THE MEDTECH CONFERENCE

Powered by AdvaMed

September 23-25, 2019

*Boston Convention and Exhibition Center* | Boston, MA

# Agenda as of August 25, 2019

**Pediatric Device Symposium**
**9/22/2019 | 8:00:00 AM - 5:00:00 PM | Room 052**
*On September 22, one day before The MedTech Conference, 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 The MedTech Conference attendees won't want to miss.*
*Learn more at www.pediatric-device-symposium.org*

**Registration Open and Badge Pick-Up**
**9/22/2019 | 12:00:00 PM - 7:00:00 PM | NE Lobby A (Level 1)**

**US Market Access Seminar**
**9/22/2019 | 12:30:00 PM - 5:00:00 PM | Room 156 C**

**International Reception**
**9/22/2019 | 5:30:00 PM - 7:30:00 PM | Legal Harborside**
*Mix and mingle with attendees from across the globe as we welcome you to Boston! All attendees are encouraged to attend our preconference reception at Legal Harborside (270 Northern Avenue, Boston, MA 02210). Enjoy iconic Boston fare, beautiful harbor views and great conversation.*
*Sponsored by Quebec*

**Registration Open and Badge Pick-Up**
**9/23/2019 | 7:00:00 AM - 6:00:00 PM | NE Lobby A (Level 1)**

**AdvaMed Accel Leadership Seminar**
**9/23/2019 | 8:00:00 AM - 1:00:00 PM | Room 052**
*The AdvaMed Accel Leadership Seminar provides insights into 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: Registration and Coffee***
***8:00 AM Welcome Remarks***

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

***8:15 AM De-risking MedTech Innovation by Investing in the Process Before the Product***

*Too many medtech startups 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.*

*Moderator: Paul Snyder, Vice President Healthcare, Write2Market*
*Scott Drake, President and CEO, ViewRay, Inc. (invited)*
*Benjamin Glenn, Partner, Shay Glenn LLP*
*Dev Kurdikar, President and Chief Executive Officer, Cardiac Science Corporation*
*Tiffany Wilson, CEO, Global Center for MedTech Innovation (GCMI)*

***9:15 AM Networking Break***

***9:30 AM Integrating Health Economics and Outcome Research Into the Product Development Cycle***

*The probability of reimbursement is a key factor in determining whether to proceed with a product during its development. Medical devices 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&D cycle.*

*Moderator: Deepak Sahu, Manager, Alira Health*
*Matt Benessere, Director, Global Market Access, Insulet*
*Arthi Chandran, Vice President and Head of WW Health Economics and Outcomes Research, BD*
*Martin Gold, Senior Director, Health Economics and Market Development, Integra LifeSciences*
*Maria Stewart, Global Vice President, Health Economics and Market Access, Boston Scientific*

***10:30 AM Networking Break***

***10:45 AM MedTech Innovator: Preliminary Competition and Execution Award***

*A select group of MedTech Innovator Semi-Finalists companies will pitch for the audience vote in the MedTech Innovator Execution Competition, presented to the company in the Accelerator Program that demonstrates the strongest execution plan and potential. The winner will 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 Regenesis 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.*

*Host: Paul Grand, Chief Executive Officer MedTech Innovator*

***11:45 AM Networking Luncheon - Sponsored by Medmarc***

***MedTech Innovator Execution Award Ceremony***

***Virginia Shimer Rybski Memorial Award***

*Presented by: Paul Grand, Chief Executive Officer, MedTech Innovator*
*George Ayd, Assistant Vice President, Business Development and Marketing, Medmarc*

***1:00 PM Adjourn***

**Medtech as IT**
**9/23/2019 | 8:30:00 AM - 9:00:00 AM | Room 156 AB**
*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."*

**MedTech Connect Partnering Open**
**9/23/2019 | 8:30:00 AM - 3:30:00 PM | Hall B**

**Revolutionizing the Silver Economy**
**9/23/2019 | 9:00:00 AM - 10:30:00 AM | Room 156 AB**
*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 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 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.*

