Tutorial 2: Sensor Commercialization: Critical Success Factors for Sensors Commercialization

Presenters:
Steven Walsh, PhD, Distinguished Professor Management of Technology and Entrepreneurship Strategy, Anderson School of Management, University of New Mexico
Dr. Juan Figueroa, Puerto Rico Science and Technology Trust

The objective of the Micro, Nano and Emerging Technology Commercialization Education Foundation (MANCEF) is to provide product developers with pragmatic, detailed and actionable information needed to be addressed in the design, development, manufacturing and test process to bring a product to the market with the focus on sensors and where possible, on the medical application of these devices/systems. This tutorial will present the latest approaches to overcoming the barriers to commercialization through effective design, engineering and manufacturing scalability. In addition to the presentations, this tutorial will feature a panel discussion to address key case study successes and failures and what innovative startup companies are doing to achieve success in sensors development.

Presentations will include:

Roadmapping for Commercial Success
Steven Walsh, PhD, Distinguished Professor Management of Technology and Entrepreneurship Strategy, Anderson School of Management, University of New Mexico

Technological Roadmapping was the first tool used to place technology in the strategy of a firm. Today there are at least three generations of Roadmaps. The first generation assists firms with known manufacturing technologies, units, dimensions and end projects. This traditional roadmapping technique has been used in the high-tech semiconductor world where this rapidly advancing technology has been using planar processing, microlithography, device integration and known products like memory, microcontrollers and smart power devices for decades. Second generation roadmaps were developed to assist firms in manufacturing realms where no single manufacturing technology was yet dominant. In this case, few industry standard products exist and even manufacturing measurables like line width and unit cells might be application specific. This was and in some application areas still is the case for MEMS and Nano Technology products. These techniques were used in the first MEMS and Top Down Nano Roadmaps of the late 1990’s and early 2000’s. Third generation roadmaps were designed for multiple root technologies-based products. Here there is not a simple “Moore’s Law” for semiconductor micro manufacturing and new technology product boundaries. Techniques here include developing a sigmoidal curve that will approximate the use of concepts such as TRLs (Technology Readiness Levels), MRLs (Manufacturing Readiness Levels) and new boundaries like the “Proactive Principal.” These techniques find utility in Medical applications and other industries. Here we will take time to discuss how to use the relatively well-known roadmapping tools to enable maximum value for a given application.

SBIR as a Source of Equity-Free Investments in Innovative Sensor Applications
Dr. Juan Figueroa, Puerto Rico Science and Technology Trust

The Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) program’s mission is to support scientific excellence and technological innovation through the investment of Federal research funds in critical American priorities to build a strong national economy. It is a federal government equity-free investment program where small businesses receive financial support, $100K to $250K, to determine the innovative technology proposed solution commercial viability, Phase I, followed by another round of investment for the development of a commercial prototype. This second round of investment, Phase II, ranges from ~$600K to $1M for two years; amounts vary according to the agency. To qualify for these funds the small businesses must have less than 500 employees, must be >51% US-owned by individuals and individually operated OR at least 51% owned and controlled by another for-profit business concern that is at least 51% owned and controlled by one or more individuals; all work must be performed in the US. The USA government stimulates private investments by absorbing the technical risks of new innovative technologies resulting from academic research and individual/organizations ingenuity. The SBIR (SBIR/STTR) provides an excellent vehicle to the sensors innovative community to develop new and commercially viable applications by reducing private investments risks. As new and challenging applications emerge for sensors it is important that human and financial capital risks be reduced to address market needs while creating jobs and wealth; SBIR provides the right vehicle to make this happen.

*Separate registration required
and failures and what innovative startup companies are doing to achieve success in sensors development. Our interactive panel will discuss the latest developments and will provide feedback and advice on viability to the pathway to commercialization. Don't miss this opportunity to address many issues on the topic of commercialization including barriers to the commercialization of sensor technology as well as the strategies to overcome these barriers.

The Process to Commercialize a Medical Device for Scale, Quality, Performance and Profit
David DiPaola, Managing Director, DiPaola Consulting
It is often mistaken that the commercialization process begins with a design, a lab prototype and experimental testing. So often entrepreneurs and companies come with design, prototype and validation in hand without a customer or an understanding of their needs, consideration for manufacturing and quality nor any evaluation of a supply base. This presentation challenges this thinking and presents an alternative process that starts with an idea accompanied by the end customer’s specifications, a thorough review of the method for manufacturing, definition of a quality plan and an understanding of your validation requirements at the component and device level. There should also be a consideration of your potential supply base and their capabilities. Furthermore, a plan should be developed for the path through the FDA approval process. Once this is complete, an iterative design is developed with a constant reassessment of performance, manufacturing, quality, validation and FDA approval. During the design phase, a core building block of technology should be developed such that it can be easily replicated in derivative products keeping as much of the design as possible the same (usually only the customer interfaces changing). This enables high volume production of identical components and features lowering cost. The resulting prototype is then closely representative of a production device that can then be fine-tuned through 2-3 design validations off tools capable of low volume production. Also in the design phase, testing is completed to understand the ranges in performance and failure as it relates to expected capability in materials, dimensions, manufacturing and environmental exposure. Scaling is then accomplished by adding capacity through tool replication and automation that is validated in the pilot phase with limited fine tuning. This process will be demonstrated through two case studies.

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4:00 - 6:00 pm Tutorial 6: Analytics at the Edge
Presenters:
David Goldstein, President & CEO, AssetLink Global LLC
The global technology landscape is volatile, shifting, and fast-moving. And when it comes to wireless connectivity, it seems like every day new, innovative technologies are being developed to improve the connections between people, systems, and things. The explosion in the number of connected equipment and wearables means more touch-points to monitor, manage, and monetize. With billions of new IoT edge devices projected to come online over the next decade, next-gen multi-band wireless standards are sure to surface that provide the throughput and capacity needed to manage the data needs on a massive and global scale. The ability to bake wireless "scalability", "future-proofing", and "sustainability" into the IoT solution will be increasingly difficult. This tutorial will discuss strategies to improve timely access to large volumes of data, to improve actionable intelligence and predictive analytics.

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4:00 - 6:00 pm Tutorial 5: Overcoming the Pitfalls to Commercialization – Achieving Success through Effective Strategic Planning & Implementation
Presenters:
Roger Grace, President, Roger Grace Associates; Vice President Americas, MANCEF (Micro and Nanotechnology Commercialization Education Foundation)
David DiPaola, Managing Director, DiPaola Consulting
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Roger Grace, President, Roger Grace Associates; Vice President Americas, MANCEF (Micro and Nanotechnology Commercialization Education Foundation)
This session will feature a panel of experts to discuss key case study successes and failures and what innovative startup companies are doing to achieve success in sensors development. Our interactive panel will discuss the latest developments and will provide feedback and advice on viability to the pathway to commercialization. Don't miss this opportunity to address many issues on the topic of commercialization including barriers to the commercialization of sensor technology as well as the strategies to overcome these barriers.

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For additional information regarding sponsorship and exhibit availability, please contact: Jon Stroup
Senior Manager, Business Development
781.972.5483 | jstroup@cambridgeinnovationinstitute.com
TUESDAY, DECEMBER 10

7:30 am Registration and Morning Coffee

Plenary Session

8:20 Chairperson's Remarks
Christopher Hartshorn, PhD, Program Director, Cancer Treatment & Diagnosis, National Institutes of Health; National Cancer Institute

8:30 Predictive Analytics in Digital Diagnostics for Management of Chronic Conditions
Rafael Carbunaru, PhD, Vice President R&D, Boston Scientific

9:00 Regulatory Considerations during Mobile Medical App Development for Commercial and Clinical Trial Use
Mike Benecky, Senior Director, Global Regulatory Affairs in Precision and Digital Medicine, GlaxoSmithKline

Mobile medical apps are defined as medical devices from their intended use. Mobile medical app regulation is health risk-based to balance patient safety and barriers to technological innovation. Medical device patient risk analysis is a critical prerequisite prior to sensor/app inclusion within a clinical trial. Key components of quality management systems for mobile medical apps include: software requirements/specifications, user acceptance testing, software postmarket surveillance, software version control, and medical device adverse event reporting.

9:30 Nanotechnology, MEMS, Microfluidics for Health 4.0: Hypermobility
Anita Rogacs, PhD, Head of Life Sciences Strategy and R&D, HP Labs

New imperatives of healthcare are focusing on prevention, personalization of diagnostics and treatment, and democratization, including access to everyone, anywhere, anytime at a low cost. The technology convergence in medicine is enabled by the powerful combination of microelectronics, microfluidics, advanced (bio)chemistry, distributed network, and data analytics.

10:00 Networking Coffee Break

10:30 Roundtable Discussions

TABLE 1: How Biosensors Can Address Global Health Challenges
Lisa Diamond, CEO, Pinpoint Science LLC

- Where can access to biosensor solutions save lives in the developing world?
- How can novel biosensor technologies contribute to fighting emerging pandemic threats?
- What new tools can be offered to consumers to monitor and diagnose their own health status?
- How do we best handle data collected from connected biosensors, protecting patient privacy while informing public health agencies?
- What new applications for biosensors are needed in veterinary medicine, agriculture and food safety?

