

Medical Device Innovation in Maryland: from Technology to Lab to Market



Tuesday, March 7th
Jeong H. Kim Engineering Building
University of Maryland, College Park

#MDInnovation2017

8:00 AM	REGISTRATION		<i>University Technologies at the University of Maryland, Baltimore</i> James Hughes University of Maryland UM Ventures
8:30 AM	WELCOME William E. Bentley Robert E. Fischell Institute for Biomedical Devices Steve Pennington Maryland Department of Commerce		<i>University Technologies at Johns Hopkins University</i> S. Hassan Naqvi Johns Hopkins Technology Ventures
8:45 AM <i>Moderator:</i>	TRENDS & FUTURE TECHNOLOGIES IN MEDICAL DEVICES Kirsten Rieth RTI International <i>Cybersecurity & Medical Device Product Design</i> Gavin O'Brien National Institute of Standards and Technology (NIST) <i>Convergence of Medical Devices & Pharma</i> William E. Bentley Robert E. Fischell Institute for Biomedical Devices <i>Prosthetics & Robotics</i> Mike McLoughlin Johns Hopkins University Applied Physics Laboratory (JHUAPL) <i>Additive Manufacturing</i> Lex Schultheis Robert E. Fischell Institute for Biomedical Devices	11:15 AM <i>Moderator:</i>	STARTUP SUPPORT ORGANIZATIONS Bret Shreiber Maryland Department of Commerce <i>TEDCO</i> Neil Davis <i>BioHealth Innovation</i> Ethel Rubin <i>FastForward Innovations</i> Brian Stansky Johns Hopkins Technology Ventures <i>Maryland Development Center</i> Gil Blankenship
9:50 AM	NETWORKING BREAK: EXHIBIT TABLES	12:00 PM	NETWORKING LUNCH & EXHIBIT TABLES
10:20 AM	REGIONAL ECOSYSTEM RESOURCES AVAILABLE TO INDUSTRY <i>Snapshot of the Maryland Medical Device Innovation Ecosystem</i> Ursula Powidzki Maryland Manufacturing Extension Partnership (Maryland MEP) Kirsten Rieth RTI International	1:00 PM <i>Moderator:</i>	FUNDING SOURCES Arti Santhanam TEDCO <i>NIH Small Business Innovation Research (SBIR)</i> Rob Vinson National Institutes of Health (NIH) SBIR/STTR Program Office <i>Abell Foundation</i> David Wise <i>Epidarex Capital</i> Matthew Miessau
10:30 AM <i>Moderator:</i>	TECHNOLOGIES & FACILITIES Ursula Powidzki Maryland Manufacturing Extension Partnership (Maryland MEP) <i>Medical Device-Related Federal Labs in Maryland</i> Rob Griesbach Federal Laboratory Consortium (FLC), Mid-Atlantic <i>Facilities - NIST Facilities Available</i> Honeyeh Zube National Institute of Standards and Technology (NIST)	1:45 PM	NETWORKING BREAK: EXHIBIT TABLES
		2:15 PM <i>Moderator:</i>	SUPPLY CHAIN SUPPORT TO SCALE FOR MARKET Bob Storey The MVR Company

continued...

Medical Device Product Development

Jenny Regan
Key Tech

GMP Contract Manufacturing

Kevin Barnes
Harbor Designs

Manufacturing Extension Partnership (MEP) Services

Michael Kelleher
Maryland Manufacturing Extension Partnership (Maryland MEP)

3:00 PM

Moderator:

NAVIGATING THE REGULATORY ENVIRONMENT

Anita Nosratieh
Food and Drug Administration, Center for Devices and Radiological Health

Engaging with Payers and Health Systems

Sean Tunis
Center for Medical Technology Policy

Regulatory Advisory Services Programs for Startups

Steve Brooks
Brooks Medtech, LLC

3:30 PM

Moderator:

FINDING C-LEVEL LEADERS

Rich Bendis
BioHealth Innovation

Bob Storey
The MVR Company

Richard Huguen
Cellth Systems and Life Science Planning

4:00 PM

Moderator:

CALL TO ACTION

William E. Bentley
Robert E. Fischell Institute for Biomedical Devices

4:20 PM

TOUR OF A. JAMES CLARK HALL

5:15 PM

HAPPY HOUR NETWORKING EVENT

Looney's Pub of Maryland
8150 Baltimore Avenue, College Park, Maryland 20740

EXHIBITORS

Federal Laboratory Consortium (FLC)
Tom Brown

Food and Drug Administration
Technology Transfer
Whitney Hastings

Johns Hopkins Technology Ventures
S. Hassan Naqvi

Maryland Manufacturing Extension Partnership (MEP)
Michael Kelleher

Medical Technology Transfer Office,
U.S. Army Medical Research and Materiel
Command (USAMRMC)
Thomas Houze

