From Lab to Life: Field Based Applications of Micro- and Nano-systems
Dr. Ian White

On March 10, 2014, the Mid-Atlantic Micro-Nano Alliance (MAMNA), in partnership with the University if Maryland, and with financial support from the Maryland Center for Excellence in Regulatory Science and Innovation (M-CERSI), hosted its annual symposium. The symposium was hosted at the University of Maryland BioPark in Baltimore, MD. The symposium was designed to emphasize regulatory challenges and opportunities in the fields of micro and nanosystems, in particular those related to bringing technologies out of the central lab and into the field. A total of 87 participants registered (it is estimated that over 80% of registrants attended at least a portion of the symposium), including 23 from industry, 31 from universities, and 33 from federal research labs or federally affiliated labs. Included among the registrants were 15 from the FDA. The symposium featured eight invited speakers, including speakers from the FDA, local startup companies, federal laboratories, and universities. In addition, two tutorials were provided: (i) a tutorial on the FDA approval process by an industry consultant and (ii) a tutorial on the regulatory issues of human factors engineering from a local research institution. The symposium also featured a poster session with dozens of research posters. During the poster session, a career networking session was held in order for attendees to learn about local companies and institutions.

Included in this report are the following documents:

- Text of the welcome letter distributed to attendees.
- Biographies of the invited speakers.
- Symposium schedule.

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Welcome Letter

Dear Colleague:

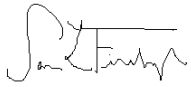
Welcome to the 2014 Mid-Atlantic Micro/Nanosystems Alliance Symposium, *From Lab to Life: Field Based Applications of MEMS & NEMS*. In the tradition of our annual symposia, this meeting aims to bring together the micro/nano community from the Mid-Atlantic region, including academicians, federal researchers, entrepreneurs, and established members of the micro/nano industry. Unique to this year's symposium, we have received support from the University of Maryland's Center for Excellence in Regulatory Science and Innovation (M-CERSI), a research center funded by the U.S. Food and Drug Administration. Through this partnership, we are emphasizing regulatory challenges and opportunities in the fields of micro and nanosystems, in particular those related to bringing technologies out of the central lab and into the field.

While participating in the symposium, we encourage you to consider the benefits of taking an active role in the Mid-Atlantic Micro/Nanosystems Alliance. Our organization is continually adding steering committee members. Those who serve on the steering committee have the opportunity to shape the Mid-Atlantic micro/nano community while forging professional relationships with companies, universities, and organizations that can add value to what you do. If you are interested in pursuing a role in the steering committee, please contact any of the steering committee members at the symposium, including your hosts.

Sincerely,

Ian M. White
Assistant Professor
University of Maryland

Brian Jamieson
President
S & B Microsystems



Samara Firebaugh
Professor
U. S. Naval Academy

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Invited Speaker Biographies

Patrick Lu, PhD
President and CEO
Sirnaomics, Inc.
"Development of Three Generations of Nanoparticle Carriers for Novel siRNA Therapeutics"

Dr. Patrick Y. Lu, the founder, President and CEO of Sirnaomics, Inc., has 25 years of biomedical research and 20 years of biopharmaceutical industry experience in molecular pharmacology specialized in nucleic acid delivery and therapeutics. Patrick has instrumentally built the senior management, consolidated key IPs, obtained funding and established R&D team at its headquarter located in Gaithersburg, Maryland (since 2007). Sirnaomics currently has also established subsidiaries in Suzhou Biobay and Guangzhou Bioisland, China. Prior to Sirnaomics, he was the co-founder and executive vice president of Intradigm Corporation (Rockville, MD, 2001-2006). During his tenure in Intradigm, Patrick led a strong R&D team building a significant IP portfolio, raised funding and established partnerships with large pharma and biotech companies. Before becoming an entrepreneur, Patrick served as lab head and senior scientist in Novartis and Digene. Patrick's leadership is also reflected through the founding of two influential Chinese American professional organizations, CBA and UCAPO, in which he has served as president. Patrick received his B.S.(1981), M.S.(1984) and Ph.D. (1987) from Sun Yat-sen University, China and completed his postdoctoral training in University of Maryland at College Park (1990) and Georgetown University Medical School (1992).