Table 2: Power Solutions for Miniaturized Implants
Robert Rubino, Senior Director, Research and Development, Integer

- How can we improve power technology to make powered implants smaller and more convenient?
- What wireless power solutions are available?
- What new battery and capacitor solutions are available that enable smaller devices?
- What are the technical hurdles that these new technologies need to overcome and how do we get there?

Table 3: Mixed-Signal Application Specific Integrated Circuits (ASICs): Advantages, Challenges, Justification, and Strategies
Andrew Kelly, BSEE, Director of Applications Engineering, Semiconductor Division, Cirtec Medical

- What advantages are offered by Application Specific Integrated Circuits (ASICs)?
- What are the primary challenges associated with an ASIC-based design?
- What are the most common applications that justify the challenges of an ASIC-based design?
- How do you approach the system/circuit partition when developing an ASIC-based design?
- What factors should be considered when deciding to either work with an ASIC supplier or develop an ASIC in-house?
- What are the most important factors when selecting an ASIC supplier?

Table 4: Overcoming the Challenges to Bringing Medical Devices to The Market
David DiPaola, Managing Director, DiPaola Consulting

- What were your biggest challenges bringing a medical device to market and what solutions did you implement?
- How were you able to expedite the FDA approval process and when in the development did you get the FDA involved?
- How do you recommend shortening the time to market for a medical device?
- What issues did you face in pilot production that were not identified in in the development stage and what steps did you take to address this?
- How did you incorporate manufacturing, test and dimensional measurement requirements into your design up front? What tools did you use?

Table 5: Advanced Materials
Stacey Standridge, PhD, Deputy Director, National Nanotechnology Coordination Office

- What advanced materials are you working with?
- What specific performance, cost, or other benefits are you targeting with these materials?
- What are the bottlenecks in deploying advanced materials in devices (e.g., technical performance, manufacturing scale, reproducibility, integration, standards, financial considerations)?
- What are potential mechanisms to address these bottlenecks?
- What lessons can be learned from prior technologies in evolution of scale, reproducibility, and quality control? Are there any new challenges that are unique to your advanced material?

Table 6: Sensors for Collaborative or Autonomous Systems: Challenges and Considerations
Tom Calef, CTO, Activ Surgical

What industries are exploring such systems and what can be learned from them? What sensor types and circuit architectures are well-suited for such systems? What factors should be considered when deciding to either work with a sensor supplier or develop in-house? What are current user-acceptance or regulatory/compliance challenges and successful case studies for overcoming them? How is data being collected, stored, and used in today’s learning models? What are the best practices for specific industries? What is required for these systems to take the next “big leap” into Level 3 autonomous behavior or beyond?

Next-Generation Wearable and Implantable Sensors

11:25 Chairperson's Remarks
Nick Van Helleputte, PhD, R&D Manager Biomedical Circuits & Systems, imec

11:30 Faults in Continuous Glucose Monitors: Cause, Effect, and Potential Solutions
Disha B. Sheth, PhD, Sr Staff Scientist, Manager, DexCom Inc.

Advancements in continuous glucose monitoring (CGM) - non-adjunctive use and zero calibrations - have been transformative for diabetes patients. Latest sensor technology and algorithms have resulted in sub-ten Mean Absolute Relative Differences (MARDs). However, there are some remaining difficult physiology related discrepancies. Complexity of immune responses, foreign body responses, patient to patient differences, and patch adhesion are
causing inaccuracies. Drug-eluting sensors, multi-sensing elements, and self-learning algorithms are some of the potential solutions to these faults.

**12:00 pm Connected-care and Companion Diagnostics using Cloth-Based Nanotechnology: From R&D to Clinical Utility to Commercialization**

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

The early days of Connected-Care R&D could not overcome necessary efficacy and safety requirements in sufficient time to live up to the hype for medical use. After nearly ten years, there are specific technologies, products, and therapeutic areas that have emerged from this challenging phase of R&D, proving their value clinically and improving patient lives from the comfort of their own home.

**12:30 Presentation to be Announced**

**1:00 Enjoy Lunch on Your Own**

### Next-Generation Wearable and Implantable Sensors (Cont.)

**1:55 Chairperson's Remarks**

*Nick Van Helleputte, PhD, R&D Manager, Biomedical Circuits & Systems, imec*

**2:00 Non-Invasive Biochemical Sensing: Breakthrough for Precision Medicine**

*Gavi Begtrup, PhD, CEO, Eccrine Systems, Inc.*

Today's non-invasive electronic health patches perform conventional measures like heart activity and body motion, while the medical field awaits continuous wearable sensing of chemical information like that found in blood draws. All this is now rapidly changing as sweat biosensing is targeting a first killer application in medication monitoring, enabling precision dosing through non-invasive, direct measurement of individual drug response.

**2:30 The Customer behind the Customer/Sensor Design for Patient Usability**

*Cavan Canavan, Co-Founder & CEO, FocusMotion Health*

In designing and implementing solutions, tech companies want to show off their bright shiny data, yet often forget the technology sophistication of the end user: the patient. Machine learning and millions of data points don't matter if we can't engage the patient or if we can't provide usable, actionable data for the surgeon or the hospital. How do we design to serve both customers?

**3:00 Advancing Continuous Glucose Monitoring Sensor Development with Machine Learning**

*Elaine Cao, PhD, Senior Principal Algorithm Development Engineer - Artificial Intelligence, Diabetes R&D, Medtronic*

A wearable continuous glucose monitoring sensor relies on an algorithm to convert sensor electrochemical signals into sensor glucose for the user. Development of a safe and reliable CGM requires large datasets to support sensor glucose algorithm development, optimization, and evaluation. Here we discuss using machine learning to leverage high-quality, time-dependent signals to improve sensor glucose accuracy in creating the next-generation CGM sensor.

**3:30 Refreshment Break in the Exhibit Hall with Poster Viewing**

**4:00 Tutorials**

**6:00 Welcome Reception in the Exhibit Hall with Poster Viewing**

**7:00 End of Day**

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**WEDNESDAY, DECEMBER 11**

**8:00 am Registration and Morning Coffee**

**Plenary Session**

**8:20 Chairperson's Remarks**

*Robert Rubino, Senior Director, Research and Development, Integer*

**8:30 Dexcom's Continuous Glucose Monitoring (CGM) Technology and its Impact on Diabetes Management, Artificial Pancreas, & Digital Health Systems**

*Peter Simpson, Vice President of Sensor R&D and Advanced Technology, Dexcom*

Recent advances in continuous glucose monitoring (CGM) technology have significantly increased its usability and impact on diabetes management. CGM’s are now widely reimbursed and are rapidly becoming the standard of care for people on intensive insulin therapy. This presentation will provide an overview of Dexcom’s CGM sensor technology, its use in digital health and artificial pancreas systems and a preview of our future products.

**9:00 Objective Measures for Clinical Assessment and Precise Understanding of Disease Progression**

*Christopher Harshorn, PhD, Program Director, Cancer Treatment & Diagnosis, National Institutes of Health; National Cancer Institute*

This talk will look at various efforts across the National Institutes of Health attempting to enable more objective measures for out-of-clinic, patient-specific assessment and longitudinal understanding of disease progression in large cohorts.

**9:30 Wearable Electrochemical Sensors – Recent Advances**

*Joseph Wang, Distinguished Professor & Chair, Nanoengineering, University of California, San Diego*

This presentation will discuss recent developments in the field of wearable electrochemical sensors integrated directly on the epidermis or within the mouth for various non-invasive biomedical monitoring applications. Particular attention will be given to non-invasive monitoring of metabolites and electrolytes using flexible amperometric and potentiometric sensors, respectively, along with related materials, energy and integration considerations. The preparation and characterization of such wearable electrochemical sensors will be described, along with their current status, future prospects, and challenges.

**10:00 Coffee Break in the Exhibit Hall with Poster Viewing**

**10:30 Roundtable Discussions**

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**Table 1: Miniaturization for Chemical and Biological Detection**

*Cory Bernhards, PhD, Research Microbiologist, CBR, Defense Threat Reduction Agency*

- How do you decide what to prioritize?
- Continuous improvement in sensitivity and specificity

**Table 2: Best Practices for AI, IoT, etc**

*Luisa Bozano, PhD, Manager, Nanoscale Fabrication Group, IBM Almaden Research Center*

- We hear about what's worked at conferences, but what about what hasn't worked?
- What standards do we like? What don't we like?
Table 3: The Small Business Innovation Research (SBIR) program and Small Business Technology Transfer (STTR) (Opportunity Available)

1:00 Enjoy Lunch on Your Own

1:25 Chairperson’s Remarks
Joshua Windmiller, PhD, MSc, Co-Founder & CTO, Biolinq, Inc.

1:30 PANEL DISCUSSION: The Medical Sensor Technologist’s Dilemma - Clinical or Consumer Sensor
Joshua Windmiller, PhD, MSc, Co-Founder & CTO, Biolinq, Inc.

Patient outcomes and standardization of care continue to benefit from smarter and sensor-enabled medical devices that provide real-time patient monitoring and device performance data. The challenge is selecting the right sensor, including deciding between consumer or clinical-grade sensors. This panel will evaluate the tradeoffs between these two sensor classes as the panelists tackle this dilemma.