**A Values-Based Approach to MedTech Business Integrity**
**9/23/2019 | 9:30:00 AM - 10:45:00 AM | Room 157 C**
*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 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*

**Articulating the Value of Diagnostics: Moving Toward Value Based Approaches**
**9/23/2019 | 9:30:00 AM - 10:45:00 AM | Room 156 C**
*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.*

**Case for Quality**
**9/23/2019 | 9:30:00 AM - 10:45:00 AM | Room 157 B**
*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.*

**The Business Value of Design: How Top Design Performers Create Twice the Value of Peers**
**9/23/2019 | 9:30:00 AM - 10:45:00 AM | Room 157 A**
*We all know examples of bad product and service design. The USB plug (always the third time lucky) or the experience of rushing to make your connecting flight at many airports. 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.*

*Great design, and the problem-solving approaches that produce it, have also made their way from the shop floor to the C-Suite where top teams are applying user-centered design methodologies to a range of business problems, from customer experience, to the experience of a manufacturing assembly worker. Until now, many business leaders have struggled to measure the true value of the design actions they are taking, or don't know where to prioritize. To help solve this problem, McKinsey undertook one of the largest and most rigorous research studies to date aimed at understanding which design actions are most closely tied to financial performance. The impact is significant.*
*In this session you'll learn more about the research findings and hear from a panel of experts on how leaders and organizations are deploying design against a range of business cases in MedTech. Attendees will walk away with a better understanding of the importance of design as a strategic differentiator and the types of actions they can take to capture this elusive prize.*

**Pediatric Innovation Framework – Working Meeting with FDA**
**9/23/2019 | 9:30:00 AM - 11:00:00 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.*

**Delivering Great Care and Technology Transformation in the World's Largest Integrated Health System**
**9/23/2019 | 11:00:00 AM - 12:15:00 PM | Room 157 B**
*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.*

**Efficiently Collect Real World Data: Industry, Policy, and Regulatory Perspectives**
**9/23/2019 | 11:00:00 AM - 12:15:00 PM | Room 156 C**
*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.*

**SME MedTech Innovations That Are Transforming Health Care in the US and Abroad**
**9/23/2019 | 11:00:00 AM - 12:15:00 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.*

**Value Based Proposed Rules**
**9/23/2019 | 11:00:00 AM - 12:15:00 PM | Room 157 C**
*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.*

**Welcome Lunch (East Registration)**
**9/23/2019 | 12:00:00 PM - 1:30:00 PM | East Registration**

**Health 2040: Medtech's Role in a Transformed Future**
**9/23/2019 | 12:15:00 PM - 1:30:00 PM | Room 156 AB**
*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 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.*

**Lessons and Learnings in LATAM Impacting MedTech Industry**
**9/23/2019 | 12:30:00 PM - 1:45:00 PM | Room 157 B**
*This two-part panel will explore Value Based Care public policy in Latin America. Part 1 will explore Value Based Care Public Policy which identifies the different needs in the health care systems, allowing the governments to develop public policies that support and promote VBC models taking into consideration sustainability, efficiency and strengthening of HCS in LATAM. Part 2 will expand the panel to explore Outcomes and Improvements, relaying success stories and best practices that demonstrate health outcome improvements in LATAM through VBC models.*

**US-China Relationship: From Cooperation to Confrontation**
**9/23/2019 | 12:30:00 PM - 1:45:00 PM | Room 157 C**
*The US - China relationship had been on a general cooperative trajectory for the almost 40 years – since Deng Xiaoping initiated "socialism with Chinese characteristics," and US 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.*

**Developing a Framework for Patient Input in Medical Device Clinical Trials**
**9/23/2019 | 1:00:00 PM - 2:00:00 PM | Room 157 A**
*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.*

**Using Data and Analytics to Demonstrate the Value of Diagnostics**
**9/23/2019 | 1:00:00 PM - 2:00:00 PM | Room 156 C**
*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.*