Andy DeHennis, PhD
Engineering Manager
Senseonics
"Implantable Wireless Sensor Development: Benchtop Modulation Through Clinical Evaluation"

Andrew David DeHennis was born in Philadelphia, PA. In 1997 he received a BS in Physics with Departmental Honors from Millersville University. After graduation, he was lead software engineer in the development of a patented package dimensioning, bar code scanning, and tracking conveyor belt system at Metrologic Instruments, Inc. (now Honeywell Scanning and Mobility). Returning to academia in 1999, he earned his MS degree in 2001 and Ph.D. degree in 2004 in Electrical Engineering from the University of Michigan, Ann Arbor. His thesis work focused on the development and integration of bulk and surface micromachined sensors that were monolithically integrated with wireless interface circuitry. Applications for these sensors ranged from environmental monitoring to intra-cranial pressure and intra-arterial flow transduction. In 2004, he joined Senseonics, Incorporated (formerly Sensors for Medicine and Science, Inc.), where he is currently Engineering Manager. His teams work focuses on the development of a long term, human implantable, wireless, continuous glucose monitoring system (CGMS) with a "grain-of-rice" sized sensor along with a wearable, external transceiver system. Realizing this unique and challenging system has required advances and innovation in RF materials, micro-assembly and packaging, sensor/circuit integration, ASIC design, as well as real time in-vivo calibration means and algorithm development. He is the lead R&D engineer working to progress the CGMS sensor platform through the FDA approval process in moving towards commercialization.

Jack A. Kent, MBA, MPH, RAC
Blue Crab Consulting
"Navigating FDA for Novel Micro/Nano Technologies"

Mr. Kent is the Founder and Principal Consultant at Blue Crab Device Consulting. The focus of this proprietorship is to assist start-up companies navigate the complex regulatory environment surrounding medical devices. In addition to improving health care delivery on a broad scale, Mr. Kent

hopes to foster economic growth in Maryland through the development of novel technologies. To this end, he studied innovation and entrepreneurship at Johns Hopkins University, earning two masters degrees (in business and public health). Mr. Kent previously served as Managing Director, Innovative Healthcare Products, at Becker & Associates Consulting, a boutique regulatory consulting firm located in Washington, D.C. Mr. Kent's activities include analysis of complex regulatory challenges and regulatory strategy for innovative products, preparation of regulatory submissions, assistance with preclinical and clinical programs, assistance with defining and planning for unique FDA approval pathways, preparation for FDA meetings and Advisory Panels, postmarket product stewardship, and due diligence for investments and acquisitions. Prior to Becker, Mr. Kent conducted circadian rhythm research at the University of Maryland School of Medicine using extracellular multi-electrode array recordings of neuronal organotypic cultures. Mr. Kent holds a B.S.E. in Bioengineering from the University of Pennsylvania, where his interests included tissue engineering and materials science.

Sarah Bergbreiter, PhD
Professor
University of Maryland, College Park
"Tiny Leaps for Robot Kind: Combining microfabrication and robotics"

Sarah Bergbreiter joined the University of Maryland, College Park in 2008 as an Assistant Professor of Mechanical Engineering, with a joint appointment in the Institute for Systems Research. She received her B.S.E. degree in electrical engineering from Princeton University in 1999. After a short introduction to the challenges of sensor networks at a small startup company, she received the M.S. and Ph.D. degrees from the University of California, Berkeley in 2004 and 2007 with a focus on microrobotics. She received the DARPA Young Faculty Award in 2008 and the NSF CAREER Award in 2011 for her research on engineering robotic systems down to sub-millimeter size scales. She has also received the Best Conference Paper Award at IEEE ICRA 2010 on her work incorporating new materials into microrobotics and the NTF Award at IEEE IROS 2011 for early demonstrations of jumping microrobots.

Dr. Hadar Ben-Yoav, PhD
University of Maryland
"Electorchemical Biosensor for Clozapine Antipsychotic Treatment Monitoring- A Step Toward Micro-Systems for Point- of- Care Monitoring in Mental Health"