PANELISTS:
- Tom Calef, CTO, Activ Surgical
- YuFeng Yvonne Chan, MD, PhD, Associate Professor & Director Digital Health, Genetics & Genomic Sciences & Emergency Medicine, Icahn School of Medicine at Mount Sinai
- Debbie Chen, PhD, Founder & CEO, Hydrostasis, Inc.

Clinical vs. Consumer Sensors

Table 4: Considerations for use of Sensor-measured Digital Endpoints during Drug Clinical Development

Mike Benecky, Senior Director, Global Regulatory Affairs in Precision and Digital Medicine, GlaxoSmithKline

- What further work needs to do to establish an "off-the-shelf" 510k cleared sensor device as a Digital Clinical Outcome Measure in a Pivotal Drug Study?
- What added value do digital sensors bring to the drug clinical development process?
- What are the regulatory challenges during utilization of a novel digital endpoint during a registrational drug clinical trial?
- What therapeutic areas appear most fertile for use of digital endpoints during drug clinical development

Table 5: Considerations for use of Sensor-measured Digital Endpoints during Drug Clinical Development

Mike Benecky, Senior Director, Global Regulatory Affairs in Precision and Digital Medicine, GlaxoSmithKline

- What will next generation physiological monitoring sensors and systems look like?
- What technologies will need to be developed to enable continuous (e.g., wearable) monitoring of additional, medically relevant, vital signs?
- Can raw data from existing sensors be used to infer other vital parameters using AI / ML approaches?
- Would there be a net gain from the consumerization of these new sensing modalities (cost versus benefit of resulting follow up / treatment)?
- What are the risks to the end-user, and can we think of approaches to mitigate them?

Ingestible and Insertable Sensors

1:55 Chairperson’s Remarks
Joshua Windmiller, PhD, MSc, Co-Founder & CTO, Biolinq, Inc.

2:00 Turning on the Lights - Improving Outcomes and Increasing Access with Digital Medicines
Jeremy Frank, PhD, Senior Vice President Digital Medicine, Digital Medicine, Proteus Digital Health

The cost of sub-optimal pharmacotherapy is immense - 125,000 lives and over $500 billion annually in the US alone. Poor patient adherence to prescriptions dominate that expense and current ineffective mitigation efforts do not address the fundamental root cause - the gap between physician expectation and patient behavior. The Proteus digital-medicine platform integrates medication with hardware, software, analytics and services to close that critical loop.

2:30 Advancing Diagnostics in Endoscopy: Quantifying Inflammation through Perfusion Sensing
George Duval, Principal Engineer, Endoscopy R&D, Boston Scientific Corp.

Inflammation is the root of a lot of digestive diseases like Ulcerative Colitis, Barrett’s Esophagus, and more. With today’s tools, gastroenterologists using direct visual observations are very subjective to interpretation. The desire to quantify inflammation objectively during an examination could mean improved patient outcomes and procedures. We have been researching a variety of sensing technologies that show promise in quantifying inflammation.

3:00 Ingestible and Insertable Technology for Advanced Monitoring of the GI System
Nick Van Helleputte, PhD, R&D Manager, Biomedical Circuits & Systems, imec

Globally metabolic health is dropping at an alarming rate. The human gastrointestinal system is a very complex system and actually rather accessible, certainly considering recent technological advances in sensing and miniaturization. This talk will focus on technological innovations needed to provide a holistic view of the human GI system in the form of ingestibles or minimally invasive insertables.

3:30 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 Tutorials

6:00 End of Day

10:30 Roundtable Discussions

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Inexpensive Materials for Biological Assays
cancer, utilizing the power of trained Deep Learning algorithms for near
review the use of state-of-the-art micro Raman spectroscopy sensing of
information for diagnosis and treatment evaluation. This presentation will
promising investigative and diagnostic tool that can assist in uncovering
progression and improve prognostic evaluation. Raman spectroscopy is a
the discovery of biomarkers that will enable better management of disease
Novel approaches toward understanding the evolution of disease can lead to
numerous diseases such as neurodegenerative diseases (Parkinsons,
Alzheimers, etc.), mental illnesses (depression, anxiety, etc.) or chronic
pain, brain augmentation, and research device.

8:35 PANEL DISCUSSION: Sensor Mergers & Acquisitions:
This panel discussion will examine the current landscape of mergers and
acquisitions with the sensors and device space. Our panel of experts will
discuss the current outlook within the marketplace and will examine past
success and failures and how the pitfalls of failure can be avoided.

12:30 Enjoy Lunch on Your Own
Market and the Path to Commercialization
1:30 How the Future of Sensing in Health Will Be Transformed with AI and 5G
John Mattison, MD, Assistant Medical Director, Chief Health Information Officer,
Kaiser Permanente; Faculty, Singularity University

Advanced Biosensor Design, Materials & Engineering
2:00 Sensors for Health Analysis from Exhaled Breath
Sterghios A. Moschos, PhD, Associate Professor in Cellular and Molecular
Sciences; Director of Research and Innovation; Director of Postgraduate
Research, Department of Applied Sciences, Northumbria University

9:25 Coffee Break in the Exhibit Hall with Poster Viewing
Advanced Biosensor Design, Materials & Engineering
9:55 Chairperson's Remarks
Marcie Black, PhD, CEO, Advanced Silicon Group
10:00 Micro Raman Sensing for Cancer Applications
Gregory Auner, PhD, Paul Strauss Endowed Chair; Professor, Department of
Surgery and Biomedical Engineering; Director, Smart Sensors and Integrated
Microsystems Program, Wayne State University
Novel approaches toward understanding the evolution of disease can lead to
the discovery of biomarkers that will enable better management of disease
progression and improve prognostic evaluation. Raman spectroscopy is a
promising investigative and diagnostic tool that can assist in uncovering
the molecular basis of disease and provide objective, quantifiable molecular
information for diagnosis and treatment evaluation. This presentation will
review the use of state-of-the-art micro Raman spectroscopy sensing of
cancer, utilizing the power of trained Deep Learning algorithms for near
instantaneous diagnosis in the OR and clinical setting.

10:30 Application of PEG-Silanes to Thermoplastic Surfaces: Toward
Inexpensive Materials for Biological Assays
Aaron Anderson, Research Scientist, Chemistry, Los Alamos Natl Lab
In this work, our known procedure to produce PEG SAMs on glass was
adapted for coating thermoplastic surfaces, which paves the way toward less
expensive and more broadly applicable-transducer systems. This presentation
presents previous work on silica-based transducers, and shows recent efforts
to bind silanes to cyclic olefin copolymer (COC) and polymethyl methacrylate
(PMMA or acrylic), and characterize the resulting thin-films in terms of their
spectroscopic properties and chemical behavior. Characterization of the films
on plastics utilized water contact angle, infrared- and X-ray photoelectron
spectroscopy, and atomic force microscopy. Furthermore, chromophore
molecules were conjugated to amine-terminated thin film surfaces, and
binding was confirmed spectroscopically. Photolithographic patterning of the
silane-based thin films allowed analysis of specific binding and resistance of
non-specific adsorption, essential qualities of any sensor system. This body of
work represents a step toward inexpensive transducers with flexible surface
chemistry for biomedical applications.

Lisa Diamond, CEO, Pinpoint Science LLC
Pinpoint Science offers unique nanosensor technology for low-cost detection
of viral, bacterial and fungal pathogens in seconds, with detection levels below
500 femtograms/ml. This unique diagnostic platform can use antibodies,
oligos, aptamers and nanobodies for rapid, label-free bioelectronic detection
and quantification of pathogens in point-of-care settings.

11:30 Electrochemical Sensors and Systems for Wearable and
Minimally Invasive Healthcare Applications
Paul Galvin, PhD, Head, ICT for Health Strategic Programs, Tyndall National
Institute
This presentation will describe some emerging electrochemical sensors and
systems to address the challenges of continuous real-time monitoring of
selected biomarkers for wearable and minimally invasive medical devices.
Challenges which will be discussed will include sensor and instrumentation
design, sensor biocompatibility, how to prevent biofouling impacting on
performance, form factor of the system, etc. Some exemplars of the emerging
systems will be showcased.

11:00 Nanosensors for 30-Second Handheld Pathogen Detection
This panel will discuss the current outlook within the marketplace and will examine past
success and failures and how the pitfalls of failure can be avoided.

12:00 pm Reliability Learnings and Benefits from Operational In-Situ
Sensor Testing
Nikesh Dhar, Staff Hardware Engineer, Google
Sensors used in consumer devices are becoming more complex and more
custom. Assessing sensor reliability is now a challenging task; custom
sensors have several critical blocks and assessing each and every block is
required to accurately assess sensor reliability. Here we will present a sample
example on how in-situ operational sensor testing is beneficial in identifying
additional failure modes which would have otherwise missed if traditional
passive reliability test methodologies and procedures were to be followed.