National Institutes of Health (NIH) Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program Office
Patti Swayne, Rob Vinson

National Institute of Standards and Technology (NIST) Technology Partnerships Office
Honeyeh Zube

National Institutes of Health (NIH) National Heart, Lung, and Blood Institute (NHLBI) Technology Transfer
Michael Shmilovich

TEDCO
Neil Davis, Arti Santhanam

University of Maryland UM Ventures
James Hughes

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ROBERT E. FISCHELL INSTITUTE FOR BIOMEDICAL DEVICES

SPEAKER BIOS



Kevin Barnes
President, Harbor Designs and Manufacturing, LLC

Harbor offers turn key product design and contract manufacturing for commercial products and medical devices. Servicing clients with products at any phase of the product life cycle, Harbor will assist with initial concept research and development, mechanical and electrical engineering, launching and managing mass production, and exploring manufacturing efficiencies.



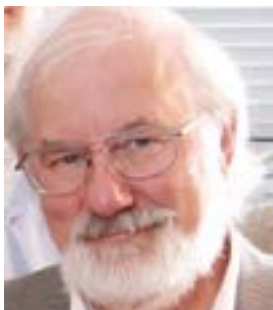
Richard Bendis
President & CEO, BioHealth Innovation, Inc.

Rich Bendis is an entrepreneur, corporate executive, venture capitalist, investment banker, innovation and technology-based economic development leader, international speaker and consultant in the technology and healthcare industries. He currently serves as the founding President and CEO of BioHealth Innovation, a central Maryland public-private partnership focused on accelerating the growth of commercially relevant science. He is also the founding President and CEO of Innovation America (IA), a national public-private partnership focused on accelerating the growth of innovation economy in America.



William E. Bentley
Director, Robert E. Fischell Institute for Biomedical Devices

William E. Bentley is Distinguished University Professor and Founding Chair of the Fischell Department of Bioengineering at the University of Maryland. At Maryland since 1989, Dr. Bentley has focused his research on the development of molecular tools that facilitate the expression of biologically active proteins, having authored over 270 related archival publications. Recent interests are on deciphering and manipulating signal transduction pathways, including those of bacterial communication networks, for altering cell phenotype. To enable discovery, his lab develops new strategies for opening 'communication' between devices and biological systems by the creation and facile assembly of biologically functional interfaces.



Gil Blankenship
Managing Partner & CEO, Maryland Development Center

Gil Blankenship is the Managing Partner and Interim CEO of the Maryland Development Center. In addition to his responsibilities at MDC, Dr. Blankenship is a Professor of Electrical Engineering at the University of Maryland, College Park, where he teaches courses in signal processing, control systems, and robotics. Dr. Blankenship has founded several high technology companies, including Techno-Sciences, Inc. (Maryland High Tech Company of the Year 2010, Deloitte Fast 500 2009-2011), the world leader in satellite aided search and rescue with installations in 30 countries.



Steven Brooks
Principal, Brooks Medtech, LLC

Steven Brooks is a multi-faceted health care consultant, publisher, cardiologist and clinical trialist. Steve's interests include regulatory strategy, scientific and medical due diligence, and medical technology commercialization. Currently, Steve is a principal in Brooks Medtech, LLC, as well as a Senior Analyst with Popper and Company, an Expert Consultant with NDA Partners. Previously, Steve served as a medical officer for the Food and Drug Administration in the Peripheral Interventional Devices Branch and Interventional Cardiology Devices Branches. In this role he performed medical device review of cardiac and vascular-related products throughout the full product lifecycle.



Neil Davis
Director of Entrepreneurial Development, Maryland Technology Development Corporation (TEDCO)

Neil Davis manages all of TEDCO's non-funding programs – the mid-PACE Program, the Executive Exchange Program, the Rural Business Innovation Initiative, the Maryland Entrepreneur Resource Listing, and all of TEDCO's educational efforts for its portfolio companies. Neil is also the Organization's liaison with the State's technology incubators, is part of the deal team for TEDCO's core seed funding programs, and is actively involved in creating new strategies designed to assist entrepreneurs. He brings more than 30 years of experience in engineering, business development, business consulting, and P&L management.