**AdvaMed's New Code of Ethics: Is Your Company Prepared to Comply?**
**9/23/2019 | 2:00:00 PM - 3:15:00 PM | Room 157 C**
*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 & 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 that will offer practical tips to get into compliance with only a quarter of the year left to prepare.*

**Chasing Value: Understanding How to Work with GPOs to Introduce New Health Care Innovation in the Supply Chain**
**9/23/2019 | 2:00:00 PM - 3:15:00 PM | Room 157 B**
*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 partnership and best practices will be explored in this highly informative session.*
***Want to learn more and talk to representatives from Intalere, 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.***

**The New World of 510(k)**
**9/23/2019 | 2:00:00 PM - 3:15:00 PM | Room 156 AB**
*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.*

**Exhibit Hall Open**
**9/23/2019 | 2:00:00 PM - 6:30:00 PM | Hall B**

**Establishing the Value of Your MedTech Innovation - It's Never Too Early**
**9/23/2019 | 2:15:00 PM - 3:15:00 PM | Room 156 C**
*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.*

**More Value for Patients & Society Through Data-Driven Health Care: US and International Perspectives**
**9/23/2019 | 2:15:00 PM - 3:15:00 PM | Room 157 A**
*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 healthcare in the US and in the Nordics. Finland's actual success in data integration and management has been used to build a revolutionary win-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 through global corporations, government and academia to learn and move to the next step of actual value from data driven health care.*

**Opening Plenary**
**9/23/2019 | 3:30:00 PM - 5:00:00 PM | Hall B, Plenary Theatre**

***State of the Industry***
*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.*

**Welcome Reception**
**9/23/2019 | 5:00:00 PM - 6:30:00 PM | Hall B**

**LGBTQIA+ Reception**
**9/23/2019 | 6:00:00 PM - 7:30:00 PM | Committee, 50 Northern Ave, Boston, MA 02210**
*You're invited to AdvaMed's inaugural LGBTQIA+ Reception! Come join us and other LGBTQIA+ medtech professionals at Committee Bar for drinks, light hors d'oeurves and networking.*
*This gathering is designed to provide you with opportunity to meet and connect with individuals from diverse medtech companies, spanning a variety of different functions and specialties in the industry. 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 at the MedTech LGBTQIA+ Reception as we look to foster new platforms for discussion of medtech and LGBTQIA+ issues.*

**MedTech Insight Awards***
**9/23/2019 | 6:00:00 PM - 10:00:00 PM | State Room, 60 State St, Boston MA**
*Make your mark at the Medtech Insight Awards, a prestigious evening celebrating and recognizing excellence among the companies, teams, and individuals driving positive change across the Medtech industry.*
*Held in partnership with 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 recognized achievements across the device and diagnostics industries, from technological innovations and partnerships, to emerging markets, to the more personal accomplishments of teams and individuals.*
*We are no longer accepting entries but there is still time to book your place - join distinguished leaders on the medtech and diagnostic industries from all corners of the globe who are nominating themselves or their colleagues for this prestigious recognition.*
*For more information and to book a table:*
*https://pharmaintelligence.informa.com/events/awards/medtech-insight-awards-2019*
***Separate registration required*

**Registration Open and Badge Pick-Up**
**9/24/2019 | 7:00:00 AM - 6:00:00 PM | NE Lobby A (Level 1)**

**Networking Breakfast Hosted by MedTech Color***
**9/24/2019 | 7:30:00 AM - 9:00:00 AM | Room 052**

**China Market Access Updates - Regulatory, Clinical, Reimbursement & IP**
**9/24/2019 | 8:30:00 AM - 12:15:00 PM | Room 157 A**
*China is the 2nd largest medtech market with 20% annual growth rate. The session will cover key China market access updates: NMPA (CFDA) Major regulatory and clinical affairs updates, IP reform, Reimbursement and their implications on overseas manufacturers.*

*China NMPA (CFDA):*
*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?*
*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?*
*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?*