8:10 AI to the Rescue: Curing and Augmenting Brain
Capabilities with the Smart Kiwi Nano-Implant
Newton Howard, PhD, Professor Neurocomputation and Neurosurgery,
Brain Sciences Foundation, Oxford University; Chairman, Board of
Directors, ni2o
Brain Computer Interface technologies are in constant improvement
with interaction modalities ranging from non-invasive (EEG, TMS, etc.)
to chronically implanted devices. We are presenting here Kiwi, a novel,
minimally invasive micro-implant using nanotechnologies to record the
electrical activity of neural tissue and stimulate using electrical and
optical stimulation modalities. Kiwi micro-implant is operating wirelessly
and is coupled to a cutting-edge AI module providing the possibility to
detect in real-time neural activity patterns and adjust the stimulation
parameters accordingly. This adaptive, minimally invasive and smart
BCI opens a new way for personalized therapeutic applications in
diverse diseases such as neurodegenerative diseases (Parkinsons,
Alzheimers, etc.), mental illnesses (depression, anxiety, etc.) or chronic
pain, brain augmentation, and research device.

8:35 PANEL DISCUSSION: Sensor Mergers & Acquisitions:
Models for Success and Lessons from Failures
MODERATOR: Andy Glicinski, Global Vice President, Research
Development & Engineering, Mergers and Acquisitions, SC Johnson & Son
This panel discussion will examine the current landscape of mergers and
acquisitions with the sensors and device space. Our panel of experts will
discuss the current outlook within the marketplace and will examine past
success and failures and how the pitfalls of failure can be avoided.

PANELISTS:
Joshua Windmiller, PhD, MSc, Co-Founder & CTO, Biolinq, Inc.
Ali Tinazli, PhD, Chief Commercial Officer, Fluxergy
Rudy Burger, Managing Partner, Woodside Capital

7:30 am Registration and Morning Coffee
Plenary Session
8:00 Chairperson's Remarks
Craig Wohlers, Executive Director, Conferences, Cambridge Innovation Institute

HEAL THCARE APPLICATIONS STREAM
THURSDAY, DECEMBER 12

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Since breath alcohol measuring devices became handheld, many companies have tried to replicate this success for other conditions and diseases with no success. The problem has proven to be high variability, sample contamination risks, and even sample loss, all contributing to unreliable data, even with 35-pound desktop instruments. We have addressed these three problems specifically by developing a new, handheld breath capture device. Our preliminary data further show that our solution is capable of detecting and analysing microorganisms living deep in the lung, in a fully non-invasive manner. The patent-protected technology has utility beyond human/veterinary healthcare and well-being in the biodefence, environmental monitoring, agriculture and food sectors.

2:30 **Silicon Nanowire Biosensors**
Marcie Black, PhD, CEO, Advanced Silicon Group
We present Advanced Silicon Group's nanowire biosensor which enables low cost, multiplexed, and rapid detection of proteins and DNA using one test. The nanowires make the sensor more sensitive to its environment allowing detection of dilute solutions. Our vision is to make diagnostics rapid, easy to use, and low cost so that everyone has access to good healthcare.

3:00 **Refreshment Break in the Exhibit Hall with Poster Viewing**

3:30 **Wearable, Novel, Optical Sensor for Continuous Noninvasive Blood Pressure (cNIBP) Monitoring**
Mohan Thanikachalam, Assistant Professor, Tufts University School of Medicine
ViTrack™ is a first-of-its-kind, cuff-less, wearable, standalone technology for cNIBP monitoring, which includes a novel optical sensor capable of 3D contact sensing at microscale. The wrist wearable ViTrack™ device captures the spatiotemporal force distribution within the contact region of the skin and utilizes a proprietary new methodology to directly measure (self-calibrate) and continuously track systolic and diastolic BP.

4:00 **Health and Wellness through Salivary Diagnostics**
Manesh Kalayil Manian, PhD, Research & Development Lead, Traq
Noninvasive approach to monitor individual’s physiological and pathological state is one of the most desirable goals in healthcare research. The presence of various disease-signaling biomarkers and ease of sampling and storage makes saliva a useful medium of detection. Traq makes cost efficient, accurate and portable biosensors that can track activity and health data using saliva as a medium in real time. Traq products are designed to go anywhere, giving flexibility of where and when you track personal health and wellness data, decreasing the need for hospital and physician office visits. This powerful solution creates a synergy that can change the way we all approach health. Own Your Health™. This presentation overviews the clinical importance of saliva as a diagnostic medium and portrays the current research and technology development in Traq.

4:30 **AI Powered Sensing for Next-Generation Health-Tracking**
Karim Arabi, PhD, CEO, Atlazo
Sensing and computing have traditionally been separate functions. Recently, we have seen a trend towards integration of sensing and computing, and with the advent of AI, this trend is accelerating. This talk highlights the benefits of sensing and AI integration for voice activation, context awareness and health-tracking applications.

5:00 **Close of Summit**
**Materials, Design & Engineering for Sensor Manufacturing**

Optimizing Sensor Design & Integration

**TUESDAY, DECEMBER 10**

**7:30 am Registration and Morning Coffee**

**Plenary Session**

**8:20 Chairperson’s Remarks**
Christopher Hartshorn, PhD, Program Director, Cancer Treatment & Diagnosis, National Institutes of Health; National Cancer Institute

**8:30 Predictive Analytics in Digital Diagnostics for Management of Chronic Conditions**
Rafael Carbunaru, PhD, Vice President R&D, Boston Scientific

**9:00 Regulatory Considerations during Mobile Medical App Development for Commercial and Clinical Trial Use**
Mike Benecky, Senior Director, Global Regulatory Affairs in Precision and Digital Medicine, GlaxoSmithKline

Mobile medical apps are defined as medical devices from their intended use. Mobile medical app regulation is health risk-based to balance patient safety and barriers to technological innovation. Medical device patient risk analysis is a critical prerequisite prior to sensor/app inclusion within a clinical trial. Key components of quality management systems for mobile medical apps include: software requirements/specifications, user acceptance testing, software postmarket surveillance, software version control, and medical device adverse event reporting.

**9:30 Nanotechnology, MEMS, Microfluidics for Health 4.0 Hypermobility**
Anita Rogacs, PhD, Head of Life Sciences Strategy and R&D, HP Labs

New imperatives of healthcare are focusing on prevention, personalization of diagnostics and treatment, and democratization, including access to everyone, anywhere, anytime at a low cost. The technology convergence in medicine is enabled by the powerful combination of microelectronics, microfluidics, advanced (bio)-chemistry, distributed network, and data analytics.

**10:00 Networking Coffee Break**

**10:30 Roundtable Discussions**

**TABLE 1: How Biosensors Can Address Global Health Challenges**
Lisa Diamond, CEO, Pinpoint Science LLC

- Where can access to biosensor solutions save lives in the developing world?
- How can novel biosensor technologies contribute to fighting emerging pandemic threats?
- What new tools can be offered to consumers to monitor and diagnose their own health status?
- How do we best handle data collected from connected biosensors, protecting patient privacy while informing public health agencies?
- What new applications for biosensors are needed in veterinary medicine, agriculture and food safety?

**Table 2: Power Solutions for Miniaturized Implants**
Robert Rubino, Senior Director, Research and Development, Integer

- How can we improve power technology to make powered implants smaller and more convenient?
- What wireless power solutions are available?
- What new battery and capacitor solutions are available that enable smaller devices?
- What are the technical hurdles that these new technologies need to overcome and how do we get there?

**Table 3: Mixed-Signal Application Specific Integrated Circuits (ASICs): Advantages, Challenges, Justification, and Strategies**
Andrew Kelly, BSEE, Director of Applications Engineering, Semiconductor Division, Cirtec Medical

- What advantages are offered by Application Specific Integrated Circuits (ASICs)?
- What are the primary challenges associated with an ASIC-based design?
- What are the most common applications that justify the challenges of an ASIC-based design?
- How do you approach the system/circuit partition when developing an ASIC-based design?
- What factors should be considered when deciding to either work with an ASIC supplier or develop an ASIC in-house?
- What are the most important factors when selecting an ASIC supplier?

**Table 4: Overcoming the Challenges to Bringing Medical Devices to The Market**
David DiPaola, Managing Director, DiPaola Consulting

- What are your biggest challenges bringing a medical device to market and what solutions did you implement?
- How were you able to expedite the FDA approval process and when in the development did you get the FDA involved?
- How do you recommend shorting the time to market for a medical device?
- What issues did you face in pilot production that were not identified in the development stage and what steps did you take to address this?
- How did you incorporate manufacturing, test and dimensional measurement requirements into your design up front? What tools did you use?

**Table 5: Advanced Materials**
Stacey Standridge, PhD, Deputy Director, National Nanotechnology Coordination Office

- What advanced materials are you working with?
- What specific performance, cost, or other benefits are you targeting with these materials?
- What are the bottlenecks in deploying advanced materials in devices (e.g., technical performance, manufacturing scale, reproducibility, integration, standards, financial considerations)?
- What are potential mechanisms to address these bottlenecks?
- What lessons can be learned from prior technologies in evolution of scale, reproducibility, and quality control? Are there any new challenges that are unique to your advanced material?

**Table 6: Sensors for Collaborative or Autonomous Systems: Challenges and Considerations**
Tom Calef, CTO, Activ Surgical

What industries are exploring such systems and what can be learned from them? What sensor types and circuit architectures are well-suited for such systems? What factors should be considered when deciding to either work with a sensor supplier or develop in-house? What are current user-acceptance or regulatory/compliance challenges and successful case studies for overcoming them? How is data being collected, stored, and used in today’s learning models? What are the best practices for specific industries? What is required for these systems to take the next “big leap” into Level 3 autonomous behavior or beyond?