Rob Griesbach
Deputy Assistant Administrator, Office of Technology Transfer, U.S. Department of Agriculture, Agricultural Research Service (USDA-ARS)

Rob Griesbach earned a Ph.D. in genetics from Michigan State University in 1980. The following year, he joined USDA-ARS. Rob conducted a broad based research program in the plant genetics. He authored over 125 scientific papers and popular publications, and presented over 200 scientific seminars and popular talks. Rob currently is the Deputy Assistant Administrator for Technology Transfer. In this role, Rob coordinates programs to optimize the transfer of research results across USDA-ARS to the private sector and other users for development and commercialization.



Richard Hughen
Cellth Systems and Life Science Planning

Richard Hughen's 30 years of professional experience in the life science industry span three start-ups, a mid-cap and three Fortune 500 companies. He is currently CEO of Cellth Systems, a start-up based upon proprietary Circulating Tumor Cell (CTC) analysis technology. Ric's background crosses diverse clinical fronts including interventional pulmonology, thoracic surgery, interventional cardiology, gastroenterology, ENT, oncology, orthopedics, gynecology, wound care, molecular diagnostics and health-IT. He is founder of Life Science Planning, a strategic consultancy for life science companies with focus on fast paced start-up, early stage and emerging growth companies.



James L. Hughes
Director, UM Ventures

Jim Hughes is the Director of UM Ventures, a joint entrepreneurial initiative of the University of Maryland College Park and the University of Maryland, Baltimore (UMB). In this role, he is increasing technology commercialization and industry collaboration based on the \$1 billion in research conducted by the two Universities. As UMB's Vice President and Chief Enterprise and Economic Development Officer, he is responsible for UMB's Office of Research and Development, the Center for Global Health Initiatives, and the Center for Community-Based Engagement and Learning. Mr. Hughes is also president of the University of Maryland BioPark, which is developing a 12-acre, 2 million square-foot research park.



Michael Kelleher
CFO and COO, Maryland Manufacturing Extension Partnership (MDMEP)

As part of the national MEP network, the MD MEP provides programs and services for the manufacturing community within the State of Maryland. Mr. Kelleher has been with the organization from the beginning and has helped develop and build the relationships necessary to provide manufacturers with both the technical resources to solve problems and the business resources to enable growth. Mr. Kelleher has nearly twenty years of experience in consulting, accounting and organizational improvement and has led a successful management consulting firm as well as a startup pharmaceutical consulting group.



Michael P. McLoughlin
Chief Engineer, Research and Exploratory Development, Johns Hopkins University Applied Physics Laboratory

Mike McLoughlin is the Chief Engineer for the Research and Exploratory Development Department, Johns Hopkins University Applied Physics Laboratory. He is the Principal Investigator for the Revolutionizing Prosthetics Program (RP) and leads efforts to transition RP related technologies to clinical and nonclinical applications. During his career, he has focused on the rapid development and demonstration of transformative technologies for national security applications including: brain machine interfaces, neuroprosthetics, human integrated robotics, biomedicine and biodefense.



Matthew Miessau
Analyst, Epidarex Capital

Matthew Miessau is an Analyst at Epidarex Capital, an early-stage life science venture capital fund. Mr. Miessau joined Epidarex in 2014 and focuses on conducting due diligence on prospective fund investments as well as sourcing and analyzing opportunities for Epidarex's strategic investors. Mr. Miessau is also currently an instructor at the NIH Foundation for Advanced Education in the Sciences (FAES). Prior to joining Epidarex, he was the Program Manager for the Georgetown University Center for Drug Discovery. Mr. Miessau holds an M.S. in biotechnology and a B.S. in biochemistry from Georgetown University.



S. Hassan Naqvi
Associate Director, Physical Sciences and Licensing Compliance, Johns Hopkins Technology Ventures

Dr. Hassan Naqvi brings 12 years of experience in research and business. At JHU, he is responsible for leading a team focused on licensing and commercializing inventions from the Physical Sciences area as well as a group focusing on License Compliance. Prior to joining Johns Hopkins, he was at Vanderbilt University where he was responsible for the commercialization program for (i) Healthcare IT technologies; (ii) Precision Healthcare; and (iii) Vanderbilt Vaccine Center, and also oversaw licensing compliance activities for the institution. Hassan moved to Vanderbilt from the Cleveland Clinic where he focused on commercializing technologies in the diagnostic, therapeutic and device spaces.



