investment banking, investment management, and private wealth management. We provide advisory services, strategies, and solutions to meet our clients' evolving needs. As an independent and employee-owned firm, together with our strategic partners, we operate in more than 20 offices worldwide.

## Ximedica

### Booth #253

Ximedica transforms bold ideas into life-changing innovations with 30 years of experience and hundreds of satisfied clients. Healthcare companies partner with Ximedica to strategize, design and develop medical devices and diagnostics because Ximedica is where the future is created. Your bold ideas. Our visionary team. Iconic results that change the world.

## XR Health

### Booth #152

## Zimmer Biomet

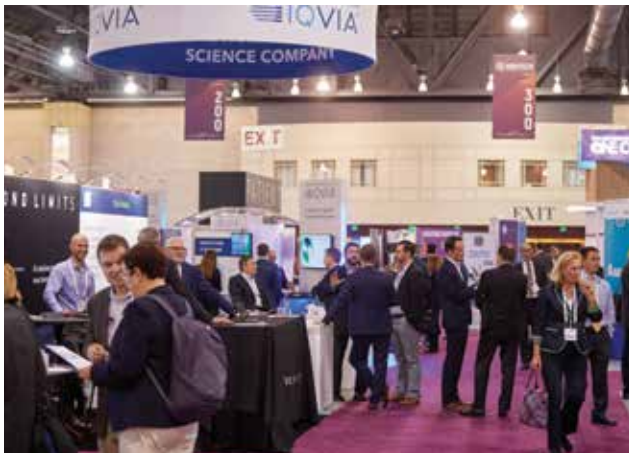
### Patient Pavilion, Booth #128

Zimmer Biomet designs and manufactures orthopedic and dental implants, biologics, spinal, craniomaxillofacial and thoracic products, and related surgical products. We manufacture products in 25 countries and sell products in more than 100. Together with healthcare professionals around the world we help millions of people live better lives. Visit [www.zimmerbiomet.com](http://www.zimmerbiomet.com) or [www.twitter.com/Zimmerbiomet](http://www.twitter.com/Zimmerbiomet).