**MedTech Connect Partnering**
**9/24/2019 | 9:00:00 AM - 6:00:00 PM | Hall B**

**Exhibit Hall Open**
**9/24/2019 | 9:00:00 AM - 6:30:00 PM | Hall B**

**MedTech Innovator Showcase - Cardiovascular**
**9/24/2019 | 9:15:00 AM - 9:45:00 AM | Hall B, 500 Aisle**

**Transformational Innovation: Delivering Outcomes, Fueling the Future**
**9/24/2019 | 9:15:00 AM - 10:00:00 AM | Hall B, 300 Aisle**
*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 5 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.*

**FDA's New Approaches to Software Regulation: Pre-Certification and Artificial Intelligence**
**9/24/2019 | 9:15:00 AM - 10:30:00 AM | Room 156 C**

*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.*

**Bridging Commercial and Military Market Needs to Advance Medical Device Development**
**9/24/2019 | 9:25:00 AM - 9:55:00 AM | Hall B, 500 Aisle**
*In any economy, R&D executives must maximize their resources in order to advance next generation medical technologies and product lines. The US 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.*

**Investor Trends in Medtech**
**9/24/2019 | 9:45:00 AM - 10:15:00 AM | Hall B, Innovation Pavilion (#441)**
*The number of innovations taking place at the intersection of medical devices and technology are 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.*

**Seeing is Not Always Believing – Tackling Legal Advertising Disguised as Medical Alerts**
**9/24/2019 | 9:45:00 AM - 11:00:00 AM | Room 157 C**
*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.*

**The New World of Medtech M&A Valuation: Strategies to Adapt and Thrive**
**9/24/2019 | 9:45:00 AM - 11:00:00 AM | Room 157 B**
*Continued strong sector fundamentals, improving end markets and new product launches and healthy pipelines has 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.*
*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?*

**MedTech Innovator Showcase - Vascular Solutions**
**9/24/2019 | 9:50:00 AM - 10:20:00 AM | Hall B, 500 Aisle**

**Preparing for Medical Device Cybersecurity in 2020**
**9/24/2019 | 10:00:00 AM - 10:20:00 AM | Hall B, 200 Aisle**
*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.*

**From Data to Data Science**
**9/24/2019 | 10:30:00 AM - 10:50:00 AM | Hall B, 200 Aisle**
*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.*

**Connected Ecosystems for Smarter Decisions**
**9/24/2019 | 10:30:00 AM - 11:00:00 AM | Hall B, 500 Aisle**
*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 professional 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.*

**MedTech Innovator Showcase - Oncology**
**9/24/2019 | 10:30:00 AM - 11:00:00 AM | Hall B, 500 Aisle**

**How Data Will Transform Patient Outcomes, Medtech and Practice of Health, Why It Hasn't Happened**
**9/24/2019 | 11:00:00 AM - 11:45:00 AM | Hall B, 300 Aisle**
*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.*

**It Takes a Village: How the Health Care Community is Working Together to Tackle Cybersecurity**
**9/24/2019 | 11:00:00 AM - 12:15:00 PM | Room 156 AB**
*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.*

**MedTech Innovator Showcase - Molecular Diagnostics**
**9/24/2019 | 11:05:00 AM - 11:35:00 AM | Hall B, 500 Aisle**

**Successful Elevator Pitches and Investor Interactions**
**9/24/2019 | 11:15:00 AM - 11:45:00 AM | Hall B, Innovation Pavilion (#441)4**
*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.*

**Diverse Perspectives on Developing and Deploying Digital Technologies**
**9/24/2019 | 11:15:00 AM - 12:15:00 PM | Room 157 B**
*The advent of technologies which 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.*

**Small Companies Selling Big Ideas to Huge Corporations**

**9/24/2019 | 11:15:00 AM - 12:15:00 PM | Room 157 C**
*What does it take for a startup to sell to corporate giants? The panel will examine ways for small size companies to pitch big ideas to hardly accessible clients. As commerce becomes more virtual and distances shrink, what are the new ways for small enterprise from the medtech and digital health industries to perform their larger peirs.*
*Through the analysis of success stories and failures, the panelists will discuss on what it takes to make it big when you're small.*