**Market and the Path to Commercialization**

**11:25 Chairperson’s Remarks**
Steve Lerner, CEO, Alpha Szenszor

**11:30 BARDA’s New Division of Research Innovation for the Development of Next-Generation Wearables**
Justin Yang, Program Officer, Acting Program Manager, Early Notification to Act, Control and Treat (ENACT) Program, DRIVe Division, Biomedical Advanced Research and Development Authority in the Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health & Human Services

This presentation will provide an overview of the vision of the Biomedical Advanced Research & Development Authority’s new Division of Research, Innovation, and Ventures in the Department of Health and Human Services and their new focus on wearable technologies. We are funding multiple projects seeking to improve healthcare and health outcomes by enabling Americans to monitor their own health. We seek wearable technologies to enable a notification of impending disease before symptoms arise.
Advanced Sensor Materials & Engineering

12:00 pm Miniaturization Technologies for Implantable Devices
Robert Rubino, Senior Director, Research and Development, Integer

In order to make future implantable medical devices as minimally invasive and cost-effective as possible, devices will need to become smaller and easier to implant. This will require the development of alternative assembly technologies and materials. Reduction in the size of the power source, while still retaining the high level of reliability required, will be one critical element to reduce device size. New concepts to allow for miniature scale assembly of hermetic, biocompatible coin cells and thin film cells have been developed by leveraging traditional glass-to-metal and ceramic-to-metal seal technologies. Ceramic device enclosures, which allow for more efficient energy transfer to the device from external power sources due to reduced eddy currents, have been developed to minimize recharge time or eliminate the need for a power source completely. In addition, biocompatible, hermetic conductive vias through ceramic substrates enable further size reduction of device feedthroughs and can act as active electrodes for sensing or therapy. Combined, these technologies can be used to produce sensing and stimulating implants that provide enhanced convenience for patients and physicians.

12:30 Sponsored Presentation (Opportunity Available)

1:00 Enjoy Lunch on Your Own

Advanced Sensor Materials and Engineering

1:55 Chairperson's Remarks
Roger Grace, President, Roger Grace Associates

2:00 Radio Ranging with Ultra-High Resolution with Passive Markers
Edwin Kahn, PhD, Principal Investigator & Professor, School of Electrical and Computer Engineering, College of Engineering, Cornell University

Accurate locating of specific points in an indoor setting is critical for applications, including robotic feedback control and non-intrusive structural integrity monitoring. Current optical and ultrasound approaches often suffer from insufficient accuracy, obstruction by other objects, and ambiguous identification. Alternatively, conventional radar-like radio frequency (RF) methods can suffer from problems such as multipath ambiguity, small time of flight, and limited item recognition. Attachment of a passive RF identification (RFID) tag can provide a unique marker by modulating the backscattering signal, but current systems struggle with large interference and noise, and thus have poor ranging accuracy. Here we show that a 1 GHz harmonic RFID system can provide a ranging resolution of less than 50 microns in air and less than 5 microns in water with a sampling rate of greater than 1 kHz. The fundamental limits on ranging precision in our system are traced to the phase noise of the RF source and the aperture jitter of the data converter. Due to the low signal loss of the RF band we choose, the small passive tag to be precisely tracked can be embedded in underwater objects as well as within building structures.

2:30 Low Power, Highly Scaled IoT Gas Sensors Using Carbon Nanotubes
Steve Lerner, CEO, Alpha Szensor

In the world of gas sensors that currently contend for Edge-based detection, incumbent technologies carry significant limitations with respect to integration, cost and power consumption. Sensor power consumption is a fundamental constraint for all portable sensing devices, particularly as the vision of energy harvesting and ubiquitous sensing at the Edge materialize. More recently, Carbon Nanotube sensors have evolved to being one of the most cost-effective options with greater packing density, higher sensitivity and selectivity, than most gas sensors, while consuming up to 3 orders of magnitude less power. This talk will discuss the inherent advantages of ultra-low power gas sensors and some of the applications that are being enabled as a result. From medical diagnostics to fitness monitors to environmental applications analyzing the quality of air, soil, water and food. CNT sensors are positioned to revolutionize our automated sense of smell and taste.

3:00 The Integration of Flexible Tactile Sensors into Biomedical and Consumer Products

Robert Podoloff, CTO, Tekscan; Lecturer, Massachusetts Institute of Technology

This talk will focus on the information that flexible tactile sensors can provide and the process for integrating them into consumer products. Several applications examples ranging from prevention of occlusion in insulin delivery lines to the measurement of dynamic automobile tire footprints will be presented along with a live demonstration of the technology.

3:30 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 Tutorials (See page 3 for details.)

6:00 Welcome Reception in the Exhibit Hall with Poster Viewing

7:00 End of Day

WEDNESDAY, DECEMBER 11

8:00 am Registration and Morning Coffee

Plenary Session

8:20 Chairperson's Remarks
Robert Rubino, Senior Director, Research and Development, Integer

8:30 Dexcom's Continuous Glucose Monitoring (CGM) Technology and Its Impact on Diabetes Management, Artificial Pancreas, & Digital Health Systems
Peter Simpson, Vice President of Sensor R&D and Advanced Technology, Dexcom

Recent advances in continuous glucose monitoring (CGM) technology have significantly increased its usability and impact on diabetes management. CGM’s are now widely reimbursed and are rapidly becoming the standard of care for people on intensive insulin therapy. This presentation will provide an overview of Dexcom’s CGM sensor technology, its use in digital health and artificial pancreas systems and a preview of our future products.

9:00 Objective Measures for Clinical Assessment and Precise Understanding of Disease Progression
Christopher Hartshorn, PhD, Program Director, Cancer Treatment & Diagnosis, National Institutes of Health; National Cancer Institute

This talk will look at various efforts across the National Institutes of Health attempting to enable more objective measures for out-of-clinic, patient-specific assessment and longitudinal understanding of disease progression in large cohorts.

9:30 Wearable Electrochemical Sensors – Recent Advances
Joseph Wang, Distinguished Professor & Chair, Nanoengineering, University of California, San Diego

This presentation will discuss recent developments in the field of wearable electrochemical sensors integrated directly on the epidermis or within the mouth for various non-invasive biomedical monitoring applications. Particular attention will be given to non-invasive monitoring of metabolites and electrolytes using flexible amperometric and potentiometric sensors, respectively, along with related materials, energy and integration considerations. The preparation and characterization of such wearable electrochemical sensors will be described, along with their current status, future prospects, and challenges.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:30 Roundtable Discussions

Table 1: Miniaturization for Chemical and Biological Detection
Cory Bernhards, PhD, Research Microbiologist, CBR, Defense Threat Reduction Agency

- How do you decide what to prioritize?
Materials, Design & Engineering for Sensor Manufacturing

Table 2: Best Practices for AI, IoT, etc
Luisa Bozano, PhD, Manager, Nanoscale Fabrication Group, IBM Almaden Research Center
- We hear about what’s worked at conferences, but what about what hasn’t worked?
- What standards do we like? What don’t we like?

Table 3: The Small Business Innovation Research (SBIR) program and Small Business Technology Transfer (STTR)
Dr. Juan Figueroa, Puerto Rico Science and Technology Trust
- When was the first time you heard about SBIR/STTR? What are the similarities and differences from what you heard today?
- Are you aware of any SBIR/STTR award winner? Are you aware of a company with a potential for >$1M equity free and hold on to IP? Why wouldn’t you invest in it/them? Why would you invest in it/them?
- Are you afraid the federal government will take the IP?
- Are you afraid the grantees (contractors) do not have the experience to move the company forward?
- Do you have a horror story about an SBIR/STTR company? A positive story? What went wrong? What went right?
- What do you want to hear to make you look favorably towards investing in an SBIR/STTR grantee?

Table 4: Non-Invasive Physiological Monitoring Beyond Activity, PPG, RR and ECG - Adding More Medically Relevant Vital Signs
Ashish V. Pattekar, Principal Scientist, PARC, a Xerox Company
- What will next generation physiological monitoring sensors and systems look like?
- What technologies will need to be developed to enable continuous (e.g., wearable) monitoring of additional, medically relevant, vital signs?
- Can raw data from existing sensors be used to infer other vital parameters using AI / ML approaches?
- Would there be a net gain from the consumerization of these new sensing modalities (cost versus benefit of resulting follow up / treatment)?
- What are the risks to the end-user, and can we think of approaches to mitigate them?