Anita Nosratieh
Food and Drug Administration, Center for Devices and Radiological Health (CDRH) Innovation

Anita Nosratieh has a PhD in Biomedical Engineering from University of California Davis, with a background in medical physics. Her experience spans preclinical research, clinical trials and regulatory affairs. As a FDA/CDRH Lead Reviewer in the Office of In Vitro Diagnostics and Radiological Health, she primarily reviewed Class III mammography devices for breast cancer screening and diagnosis. She recently joined CDRH Innovation to work with outside stakeholders in the medical device ecosystem in order to expedite patient access to safe and effective medical devices.



Gavin O'Brien
Computer Scientist, National Cybersecurity Center of Excellence (NCCoE), National Institute of Standards and Technology (NIST)

Gavin O'Brien launched NCCoE's first health IT use case and, since early 2013, has been overseeing a use case for mobile device security. Prior to joining the NCCoE in 2012, Mr. O'Brien spent 13 years at NIST's IT Laboratory where he spent much of his time working on healthcare testing tools. While working with groups inside the Nationwide Health Information Network (NwHIN), he also participates as a monitor for the IHE USA North American Connectathon.



Steve Pennington
Managing Director, Business and Industry Sector Development, Maryland Department of Commerce

Steve Pennington carries extensive experience as a sales leader in the telecommunications industry, from start-ups to large national enterprises where he has led diverse sales teams targeting regional businesses and national accounts as well as teams focused on healthcare and public sector accounts. Throughout his more than 30-year career, Mr. Pennington led the sales and marketing efforts at a number of companies, including Americom Inc., USA Mobility Inc., Bay Broadband and Sprint.



Ursula Powidzki
Principal, Ursula Powidzki Consulting, LLC

Ursula Powidzki offers a strong history of operational leadership in a variety of organizational settings—with over 30 years of managerial experience in economic development and commercial real estate, as well as finance and investment management. Her leadership roles have spanned privately and publicly held firms, a not-for-profit organization and government. Ursula Powidzki Consulting provides advisory services dedicated to growing promising companies and strong regional economies, with robust connections to the region's technology entrepreneurs, organizations and universities.



Jenny Regan
CEO, Key Tech

Jenny is the CEO of Key Tech, a technology development firm she co-founded in 1998 in Baltimore. Key Tech consults to global product companies in medical, industrial and consumer markets, commercializing new technologies into medical devices and precision instruments. Recent Key Tech medical products include molecular diagnostic instruments, point-of-care diagnostics, drug delivery instruments, surgical tools and wearable patient monitors. Prior to Key Tech, Jenny consulted to global power industry clients for 14 years at MPR Associates in D.C. and at Corey Regan Inc., which she also co-founded.



Kirsten Rieth
Senior Innovation Advisor, RTI International

Kirsten has 29 years of experience working at the intersection of technology, industry, and economy. Her broad and varied experience ranges from developing and rolling out large-scale services and training programs to working with individual technologies to determine value proposition and market opportunity. She advises federal laboratories and governments, large and small companies, economic development organizations, universities, and nonprofit foundations on the best opportunities for their innovations.



Ethel Rubin
Entrepreneur-In-Residence, BioHealth Innovation
Entrepreneur-In-Residence, National Heart, Lung, and Blood Institute

Dr. Ethel Rubin is currently Entrepreneur in Residence for both BioHealth Innovation, which helps co-found and advise Maryland bio & med tech companies, and the National Heart, Lung, and Blood Institute Office of Translational Alliances and Coordination, which oversees business mentoring and activities for the SBIR and NIH Centers for Accelerated Innovation programs. Previously, Dr. Rubin oversaw global clinical strategy for Medtronic's cardiac ablation business, where she built a portfolio of investments in research propelling market expansion worldwide and partnered with commercial teams on over 10 new product launches for the Cardiovascular Group.



Arti Santhanam
Manager, Life Science Investment Fund, TEDCO

Dr. Santhanam manages life science investments at the Maryland Technology Development Corporation (TEDCO) for their Seed/Life Science Investment Fund and the Maryland Venture Fund. In her role, Dr. Santhanam leverages over 15 years of experience in life science research, and a multidisciplinary background, to manage all program elements including guidelines, review, policy and portfolio management, as well as providing guidance and resources to companies as they successfully move on to their next commercialization step. Prior to joining TEDCO, Dr. Santhanam was an independent KOL to early biotechnology start-ups in Maryland, public-private partnerships as well as federal agencies.



Bret Schreiber
Director, Education & Innovation, Maryland Department of Commerce

Bret Schreiber has worked for 20 years in the field of government and community relations, driving policy and economic development initiatives and developing strong ties to local, state and national legislators. As Director of Education and Innovation for the Maryland Department of Commerce, Schreiber works with Maryland's Colleges and Universities, and the State's innovators, entrepreneurs and startups to leverage their economic potential and impact on Maryland's economic vitality. Most recently, Mr. Schreiber was Director of Governmental and Community Relations for Harford County Md., and vice president of the Maryland Independent College and University Association (MICUA).