Hadar Ben-Yoav is a post doctoral fellow at the MEMS Sensors and Actuators Lab (MSAL) in the Department of Electrical and Computer Engineering (ECE) at the University of Maryland (UMD). Hadar's research interests are in basic research of Micro and Nano systems incorporating engineering sciences with life sciences for health care, medical and environmental applications. Hadar received his B.Sc. degree (2004) in Physics and Biology, M.Sc. (2006) in Biotechnology and Ph.D. degree (2010) in Electrical Engineering from Tel-Aviv University, Israel. Dr. Ben-Yoav's research interests are in addressing fundamental scientific challenges related to the integration of biomaterials, micro-systems technology and biological systems. His ultimate goal is to explore and develop the next generation of functional bio-chemical analytical micro- and nano-devices for unconventional biological environments to investigate scientific questions in basic research, diagnostics and therapeutics with the aim of identifying, monitoring, and treating neurological diseases. During his M.Sc. degree, he studied the antimicrobial activity of silver-glucose oxidase hybrid on microbial biofilms. His Ph.D. thesis was focused on development of electrochemical low profile whole-cell biochips. He joined MSAL in April 2011 and is primarily involved in the fundamental investigation, design, system-level integration and development of novel portable micro-devices in the research area of Mental Health Treatment Analysis. Dr. Ben-Yoav has published over 21 peer-reviewed journal papers and a book chapter, presented over 30 posters and lectures, and been awarded a US patent. He has reviewed for over 17 engineering and electrochemistry

journals, and he is currently an active member at the Electrochemical Society (ECS) and the International Society of Electrochemistry (ISE).

Jikun Liu, PhD
United States Food and Drug Administration
"Developing a new Point-of-Care Tests for Rapid and Sensitive Detection of Pathogens Using Nano-Micro Technologies"

Jikun Liu is an ORISE research fellow at the Laboratory of Molecular Virology (LMV) in the Center of Biological Research and Evaluation (CBER) at the Food and Drug Administration (FDA). He completed his Ph.D. study (2006) in Analytical Chemistry at Brigham Young University, Provo, Utah, USA after finished his M.S. (2000) and B.S. (1997) education in Chemistry from Sichuan University, Chengdu, China. Before joining FDA/CBER/LMV, he received a postdoctoral training at MEMS & Microfluidics Laboratory (MML) in the Department of Mechanical Engineering at the University of Maryland College Park. Dr. Jikun Liu authored and co-authored over 20 publications on peer-reviewed journals in the area of analytical separations, polymer surface modification, biosensing and lab-on-a-chip technology. His current research interests include development of low-cost point-of-care diagnostic platforms for rapid and sensitive detection of pathogens in various settings combining nanotechnology, polymer microfabrication and novel materials, and application of recently emerging highly sensitive biosensing techniques, nanomaterials and microarray-based technique to disease diagnosis and biomarker discovery.

Kevin Lorick, PhD
United States Food and Drug Administration
"Classification and Marketing of Devices Outisde of a Traditional Setting"

Kevin Lorick holds a Bachelor of Science in Biological Chemistry from the University of Chicago and a Ph.D. in Molecular and Cellular Biology from Tulane University where he studied disruption of retinoic acid signaling pathways by Dioxin and related environmental contaminants. His Post-doc was at NCI in Bethesda where he discovered that RING finger proteins act as Ubiquitin-protein ligases. He worked in Industry as a Synthetic Organic Chemist, Cell Biologist, Director of Experimental Design, Small Business Entrepreneur. Currently he is at FDA' Center for Devices and Radiological Health in the Office of In Vitro Diagnostics and Radiological Health

- *Regulatory Scientist*
- *Consumer Safety Officer*
- *Member of Specialty Task Group on Nanotechnology*
- *Co-Director of CDRH/FDA Nanotechnology Reviewer's Network*

Teresa Croce, Ph.D
(unfortunately Dr. Croce was unable to attend after a weather driven schedule change)
United States Food and Drug Administration
" FDA's Regulation of Nanotechnology in Food Ingredients"

Teresa Croce joined FDA in 2010 as a Consumer Safety Officer in the Division of Petition Review where she is responsible for managing and coordinating the scientific and safety review of food additive and color additive petitions. She serves as a representative to FDA's Nanotechnology Task Force and recently completed a 120-day detail as a Project Manager in the Office of the Chief Scientist at FDA focusing on nanotechnology regulatory science research coordination across the agency. In that capacity, she was responsible for the management and oversight of the nanotechnology regulatory science program to

help support the responsible development of nanotechnology in products regulated by FDA. Prior to joining FDA, Dr. Croce earned a PhD in chemistry from Vanderbilt University where she designed and synthesized polymeric drug delivery systems.