**Device Connectivity Platform as a Service: Build vs Buy, Accelerate Time to Market**
**9/24/2019 | 11:30:00 AM - 11:50:00 AM | Hall B, 200 Aisle**
*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 is help speed up go-to-market strategy. The idea of the discussion is to analyze, debate the pros & cons of such strategies.*

**MedTech Innovator Showcase - Neurotechnology**
**9/24/2019 | 11:45:00 AM - 12:15:00 PM | Hall B, 500 Aisle**

**Everyone Knows Health Care Is DOJ's Favorite Target; What Does That Mean for MedTech Executives?**
**9/24/2019 | 11:55:00 AM - 12:25:00 PM | Hall B, 500 Aisle**
*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*

**Plenary Lunch**
**9/24/2019 | 12:30:00 PM - 2:00:00 PM | Hall B, Plenary Theatre**

**Emerging Issues Regarding the HCPCS Coding Process for Medical Devices**
**9/24/2019 | 2:10:00 PM - 2:50:00 PM | Hall B, 500 Aisle**
*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.*

**MedTech Innovator Showcase - Chronic Disease Management**
**9/24/2019 | 2:15:00 PM - 2:45:00 PM | Hall B, 500 Aisle**

**Perfecting Partnership**
**9/24/2019 | 2:15:00 PM - 2:45:00 PM | Hall B, Innovation Pavilion (#441)4**
*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.*

**Leadership Views on Diagnostics**
**9/24/2019 | 2:15:00 PM - 2:55:00 PM | Hall B, 300 Aisle**
*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.*

**Going Viral: Best Practices in Social Media**
**9/24/2019 | 2:15:00 PM - 3:30:00 PM | Room 157 A**
*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 the 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.*

**Medtech, Look to Marketing for the Solution**
**9/24/2019 | 2:15:00 PM - 3:30:00 PM | Room 156 C**
*90% 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.*

**Pulse of the Industry 2019**
**9/24/2019 | 2:15:00 PM - 3:30:00 PM | Room 156 AB**
*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.*

**Global Markets; Where to Invest?**
**9/24/2019 | 2:15:00 PM - 3:45:00 PM | Hall B, 200 Aisle**

*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 14-minute power presentations outlining the investment incentives available in various regions of the world.*
*Oh, the places you'll go!*
*Schedule*
*2:15 p.m. Latin America*
*2:30 p.m. Costa Rica*
*2:45 p.m. Finland*
*3:00 p.m. India*
*3:15 p.m. Guangzhou*

**International Digital Testbeds: Perspectives on Partnerships and Organic Investment Models**
**9/24/2019 | 2:30:00 PM - 3:45:00 PM | Room 157 B**
*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.*

**Price Monitoring of Medical Devices in Brazil**
**9/24/2019 | 2:45:00 PM - 3:15:00 PM | Room 157 C**

**MedTech Innovator Showcase - Personalized and Precision Medicine**
**9/24/2019 | 2:50:00 PM - 3:20:00 PM | Hall B, 500 Aisle**

**Advancing Inclusion and Diversity**
**9/24/2019 | 3:05:00 PM - 3:45:00 PM | Hall B, 300 Aisle**
*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.*

**ANVISA – The State of Regulatory Efficacy at 20 Years**
**9/24/2019 | 3:15:00 PM - 3:45:00 PM | Room 157 C**
*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 it's policy prioritization of the use of international standards and practices toward this objective.*

**EtO Sterilization of Medical Devices: The Impact of Evolving Regulatory Requirements**
**9/24/2019 | 3:45:00 PM - 5:00:00 PM | Room 157 A**

*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.*

**MDR/IVDR - What Now?**
**9/24/2019 | 3:45:00 PM - 5:00:00 PM | Room 156 AB**
*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.*