Table 5: Considerations for use of Sensor-measured Digital Endpoints during Drug Clinical Development
Mike Benecky, Senior Director, Global Regulatory Affairs in Precision and Digital Medicine, GlaxoSmithKline
- What further work needs to done to establish an “off-the-shelf” 510k cleared sensor device as a Digital Clinical Outcome Measure in a Pivotal Drug Study?
- What added value do digital sensors bring to the drug clinical development process?
- What are the regulatory challenges during utilization of a novel digital endpoint during a registrational drug clinical trial?
- What therapeutic areas appear most fertile for use of digital endpoints during drug clinical development

Enabling Sensor Commercialization through Collaborative Initiatives

11:25 Chairperson’s Remarks
Robert Rubino, Senior Director, Research and Development, Integer

11:30 The NNI Sensors Signature Initiative: Facilitating Collaboration to Advance Nanosensor Development and Commercialization
Stacey Standridge, PhD, Deputy Director, National Nanotechnology Coordination Office
The NNI’s Nanotechnology for Sensors and Sensors for Nanotechnology Signature Initiative (Sensors NSI) coordinates efforts and stimulates existing and emerging projects across federal agencies to explore the use of nanotechnology for the development and commercialization of sensors. This presentation will provide an update regarding current and planned activities of the Sensors NSI, with specific focus on needs, funding opportunities, and recent activities related to wearable and implantable sensors. The NNI is a U.S. Government research and development initiative involving 20 departments and independent agencies working together toward the shared vision of “a future in which the ability to understand and control matter at the nanoscale leads to a revolution in technology and industry that benefits society.”

12:00 pm ANSI, the Value of Its Public-Private Partnership
Michelle Deane, Director of Standards Facilitation, American National Standards Institute
ANSI enhances both the global competitiveness of U.S. business and the U.S. quality of life by promoting and facilitating voluntary consensus standards and conformity assessment systems, and safeguarding their integrity. One of the great strengths of the U.S. approach to standards and conformance is its “public-private partnership.” This presentation will provide an overview of this partnership, the U.S. standards process and how the Institute bridges the gap between industry and government and enables information exchange and access among standards developing organizations and public-sector leaders, agencies, and legislators.

12:30 Sponsored Presentation (Opportunity Available)

1:00 Enjoy Lunch on Your Own

Sensor Design and Engineering for Manufacturing

1:55 Chairperson’s Remarks
Stacey Standridge, PhD, Deputy Director, National Nanotechnology Coordination Office

2:00 Sputtered Metal Oxide N-P Heterojunctions for Sub-PPM Volatile Organic Compound Sensing
Andrea Fasoli, PhD, Senior Sensor Engineer, RSM, IBM Almaden Research Center
We present the fabrication and characterization of sputtered SnO2/NiO n-p heterojunctions thin films and their response to Volatile Organic Compounds (VOCs) at sub-ppm concentrations. In optimal processing conditions, the response of the films to VOCs can be greatly increased and its dependence on temperature, typically described in the context of a Diffusion-Reaction model, altered. In addition, we show that p-type NiO layers of given thickness can trigger a reversal in the response pattern of ultra-thin n-type SnO2 underlayers.

2:30 The role of software in MEMS sensors: the silent stars of today’s and future applications
Francois Beauchaud, Principal Engineer - Business Development, Bosch Sensortec MEMS sensors have become the heart of many consumer electronic devices but each application has different requirements resulting in varying needs for fused sensor data. In this talk, we will introduce solutions at different complexity levels of sensor related software such as fusion, user features and deployment of modern edge AI techniques, to provide a stage to the silent stars within our daily devices.

3:00 Enabling Permanently-Powered Deeply Embedded Sensor Systems
Mark Buccini, Director Advanced Product Platforms, Advanced Product Platforms, Texas Instruments
This presentation describes the architecture choices and design techniques that have been proven to enable deeply embedded sensor systems to operate for a lifetime from a single non-replaceable or rechargeable primary battery source. The solution discussed is usable as a template to implement permanently-powered fitness, monitoring, portable health care and wearable devices. A practical step-by-step series of examples build a complete ultra-low power cost-sensitive microcontroller-based embedded system. Exactly where at a system level power is consumed and how to minimize it is the focus of the presentation.

3:30 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 Tutorials (See page 3 for details.)

6:00 End of Day
10:30 Scalable Manufacture of CNT-Based Microsensor for Lactate Detection in Sweat
Ahmed Busnaina, PhD, William Lincoln Smith Professor, Distinguished University Professor and Director, NSF Nanoscale Science and Engineering Center for High-Rate Nanomanufacturing, Northeastern University

Non-invasive detection of lactate can help identify hypoxia and exercise-induced muscle fatigue in addition to several other morbidities. To address this gap, we present a novel chemiresistor-like amperometric carbon nanotube (CNT) enabled flexible lactate sensor with a focus on manufacturability and scalability. Sensors are printed using directed assembly of CNTs that are enzymatically functionalized for lactate detection. The sensors are capable of detecting L-lactate with excellent sensitivity (300 µA mM⁻¹ cm⁻²) and short response time.

11:00 Building Next-Generation Neural Interfaces Using Nanoscale Manufacturing
Ingrid van Welie, Founder and CEO, Neural Dynamics Technologies LLC

Neurological disease is projected to be the second largest cause of chronic disease in coming decades, but to confront this development, we need a better understanding of the neural circuit activity that underlies both healthy as well as diseased brain function. To understand the function of dynamical neural circuits we need technologies with the capability to measure the activity of many individual neurons in vivo, in intact brains. Neural Dynamics Technologies focuses on the development of new neural interfaces that can record the activity of hundreds to thousands of neurons simultaneously within and across brain regions that will be available at low cost and that offer customizability and compatibility with existing hardware and analysis methods. We use a combination of CMOS and Ebeam lithography to develop devices that have hundreds to thousands of individual recording sites and we are working on integrating stimulation, optical and fluidic capabilities onto our devices.

9:25 Coffee Break in the Exhibit Hall with Poster Viewing

9:55 Chairperson's Remarks
Roger Grace, President, Roger Grace Associates

10:00 Bulk Acoustic Wave Resonators for Size Reduction in Wireless Microcontroller Units
Jeronimo Segovia-Fernandez, R&D Systems Engineer, Texas Instruments

Bulk Acoustic Wave (BAW) resonators enable high performance, timing-accurate oscillators, which when integrated into the MCU package eliminate the need for bulky external crystals without compromising power, latency or frequency stability. In this talk, I will describe how BAW works, the advantages of adopting this technology in wireless MCUs providing smaller footprints, better cost optimization and more robust designs, and give some guidelines on what aspects of BAW are currently investigated to further enhance resonator performance.

1:25 Chairperson's Remarks
Ahmed Busnaina, PhD, William Lincoln Smith Professor, Distinguished University Professor and Director, NSF Nanoscale Science and Engineering Center for High-Rate Nanomanufacturing, Northeastern University
Next-Generation Design and Engineering for MEMS Applications

2:00 Sensor Fusion for Self-Navigating Cars Using Inertial MEMS and Odometry
Igor Prikhodko, PhD, Staff MEMS Design Engineer, Analog Devices

We demonstrate inertial navigation for automobiles with position accuracy reaching GPS-like accuracies using a tactical-grade Inertial Measurement Unit (IMU) for direction estimation and a speedometer for velocity estimation. The navigation module fuses inputs from the IMU, On-Board Diagnostics, and GPS to provide a vehicle trajectory estimate in real-time. Based on field tests the position error was 30 centimeters after 5 minutes of drive without GPS.

2:30 Recent Developments in Patient Monitoring, MEMS-Based Drug Screening, and Transdermal Drug Delivery
Ashish V. Pattekar, Principal Scientist, PARC, a Xerox Company

This talk will provide an introduction into our work on patient monitoring at hospitals for improved healthcare delivery and reducing post-discharge hospital admissions and share recent results from ongoing efforts developing MEMS / microfluidics based technologies for High-throughput drug screening (HTS) and Transdermal drug delivery.

3:00 Refreshment Break in the Exhibit Hall with Poster Viewing

3:30 Time-Domain Sensor and System Simulations: Enabling Digital Twin and IoT Development
Mihir S. Patel, PhD, Director of Engineering, OnScale

4:00 Design Challenges and Modeling of MEMS Based Sensor Products
Mary Ann Maher, PhD, Founder & CEO, SoftMEMS

Many of the challenges now seen in bringing MEMS based products to market are occurring as MEMS and companion integrated circuits are combined into systems often on flexible substrates. Current products are increasing in system complexity and often include multiple sensors with special purpose hardware for running sensor fusion and AI algorithms such as neural networks. This talk will cover the challenges and opportunities for designing innovative MEMS systems particularly focusing on the Integrated circuit/ MEMS/Package/Substrate co-design and optimization issues. It will further discuss modeling and simulation of MEMS beginning with detailed sensor design and ending with using the sensor data to drive AI algorithms for IoT based applications. Examples of design issues and their solutions utilizing computer-aided design tools (CAD) are given. Finally, a perspective on the future design, standards, and ecosystem needs in the MEMS industry as new types of sensors and actuators in the bio/chemical and flexible/stretchable/printed technologies are rolled out is also presented.

4:30 Stretchable Hybrid Sensor System Constructions Based on a Novel Thermosetting Polymer System
Takatoshi Abe, Engineer, Electronics Materials, Panasonic Industrial Devices

Sensor systems for printed and wearable electronics are an area of active research. Current technology based on polymer materials like polyester or thermoplastic polyurethane technology face severe assembly and end-use challenges because of their low temperature tolerances and permanent plastic deformation tendency. Researchers with Panasonic Electronic Materials Division have been developing new materials based on a unique stretchable thermosetting polymer. This presentation will introduce these materials and examples of sensor system constructions based on this technology.

5:00 Close of Summit

PRESENT A POSTER AND SAVE $50!