Lex Schultheis
Robert E. Fischell Institute for Biomedical Devices

Dr. Schultheis received his MD from the University of Pennsylvania, School of Medicine and his Ph.D. in biomedical engineering from Johns Hopkins University. He completed a residency and fellowship in anesthesiology and critical care medicine at Johns Hopkins Hospital. He has over twenty years of experience as practitioner, and clinical director. While continuing to practice medicine, Dr. Schultheis also served as a Medical Officer and Branch Chief at the Food and Drug Administration evaluating new drugs, devices and combination products. In the Fischell Department of Bioengineering, Dr. Schultheis works in collaboration with FDA to develop new scientific tools for regulatory review.



Brian Stansky
Director, FastForward

Brian Stansky is the Director of FastForward, Johns Hopkins' accelerator for the advancement and commercialization of innovations. Prior to joining Johns Hopkins, Brian was a Managing Director at Integral Capital Partners where he invested in late-stage venture and public equity securities of companies in the life sciences industries. Prior to joining Integral, he was a partner at ABACUS Investments LLC, a hedge fund specializing in the technology, media, and telecommunications industries.



Robert Storey
Principal, The MVR Company

Robert Storey is the Principal of The MVR Company, which focuses on the assessment and creation of new ventures, with a particular emphasis on medical technologies. He is currently Executive Chairman for OsteoVantage, a medical device company focused on novel instrumentation used in spinal fusion procedures, and Executive Chairman for Vixiar Medical, a company focused on the remote/non-invasive monitoring of chronic cardiopulmonary diseases and disorders. He concurrently serves as Executive in Residence for Johns Hopkins University, MD Anderson Cancer Center and the University of Maryland, supporting the development and commercialization of medical and engineering technologies. He is the Johns Hopkins advocate for medical device and engineering investment submissions to the Maryland Innovation Initiative, and serves as the lead instructor for the MD Anderson innovation program at the Texas Medical Center in Houston.



Sean Tunis
President and Chief Executive Officer, Center for Medical Technology Policy (CMTP)

CMTP is an independent, non-profit organization that provides a neutral platform for multi-stakeholder collaborations that promote high value innovation by improving the quality, relevance, and efficiency of clinical research. Through September of 2005, Dr. Tunis was the Director of the Office of Clinical Standards and Quality and Chief Medical Officer at the Centers for Medicare and Medicaid Services (CMS). He also served as the Director of the Health Program at the Congressional Office of Technology Assessment and as a health policy advisor to the U.S. Senate Committee on Labor and Human Resources. Dr. Tunis serves as Vice-President of Health Technology Assessment International, a member of the Health Sciences Policy Council for ISPOR and on several other public and private governing and advisory boards.



Robert Vinson
Program Manager, National Institutes of Health (NIH) SBIR/STTR Program, Office of Extramural Programs (OEP), Office of Extramural Research

Robert Vinson is responsible for providing resources to Federal staffers and access to critical information for the small business community seeking early-stage Federal funding. His duties include serving as the primary Contracting Officer's Representative for the NIH Niche Assessment Program and secondary for the Commercialization Accelerator Program. These programs provide technical assistance, market analysis, and commercialization guidance for NIH SBIR/STTR Phase I and Phase II awardees. Rob is also the OEP Task Manager for the NIH Performance Outcomes Data System.



David Wise
Venture Advisor, Abell Foundation

With Abell Foundation, David Wise has been involved in late seed and A round investments in numerous medical device companies, as well as working to help bring medical device manufacturing capability into Baltimore. He is also the CEO for vaccine delivery technology startup Pharos Biologicals, LLC, which holds a range of licenses from Johns Hopkins University. Wise came to Abell after a thirty year career as a business executive, most recently as the CEO of The Genetics & IVF Institute (GIVF) in Fairfax, Virginia.



Honeyeh Zube
Senior CRADA and License Officer, Technology Partnerships Office, National Institute of Standards and Technology (NIST)

Honeyeh Zube works with NIST investigators and with external organizations to develop projects, and to negotiate Cooperative Research Agreement and Development Agreement (CRADAs), patent licenses and other technology transfer agreements. Honeyeh joined NIST in 2013, after working as a technology transfer specialist at the National Cancer Institute, an institute within the National Institutes of Health, under the Cancer Research Training Award program.

NOTES