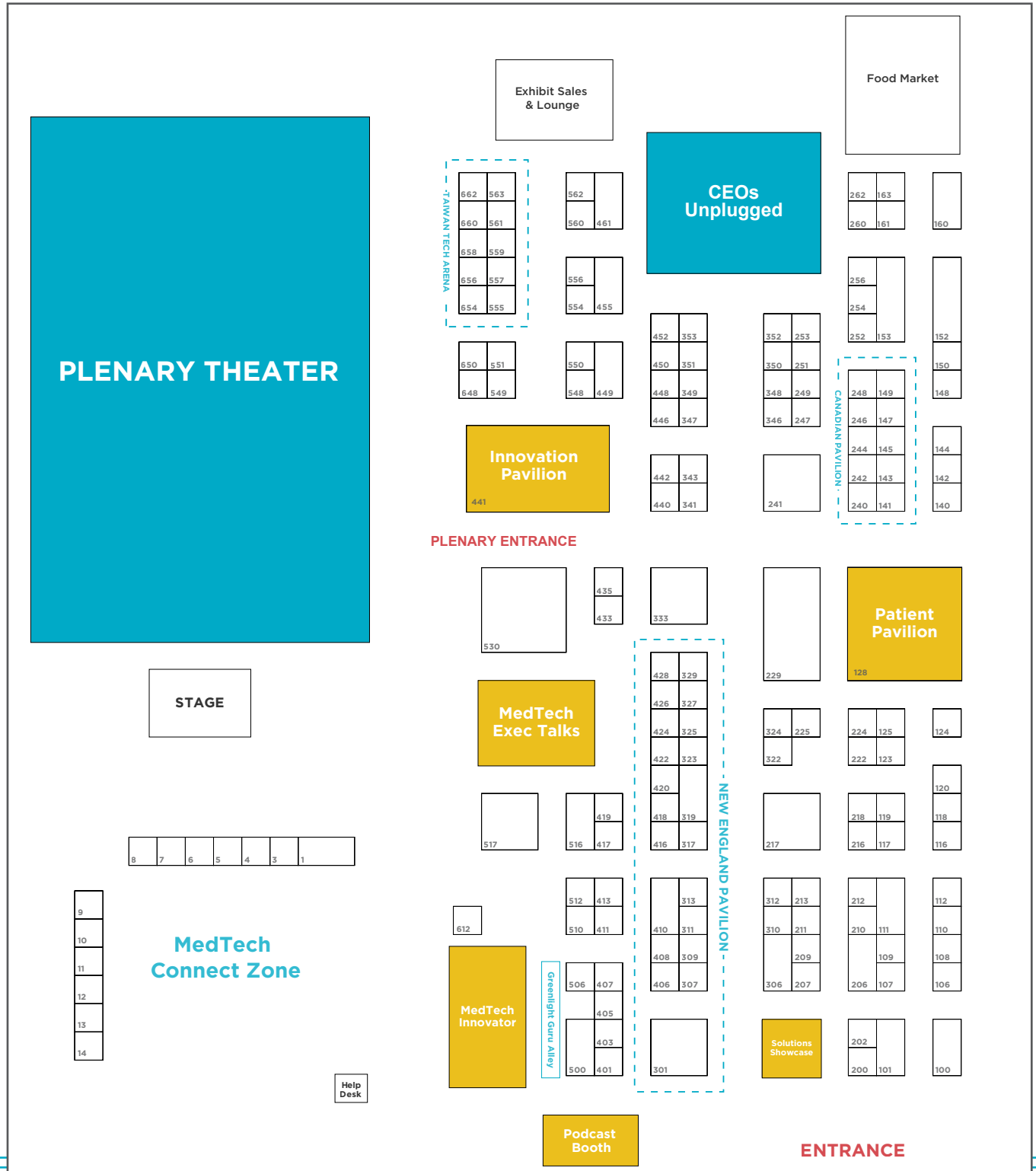
## ZS Associates

### Booth #353

ZS is a professional services firm that works side by side with companies to help develop and deliver products that drive customer value and company results. We leverage our deep industry expertise, leading-edge analytics, technology and strategy to create solutions that work in the real world.



# EXHIBIT HALL *Floor Plan*



# 2020 ONSITE *Space Selection*

Get a head start on The MedTech Conference 2020! Visit our sales office on the Exhibit Floor to discuss exhibit and sponsorship opportunities for next year.

» LOCATION:  
**EXHIBIT SALES & LOUNGE**

» HOURS  
**Tuesday, September 24**  
8:30 AM – 11:30 AM & 2:00 PM – 5:00 PM  
**Wednesday, September 25**  
8:30 AM – 11:30 AM



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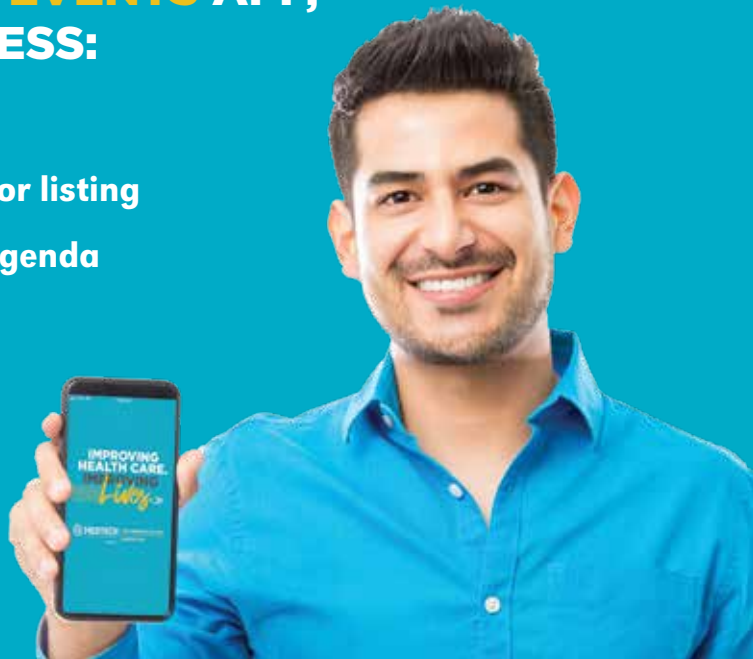
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**NOTE:** The Advamed Events app is separate from the MedTech Connect partnering app. To access the MedTech Connect partnering app, see page 126.

- » Exhibit floor plan
- » Complete exhibitor listing
- » Full conference agenda
- » Speaker listing
- » Sponsor listing



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# MEDTECH *Connect*

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To use the QR code, open your camera app and point your lens at the QR code.

Having issues downloading? Visit [themedtechconference.com/medtech-connect](http://themedtechconference.com/medtech-connect) for an app download link.

Use MedTech Connect to network with 3,000+ attendees of The MedTech Conference. MedTech Connect is provided to all Full Access attendees and is the go-to resource to help you find key stakeholders at the conference and request one-on-one meetings with them. Once meetings have been accepted, MedTech Connect does the scheduling for you based on mutual availability. Meetings will take place onsite in the MedTech Connect Zone (Hall B) and the Exhibit Hall (Hall B).

### Features include:

- Improved search capabilities
- The ability to build a more robust company profile
- Enhanced schedule management
- A unified company message center
- The benefits of company-to-company communication



Visit **[partnering.bio.org/MTC2019](http://partnering.bio.org/MTC2019)** to access MedTech Connect on your desktop.



**Email:** [medtechconnect@bio.org](mailto:medtechconnect@bio.org)

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### MEDTECH CONNECT ZONE (HALL B) HOURS:

Monday, September 23 | 8:30 AM – 3:30 PM

Tuesday, September 24 | 9:00 AM – 6:00 PM

Wednesday, September 25 | 8:30 AM – 12:30 PM

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### MEDTECH CONNECT HELP DESK:

Have questions onsite? Visit the MedTech Connect Help Desk in the MedTech Connect Zone to:

- Book last-minute meetings onsite
- Reschedule a meeting
- Print your meeting schedule
- Ask general questions



# AdvaMed

Advanced Medical Technology Association

**VISIT THE ADVAMED BOOTH (#229) FOR MORE INFORMATION ON:**

- » AdvaMed's Patient Portal
- » AdvaMed Advance
- » Updated AdvaMed Code of Ethics



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