Cambridge Innovation Institute encourages attendees to gain further exposure by presenting their work in the poster sessions. To secure a poster board and inclusion in the conference materials, your abstract must be submitted, approved and your registration paid in full by November 8, 2019.

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Inquiries: jring@cambridgeinnovationinstitute.com
Table 3: Mixed-Signal Application Specific Integrated Circuits

- What are the technical hurdles that these new technologies need to overcome and how do we get there?
- What new battery and capacitor solutions are available that enable smaller devices?
- What wireless power solutions are available?
- How can we improve power technology to make powered implants smaller and more convenient?
- What were your biggest challenges bringing a medical device to market and what solutions did you implement?
- What factors should be considered when deciding to either work with an ASIC supplier or develop an ASIC in-house?
- What are the most important factors when selecting an ASIC supplier?

Table 4: Overcoming the Challenges to Bringing Medical Devices to The Market

- What are the most important factors when selecting an ASIC supplier?
- What factors should be considered when deciding to either work with an ASIC supplier or develop an ASIC in-house?
- How do you approach the system/circuit partition when developing an ASIC-based design?
- What issues did you face in pilot production that were not identified in the development stage and what steps did you take to address this?
- How did you incorporate manufacturing, test and dimensional measurement requirements into your design up front? What tools did you use?

Table 5: Advanced Materials

- What are the most important factors when selecting an ASIC supplier?
- What factors should be considered when deciding to either work with an ASIC supplier or develop an ASIC in-house?
- How do you approach the system/circuit partition when developing an ASIC-based design?
- What issues did you face in pilot production that were not identified in the development stage and what steps did you take to address this?
- How did you incorporate manufacturing, test and dimensional measurement requirements into your design up front? What tools did you use?

Table 6: Sensors for Collaborative or Autonomous Systems: Challenges and Considerations

- What do you consider when deciding to either work with a sensor supplier or develop in-house? What are current user-acceptance issues?
- What issues did you face in pilot production that were not identified in the development stage and what steps did you take to address this?
- How did you incorporate manufacturing, test and dimensional measurement requirements into your design up front? What tools did you use?

Innovative Biological Detection and Challenges

- What are the technical hurdles that these new technologies need to overcome and how do we get there?
- What are the most important factors when selecting an ASIC supplier?
- What factors should be considered when deciding to either work with an ASIC supplier or develop an ASIC in-house?
- How do you approach the system/circuit partition when developing an ASIC-based design?
- What issues did you face in pilot production that were not identified in the development stage and what steps did you take to address this?
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Table 6: Sensors for Collaborative or Autonomous Systems: Challenges and Considerations

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Innovative Biological Detection and Challenges
capabilities. Aptamers are single-stranded nucleic acids folded into their 3D conformations governed by their sequence and environmental conditions. Here, we will discuss our progress in three directions. First, we enhance biodetection selectivity in complex environments. Second, we introduce our innovative methodology for selection of aptamers. Third, we introduce the highly desired reversibility of biosensors.

12:00 pm eCoating for Electrochemical Sensors – Addressing a Bottleneck to Commercialisation
Pawan Jolly, PhD, Senior Scientist, Wyss Institute, Harvard University
Affinity-based electrochemical sensors offer great potential for the development of multiplexed point-of-care (POC) diagnostics; however, their commercialization has been limited because these devices rapidly lose sensitivity due to biofouling in complex biological fluids. Here we describe a simple drop-casting method that may be used to create sensor coatings that provide potent antifouling properties while retaining electrode conductivity in human blood and plasma.

12:30 Sponsored Presentation (Opportunity Available)
1:00 Enjoy Lunch on Your Own

Innovative Biological Detection and Challenges Cont.

1:55 Chairperson's Remarks
Phillip M. Mach, Analytical Chemist, US Army

2:00 FEATURED PRESENTATION: Multifunctional Sensor Platform Enabled by Additive Manufacturing
Mahmooda Sultana, PhD, Associate Branch Head, Instrument Systems Engineering Branch, NASA Goddard Space Flight Center
In this talk, I will discuss our work on multifunctional sensor platform with a suite of environmental sensors fabricated with a variety of nanomaterials using additive manufacturing techniques. The platform is capable of sensing a variety of environmental parameters including pressure, temperature and target gases, and then transmitting the data via a wireless antenna. This technology has numerous space and terrestrial applications.

2:30 Nanotechnology Innovations Converging to Disrupt Multi-Gas Sensing
Sundip R. Doshi, Founder & CEO, AerNOS, Inc.
Multiple industries have mission critical needs for affordable, effective multi-gas monitoring capabilities. Breakthroughs in nanotechnology using MEMS circuitry, hybrid nanostructures and signal processing deliver gas sensors that dramatically improve monitoring capabilities. This presentation will use AerNOS AerN2S technology to illustrate and explore gas sensor application challenges, including low level detection, size, cross-contamination, calibration, real-time, integration, manufacturing and costs associated with building next generation multi-gas sensors.

3:00 Introducing High Accuracy Pressure Sensing into the Consumer Medical Space
Robert Robinson, General Manager, Electronic & Gas Sensing Business, Honeywell
With significant advancement in medical technology, many technological firms are beginning to grasp the opportunity to harness real-time medical monitoring from wearables devices. The progression of technology in the medical grade wearable segment is challenging the age-old perception that high accuracy devices should command high prices. This session will discuss how firms can balance between high accuracy features and cost to help them differentiate in the marketplace.

3:30 Refreshment Break in the Exhibit Hall with Poster Viewing
4:00 Tutorials
6:00 Welcome Reception in the Exhibit Hall with Poster Viewing
7:00 End of Day
Dealing with Biological Threats

11:25 Chairperson's Remarks
Cory Bernhards, PhD, Research Microbiologist, CBR, Defense Threat Reduction Agency

11:30 The BioACER Sensor: Biological Automated Collector/Defender for Expeditionary Reconnaissance
Cory Bernhards, PhD, Research Microbiologist, CBR, Defense Threat Reduction Agency

We are developing the BioACER sensor, which is a completely novel and fully automated device that conducts remote sample collection (while flying through a plume), preparation, identification, and reporting for biological aerosols within 15 minutes. This unmanned device will allow for low cost, rapid, and accurate identification of biological threats, while eliminating the risk of exposure to operators and allowing for early warning to protect both soldiers and civilian populations.

Table 3: The Small Business Innovation Research (SBIR) program and Small Business Technology Transfer (STTR)
Dr. Juan Figueroa, Puerto Rico Science and Technology Trust

- When was the first time you heard about SBIR/STTR? What are the similarities and differences from what you heard today?
- Are you aware of any SBIR/STTR award winner? Are you aware of a company with a potential for >$1M equity free and hold on to IP? Why wouldn't you invest in it/them? Why would you invest in it/them?
- Are you afraid the federal government will take the IP?
- Are you afraid the grantees (contractors) do not have the experience to move the company forward?
- Do you have a horror story about an SBIR/STTR company? A positive story? What went wrong? What went right?
- What do you want to hear to make you look favorably towards investing in an SBIR/STTR grantee?

Table 4: Non-Invasive Physiological Monitoring Beyond Activity, PPG, RR and ECG - Adding More Medically Relevant Vital Signs
Ashish V. Pattekar, Principal Scientist, PARC, a Xerox Company

- What will next generation physiological monitoring sensors and systems look like?
- What technologies will need to be developed to enable continuous (e.g., wearable) monitoring of additional, medically relevant, vital signs?
- Can raw data from existing sensors be used to infer other vital parameters using AI / ML approaches?
- Would there be a net gain from the consumerization of these new sensing modalities (cost versus benefit of resulting follow up / treatment)?
- What are the risks to the end-user, and can we think of approaches to mitigate them?

Table 5: Considerations for use of Sensor-measured Digital Endpoints during Drug Clinical Development
Mike Benecyk, Senior Director, Global Regulatory Affairs in Precision and Digital Medicine, GlaxoSmithKline

- What further work needs to be done to establish an “off-the-shelf” 510k cleared sensor device as a Digital Clinical Outcome Measure in a Pivotal Drug Study?
- What added value do digital sensors bring to the drug clinical development process?
- What are the regulatory challenges during utilization of a novel digital endpoint during a registrational drug clinical trial?
- What therapeutic areas appear most fertile for use of digital endpoints during drug clinical development

12:00 pm Nanopore Sequencing for Rapid Identification of Biological Threats in the Field and Biosurveillance
Maria Arevalo, PhD, Research Microbiologist, Defense, Defense Threat Reduction Agency

The warfighter needs quick and relevant information on emerging biological threats that may present themselves in the field. Next generation sequencing technologies allow for the analyses of whole genomes for unbiased, conclusive identification of pathogens, but can also help to detect and distinguish novel and synthetically modified threats. We are developing rapid sample-to-answer workflows for processing, sequencing, and automated analysis of environmental samples to identify biological threats in the field.