Vicki R. Lewis, Ph.D
Scientific Director, National Center for Human Factors Engineering in Healthcare
MedStar Health Research Institute
"Incorporating Human Factors Engineering into Your Product Life Cycle"

Vicki R. Lewis, PhD, is the Scientific Director for MedStar Health's National Center for Human Factors Engineering in Healthcare. Dr. Lewis came to the Center from a Healthcare Research Scientist position in the Grado Department of Industrial and Systems Engineering at Virginia Tech, where she applied her background in Human Systems Integration (HSI), human-factors engineering, safety, training, and user interface design to the healthcare field. Dr. Lewis has almost 20 years of experience conducting human factors and safety engineering research and previously served as Director of the Center for Vehicle-Infrastructure Safety at Virginia Tech. While there, Dr. Lewis conducted a program applying the HSI philosophy to issues, such as driver fatigue, driver distraction, and evaluation of in-vehicle information and warning systems. She has received more than $18 million as a Principal Investigator (PI) and $5.5 million as a Co-PI in research sponsorship from federal, state, and industrial sponsors. Dr. Lewis is a seasoned leader and program manager. Prior to her work at Virginia Tech, Dr. Lewis developed training systems for the Federal Aviation Administration and the Occupational Safety and Health Administration and designed documents and computer interfaces for various applications and organizations. Dr. Lewis received her PhD in Industrial and Systems Engineering/Human Factors Engineering from Virginia Tech in Blacksburg, and Bachelors and Masters degrees in Psychology from the University of Idaho. She has published more than 90 scientific articles, technical reports, and book chapters, in addition to two transportation-related safety standards.

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Symposium Schedule

8:00 AM **Registration and Welcome Reception**

9:00 AM **Conference Plenary I: New micro/nanosystems technologies for field deployment**

Discover Auditorium

Development of Three Generations of Nanoparticle Carriers for Novel siRNA Therapeutics

Patrick Lu, Sirnaomics, Inc.

Implantable Wireless Sensor Development: Benchtop Modulation Through Clinical Evaluation
Andy DeHennis, Senseonics

9:45 AM **Break**

10:00 AM **Tutorial: Navigating FDA Novel Micro/Nano Technologies**
Discover Auditorium
Jack Kent
Blue Crab Consulting

MEMS/NEMS Platform Session
Invent Room

Tiny Leaps for Robot Kind: Combing Microfabrication and Robotics
Invited speaker: Professor Sarah Bergbreiter, University of Maryland

Analysis of Flapping Mechanism for Acoustically Actuated Microrobotics
Samara Firebaugh, United States Naval Academy

Integrated Silicon Optomechanical Transducers and their Application in Atomic Force Microscopy
Jie Zou, University of Maryland

Progress Towards a MEMS Tunable Infrared Filter using Porous Silicon
Dmity A. Kozak, Naval Research Laboratory

Point of Care Diagnostic Platform Session
Advance Room

Electrochemical Biosensor for Clozapine Antipsychotic Treatment Monitoring – A Step Towards Micro-Systems for Point-of-Care Monitoring in Mental Health
Invited speaker: Hader Ben-Yoav, University of Maryland

Developing new Point-of-Care Tests for Rapid and Sensitive Detection of Pathogens Using Nano-Micro Technologies
Invited speaker: Jikun Liu, US Food and Drug Administration

Spatial and Spectral Multiplexing on a Planar Surface Fluorescent Immunoassay using Quantum Dots
Samantha Spindel, US Food and Drug Administration

Automated Droplet-on-a-Chip Platform for Chlamydia Trachomatis DNA Detection
Pornpat Athamanolap, Johns Hopkins University

MEMS Neural Probe with Aptamer-Based Sensing for In Vivo Molecular Detection
Emma Bigelow, Diagnostic Biochips, Inc.

11:30 AM **Break**

11:45 AM **Conference Plenary II: Regulatory Perspectives on Emerging Micro/Nanosystems for Field Deployment**
Discover Auditorium

Classification and Marketing of Devices Outside of a Traditional Setting
Dr. Kevin Lorick, US Food and Drug Administration

12:30 **Lunch**

1:30 PM **Tutorial: Incorporating Human Factors Engineering into Your Product Life Cycle**

Discover Auditorium
Andy Schaudt
MedStar Health Research Institute

Poster Session
Invent and Advance Rooms

3:00 PM **Poster Session (continued)**
Invent and Advance Rooms

Career and Networking Session
Invent and Advance Rooms

5:00 PM **Conclusion and Announcement of Poster Prize**