**MedTech Innovator Finals**
**9/24/2019 | 3:45:00 PM - 5:00:00 PM | Hall B, Plenary Theatre**

**How Major New Players Are Challenging the Current Health Care Ecosystem**
**9/24/2019 | 4:00:00 PM - 5:00:00 PM | Room 157 C**
*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 disruptive change. The insiders of the health care ecosystem are monitoring these new players 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?*
*• As players in the health care ecosystem, should we embrace and welcome their new ideas?*
*• How can MedTech players collaborate with these corporations and form new partnerships to disrupt the dynamics of the ecosystem further?*
*• Will these new entrants leverage the experience of life sciences-focused players?*
*The panel will feature speakers from major new entrants in the health care ecosystem.*

**The Role of Diagnostics in Promoting the Health and Health Care of Women**
**9/24/2019 | 4:00:00 PM - 5:00:00 PM | Room 157 B**
*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, disproportionally or differently affect women.*

**AdvaMed Advance Meetup by Women's Executive Network**
**9/24/2019 | 5:00:00 PM - 6:00:00 PM | Hall B, 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.*

**Chairmen's Networking Reception**
**9/24/2019 | 5:00:00 PM - 6:30:00 PM | Hall B**

**MTC LIVE! (Formerly MedTech After Party)**
**9/24/2019 | 8:30:00 PM - 10:00:00 PM | Lawn on D**

**Networking Breakfast with Exhibitors Sponsored by Leavitt Risk Partner (Hall B1)**
**9/25/2019 | 8:00:00 AM - 9:00:00 AM | Hall B**

**Registration Open and Badge Pick-Up**
**9/25/2019 | 8:00:00 AM - 1:00:00 PM | NE Lobby A (Level 1)**

**Exhibit Hall Open**
**9/25/2019 | 8:00:00 AM - 2:00:00 PM | Hall B**

**Innovation, Regulation, and Adaptation: Emerging Legal Issues in Digital Health**
**9/25/2019 | 8:15:00 AM - 8:45:00 AM | Hall B, 500 Aisle**
*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:*
*(i) how the existing regulatory framework, from FDA and other governmental actors, will govern digital health technologies*
*(ii) 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.*

**Health Care Fraud: The Government View and the Compliance Perspective**
**9/25/2019 | 8:30:00 AM - 9:30:00 AM | Room 157 C**
*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.*

**Value Based Health Care in Action: Enhancing Patient Outcomes and Managing Costs**
**9/25/2019 | 8:30:00 AM - 9:30:00 AM | Room 157 B**
*Value Based Health Care in Action: Enhancing Patient Outcomes and Managing Costs*
*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 US 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 understand 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*

**MedTech Connect Partnering**
**9/25/2019 | 8:30:00 AM - 12:30:00 PM | Hall B**

**Beyond Silos: Fusing Digital Across the Enterprise**
**9/25/2019 | 9:00:00 AM - 9:30:00 AM | Hall B, 500 Aisle**
*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 US and UK 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.*

**MedTech Innovator Showcase - Critical Care**
**9/25/2019 | 9:15:00 AM - 9:45:00 AM | Hall B, 500 Aisle**

**Inspections and MDSAP**
**9/25/2019 | 9:15:00 AM - 10:30:00 AM | Room 156 C**
*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."*

**Personalized Medicine: Changing the Way We Think About, Identify and Manage Health**
**9/25/2019 | 9:15:00 AM - 10:30:00 AM | Room 157 A**
*Personalized Medicine is the ability to tailor medical treatment to reduce side effects and improve outcomes based on understanding the genetic makeup of an individual patient. Advances in molecular diagnostics and other diagnostic technologies, including data analytics, are the drivers that allow individualizing treatments to become reality. This session will feature leaders from diagnostic companies and drug developers to discuss the advances, challenges and future of personalized medicine.*

**Digital Transformation of the Medical Technology Market - the Disruptor or Enabler?**
**9/25/2019 | 9:45:00 AM - 10:15:00 AM | Hall B, 500 Aisle**
*The four main pillars of digital transformation of Medical Technology industry are Internal Operations Digitization, Care Delivery Digitization, Connected Device 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?*

**Solving the Addiction Crisis with Devices, and Mobile Health and Digital Therapeutics**
**9/25/2019 | 9:45:00 AM - 11:00:00 AM | Room 157 B**
*The addiction crisis results in 142,000 preventable deaths in the US annually with an associated cost of $340 billion. Of the 21.7 million Americans who should receive 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.*