12:30 Sponsored Presentation (Opportunity Available)

1:00 Enjoy Lunch on Your Own

Miniaturized Sensing and Point-of-Care Diagnostics

1:55 Chairperson's Remarks
Cory Bernhards, PhD, Research Microbiologist, CBR, Defense Threat Reduction Agency

2:00 Silicon-Based, Miniaturized Sensing Technologies for Real-Time, Multi-Parameter Monitoring
Winny Tan, PhD, Senior Manager, Strategic Alliances, IMEC USA
Continuous analysis of biological and chemical substances offers great promises for applications such as environmental monitoring, diagnostics, precision agriculture, food analysis, and process analytical tools for monitoring pharmaceutical manufacturing processes. However, if we want to realize these promises, we need to drastically decrease the cost, size and power consumption of current solutions - while increasing their performance. Hence the unique value of semiconductor-based technologies and their opportunities for extreme miniaturization and integration of hardware and software algorithms at the sensor node level. This presentation will give an overview of highly compact, yet extremely sensitive sensor and imaging technologies that can be applied for high-throughput, real-time analysis of biological and chemical substances. Detecting heavy metals, pollutants and even bacteria are all part of our roadmap.

2:30 Biosensors for Use in Point-of-Care Applications
Prasad Pamidi, PhD, Director Sensor Development, Instrumentation Lab, Werfen Company
Biosensor applications are rapidly growing in point-of-care testing. The majority of these sensors are used in single use applications and some of them lack operational simplicity or laboratory quality in accuracy and precision. This presentation will focus on addressing common challenges in developing point of care friendly biosensors and recent options to address such gaps in point-of-care testing.

3:00 pm Transforming Health Testing with Saliva
Stan Skafidas, PhD, Chief Technology Officer, MX3 Diagnostics Inc.
Peak physical and mental performance is dependent upon optimal hydration. The development of the MX3 test strip represents the first commercially available saliva-based electrochemical biosensor for hydration testing, measuring salivary osmolarity (SOSM), a sensitive indicator of hydration status. Using the MX3 test strip and MX3 Lab hydration status can be measured directly from the tongue in seconds, providing laboratory-grade, actionable hydration results.

3:30 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 Tutorials

6:00 End of Day
THURSDAY, DECEMBER 12

7:30 am Registration and Morning Coffee

Plenary Session

8:00 Chairperson’s Remarks
Craig Wohlers, Executive Director, Conferences, Cambridge Innovation Institute

8:10 AI to the Rescue: Curing and Augmenting Brain Capabilities with the Smart Kiwi Nano-Implant
Newton Howard, PhD, Professor Neurocomputation and Neurosurgery, Brain Sciences Foundation, Oxford University, Chairman, Board of Directors, ni2o

Brain Computer Interface technologies are in constant improvement with interaction modalities ranging from non-invasive (EEG, TMS, etc.) to chronically implanted devices. We are presenting here Kiwi, a novel, minimally invasive micro-implant using nanotechnologies to record the electrical activity of neural tissue and stimulate using electrical and optical stimulation modalities. Kiwi micro-implant is operating wirelessly and is coupled to a cutting-edge AI module providing the possibility to detect in real-time neural activity patterns and adjust the stimulation parameters accordingly. This adaptive, minimally invasive and smart BCI opens a new way for personalized therapeutic applications in numerous diseases such as neurodegenerative diseases (Parkinsons, Alzheimers, etc.), mental illnesses (depression, anxiety, etc.) or chronic pain, brain augmentation, and research device.

8:35 PANEL DISCUSSION: Sensor Mergers & Acquisitions: Models for Success and Lessons from Failures
MODERATOR: Andy Gilicinski, Global Vice President, Research Development & Engineering, Mergers and Acquisitions, SC Johnson & Son

This panel discussion will examine the current landscape of mergers and acquisitions with the sensors and device space. Our panel of experts will discuss the current outlook within the marketplace and will examine past successes and failures and how the pitfalls of failure can be avoided.

PANELISTS:
Joshua Windmiller, PhD, MSc, Co-Founder & CTO, Bioniq, Inc.
Ali Tinazli, PhD, Chief Commercial Officer, Fluxergy
Rudy Burger, Managing Partner, Woodside Capital

9:25 Coffee Break in the Exhibit Hall with Poster Viewing

5G Implications for Hardware

10:00 Wrapping Your Head around 5G: A Primer for the Enterprise Community
Joshua Ness, Senior Manager, 5G Labs, Verizon

Learn how 5G will transform Enterprise IoT and enable technologies that will spur a revolution in device technology and information access.

10:30 Review of the Field: 5G, IoT, and More
Rasmus Hellberg, PhD, Senior Director, Technical Marketing, Qualcomm

IoT Platforms for Diagnostics and Remote Monitoring

10:55 Chairperson’s Remarks
John Koon, Technology Editor/Writer/Researcher, Tech Idea Research

11:00 Review of Data Analysis and Model Classification Techniques for Olfactory IoT Platforms
Aminat Adebiyi, PhD, Research Staff Member, IBM

A discussion of the varied data analysis and machine learning techniques that enable IoT platforms for olfaction. The review will touch on the versatility of techniques applied to olfactory platforms to preprocess, model and classify odorant patterns. It will also present challenges of the data from these systems and an outlook of opportunities for connectivity in use-case applications.

11:30 Wearables and Remote Patient Monitoring
Walt Maclay, President, R&D, Voler Systems

Remote patient monitoring is developing into a new standard of care. Remote monitoring capabilities are already enabling more convenient care, resulting in better patient outcomes and allowing physicians to serve patients more effectively. Supporting this shift is the availability and affordability of sensors that perform physiological measurements, wireless technology and connectivity necessary to support remote monitoring programs.

12:00 pm Digital Endpoints Accelerate Clinical Trials: The Strategy Behind the Success
Amir Lahav, ScD, Digital Health Consultant

The idea of integrating new digital endpoints into clinical trials using remote patient monitoring technology is receiving more support towards regulatory acceptance. Focusing on case studies involving real-world data across therapeutic areas, we will highlight the essential features and emerging trends in sensor technology, advanced analytics, and patient apps that will enable us to move digital endpoints beyond the exploratory phase into what seems to be the future of medicine. We will discuss the potential impact of the digital revolution drug development and review the current challenges around validation, adherence, and value generation.

12:30 Enjoy Lunch on Your Own

Tool Sets and Best Practices for AI and Edge

1:25 Chairperson’s Remarks
John Koon, Technology Editor/Writer/Researcher, Tech Idea Research

1:30 AI at the Edge: A Review of Toolsets Available when Building an Edge Device
Srihari Yamanoor

Organizations are deploying IoT devices at an exponential scale to better serve their customers, and there is a growing need for edge devices. This is driven by a need to reduce recurring costs like cellular data charges, provide alternatives when there is poor connectivity, or react immediately to a critical sensor input, and avoid loss of productivity, identify anomalies (e.g.: leak detection) in data streams, etc. In this session, we will demonstrate the different hardware and software toolsets available to build an edge device and walk the audience through the different steps involved in building an edge device. We will also talk about the challenges involved in building and testing an edge device.

2:00 PANEL DISCUSSION: Best Practices for Data Storage and Processing
MODERATOR: Laura Kassovic, CEO & Co-Founder, Mbientlab
PANELIST: Tilak Kasturi, Founder & CEO, Predii

With billions of new devices, AI or IoT-enabled sensors are transforming the field. However without the right data management tools and strategies, investments in AI and IoT can yield limited results. Learn more about some of the data management best practices and how organizations are using advanced analytics and machine learning to enable AI and IoT use cases.

3:00 Refreshment Break in the Exhibit Hall with Poster Viewing
HOTEL & TRAVEL INFORMATION

Conference Venue and Hotel:
Hilton San Diego Resort and Spa
1775 East Mission Bay Drive
San Diego, CA 92109
Phone: 619-276-4010

Discounted Room Rate: $165 s/d plus $8.00 resort fee
Discounted Reservation Cutoff Date: November 19, 2019

RESERVATIONS:
Please visit the travel page of SensorsGlobalSummit.com for further details and to book your stay.

TOP REASONS TO STAY AT THE HILTON SAN DIEGO RESORT AND SPA
- Save money – take advantage of the deeply discounted room rate and resort fees.
- When you book in the group block, your resort fee will be reduced to $8 per night from the standard $32
- No commute and a chance to easily network with fellow attendees on property after hours
- Get a chance to enjoy beautiful Mission Bay
- Easy access to many of San Diego’s popular attractions including San Diego Zoo, SeaWorld, and Old Town San Diego

Enabling AI

3:30 Using Health Records to Enable AI in IoT Devices
Sujay Kakarmath, Digital Health Scientist, Partners HealthCare Pivot Labs
IoT devices geared towards general wellness as well as specific diseases generate a high volume of data. These data have limited utility of their own accord as they are devoid of any context about clinical or healthcare utilization outcomes. The Data Science and Artificial Intelligence team at Partners HealthCare Pivot Labs has helped enable AI in healthcare IoT devices by leveraging EMR data from a large healthcare delivery network to supplement IoT device data. This presentation will share examples from current and past collaborations.

4:00 PANEL DISCUSSION: Legal Versus Ethical Data: Sensors for Healthcare
Deborah Peel, Chair & Founder, Patient Privacy Rights Foundation
Which data is private? Heartbeat? How can patient privacy be defined and protected on connected medical equipment and what are the associated rights of that patient? Are manufacturers obligated to disclose all data being collected and its usage? Are the data collected adequate and properly validated for the intended uses? What consumer protections exist to protect patients in the event of potential discrimination or data misuse?

5:00 Close of Summit