**Strategic Use of Post Market Real World Evidence and Data Regarding Quality and Value**
**9/25/2019 | 9:45:00 AM - 11:00:00 AM | Room 157 C**
*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.*

**MedTech Innovator Showcase - Surgical Advancements**
**9/25/2019 | 9:50:00 AM - 10:20:00 AM | Hall B, 500 Aisle**

**Evolving Commercial Models In The New Health Care Ecosystem**
**9/25/2019 | 10:00:00 AM - 10:20:00 AM | Hall B, 200 Aisle**
*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 healthcare 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.*

**Essentials of Regulatory Digital Transformations**
**9/25/2019 | 10:30:00 AM - 10:50:00 AM | Hall B, 200 Aisle**
*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.*

**MedTech Innovator Showcase - Orthopedics**
**9/25/2019 | 10:30:00 AM - 11:00:00 AM | Hall B, 500 Aisle**

**Strengthening FDA's 510(k) Third Party Review Program: Streamlining the Process, Maximizing Patient Benefit**
**9/25/2019 | 10:30:00 AM - 11:00:00 AM | Hall B, 500 Aisle**
*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.*

**Global Regulatory Convergence – Emerging Trends and Future Opportunities**
**9/25/2019 | 10:45:00 AM - 12:00:00 PM | Room 156 C**
*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.*

**New Diagnostic Technologies are Transforming Testing**
**9/25/2019 | 10:45:00 AM - 12:00:00 PM | Room 157 A**
*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.*

**Mitigating Human Factors Risk**
**9/25/2019 | 11:00:00 AM - 11:20:00 AM | Hall B, 200 Aisle**
*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.*

**The Changing Payer/Provider Landscape: Opportunities for Medtech**
**9/25/2019 | 11:15:00 AM - 11:45:00 AM | Hall B, 500 Aisle**
*Transitioning to value based care models pose 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*

**Privacy, Ethics and Value in Digital Health**
**9/25/2019 | 11:15:00 AM - 12:15:00 PM | Room 157 C**
*Emerging and converging technologies are enabling wider-spread and more efficient collection and aggregation of familiar and novel data, and increasingly sophisticated analysis and use of data will supercharge the health care ecosystem. At the same time, privacy and ethical concerns are driving policymakers toward new constraints on the use of data that could inhibit the ability of technology developers and health care providers to improve patient care. Experts on the front lines discuss the political and business landscape and how medtech companies are navigating an uncertain environment.*

**What Do Hospital Administrators Really Want?**
**9/25/2019 | 11:15:00 AM - 12:15:00 PM | Room 157 B**
*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?*
*This panel will consist of a moderator and three or four HA leaders.*

*Why is this session appealing to attendees at The MedTech Conference?*
*Although the pace of consolidation has slowed, hospitals continue to evolve into larger health systems, including payers, outpatient clinics, specialty services, long-term care and physician owned practices. Especially significant is the joining of payers and providers, which will present a challenge to device makers in the future. Economic pressures will continue to grow in hospitals and will be passed down the chain to the medical device community. Collaborating with our HA customers to improve patient outcomes and reduce costs will become an essential part of our medtech strategies.*

**Phase Zero: How to be Resource-Efficient with New Product Opportunities**
**9/25/2019 | 11:30:00 AM - 11:50:00 AM | Hall B, 200 Aisle**
*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 in risk in the domains of technical functionality and product vision.*

**Lessons from a Legend**
**9/25/2019 | 11:35:00 AM - 12:20:00 PM | Hall B, 300 Aisle**
*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 proteges for an hour long fireside chat about the making of a truly legendary career and the lessons learned from it.*

**Plenary Lunch**
**9/25/2019 | 12:30:00 PM - 2:00:00 PM | Hall B, Plenary Theatre**

**CDRH Town Hall**
**9/25/2019 | 2:15:00 PM - 4:00:00 PM | Room 156 AB**
*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.*