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Smart Pills: Decoding the Science and Technology to Ensure Quality

The Smart Pills Series will feature three workshops, with Part I commencing in November 2019 in collaboration with the UK Parliament's (USP) a scientific organization focused on developing quality standards for medicines, dietary supplements and foods. The overall goal of the workshop series is to explore emerging technologies, applications and patterns around smart pills (& medtech with sensors). This includes an exploration of the benefits and challenges with the use of smart pills for monitoring, diagnosing and otherwise impacting the delivery of care as part of the "Internet of Things" effort in healthcare.

The agenda will highlight the creative engineering behind developing sensors that can be embedded into medicine in a way which the human body will tolerate, the standardization of the resulting data, data protection, the ethical issues around the use of this technology, the state of current pilot tests, emerging applications and where further development and evaluation may be needed. In addition, IEEE and USP will host roundtable sessions to explore barriers and scientific considerations that will help ensure quality in smart pills. The goal of the sessions from these sessions is a white paper to engage industry, practitioners and other stakeholders.

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Date:
21-22 November 2019

Venue:
USP Meeting Center
12601 Twinbrook Parkway
Rockville, MD 20852-1790, USA

Register

Join the Interest List

Who Should Attend?

YOU if you are in one of the following areas:

- Clinical Trials Design & Operations
- Clinical/Medical Professional
- Health Informatics Professional
- Biomedical Engineering
- Sensor Development
- Communications Network Engineering
- Blockchain/IoT Technologies: Blockchain/IoT
- Cybersecurity/Privacy
- Other: Enthusiast not mentioned in this list

Workshop Agenda

Please note the agenda is currently in development. We encourage you to visit this site often for new speaker additions and potential session title and times changes.

DAY 1: Thursday, 21 November 2019 | DAY 2: Friday, 22 November 2019

Each session will feature up to 10 mins of audience Q&A – included in the total session time.

Time	Session Name
8:00AM - 8:30AM	Registration Check-in and Breakfast
8:30AM - 8:50AM	Welcome and Introduction
8:50AM - 9:25AM	**Top Down View** *Jonathan Trinidad, Opportunities and Challenges of Smart Pills: Promoting patient interests in medication adherence and safety – Experts Ask (when someone's sick)* *Speaker: Harald Schmidt, Perelman School of Medicine, University of Pennsylvania*
9:25AM - 10:00AM	**Understanding the Regulatory Guidelines and Protocols in the Development and Approval of "Digital Pills" for Patient Use** *Speaker: Speaker: Michael Drum, President, Vescular Sciences*
10:05AM - 10:30AM	**Medication and Technology: Application of Nomenclature Standards** *Speaker: Mizi Spano, Andrew Wilk*
10:30AM - 10:45AM	BREAK
10:45AM - 11:20AM	**Smart Pills: Five Ways That They Will Transform Healthcare** *Speaker: Alfred Poor, Founding Editor, Health Tech Insider*
10:45AM - 11:15PM	**Two Parts Make a Whole: Quality Assurance Considerations in the Era of Smart Pills and Other Drug Device Combination Products**
11:20AM - 11:50PM	**Digital Pills and Pharmacy** *Speaker: Ravi Patel, University of Pittsburgh*
11:50PM - 12:20PM	**The Physician/Researcher Perspective: Understanding Patient Perspectives Surrounding Smart Pills, and Interpretation of Adherence Data** *Speaker: Peter Chai, Brigham and Women's Hospital/Harvard Medical School*
12:20PM - 1:20PM	NETWORKING LUNCH
1:20PM - 1:55PM	**The Ethical Considerations and Risks of Smart Pills** *Speaker: Robert Klitzman, Professor, Psychiatry (in Sociomedical Sciences) at the Columbia University Medical Center*
1:55PM - 2:30PM	**Gastric Resident Bio-electronics** *Speaker: Yong Lin Kong, Assistant Professor, Department of Mechanical Engineering at the University of Utah*
2:30PM - 2:45PM	BREAK
2:45PM - 3:20PM	Emerging Applications Panel: **What's Coming Next in the Use of Ingestible Sensors**
3:20PM - 4:20PM	THE TECH PANEL: **Making Sense on What "Technically" Goes into Smart Pills** *moderator:* *Eric Buffkin, electiq* *Yong Lin Kong, University of Utah* *Alfred Poor, Health Tech Insider* *Harry Travis, electiq* *Judd Sheets, Senior Mentor, IEEE*
4:20PM - 5:00PM	Closing Remarks **Whitepaper Roadmap Session Preview and Sign-Up for Day 2**
5:00PM - 5:45PM	NETWORKING RECEPTION.

Speakers: Subject Matter Experts

We are currently accepting submissions for topics for presentation. Please write to m.palombini@ieee.org with your suggested ideas.

Eric Buffkin

Eric has a passion for new ventures, new technologies, product design and development. He is a serial entrepreneur, having launched three technology, product, and services companies in the technology and healthcare sector. Over the course of his thirty years in technology ventures, Eric has been instrumental in establishing industry standards for networking the digital home. These standards have ultimately influenced how we all enjoy digital media, access information, and manage our homes with connected devices.

Eric is currently Senior VP, R&D/Operations for electiq Inc., a healthcare technology company creating a platform for digital pills and other ingestible sensors.

Eric is committed to enabling and empowering new entrepreneurs. He is an angel investor and mentor to new technology companies in his community of Gainesville, Florida and a constant promoter of the power of the innovation economy. He holds a bachelor's degree in electrical engineering from the University of Florida and an MBA from Rollins College.

On a personal note, Eric is married with three children. He is a lifelong resident of Florida and a dedicated Fisherman, boater, and outdoorsman. When he is not offline somewhere on his boat, you can reach him at the Innovation Hub or through LinkedIn.

Dr. Peter Chai

Dr. Peter X Chai is an Associate Professor of Emergency Medicine at Brigham and Women's Hospital/Harvard Medical School and affiliate research scholar at the Fenway Institute and the Massachusetts Institute of Technology. He is interested in the development of technologies to detect changes in human health with a focus in medication adherence for HIV prevention. He is the recipient of independent research grants from Gilead Sciences as well as the National Institutes of Health to investigate the use of real-time adherence monitoring using ingestible sensors to measure Pre-exposure Prophylaxis for HIV using sense-daily EMindicatoline. His interest in ingestible electronics leads to collaborations at the Massachusetts Institute of Technology where he is an affiliate research scholar to develop next generation long term ingestible sensors and drug delivery packages to optimize HIV prevention and substance use disorder treatment. He additionally collaborates with the Harvard Pain Center for Pelvic Care Policy, Bioethicology and Bioethics at Harvard Law School on and ethical implications and health law policy surrounding of electronic adherence monitoring.

Dr. Michael Drues

Michael Drues, Ph.D., is President of Vascular Sciences, an education, training, & consulting company offering a broad range of services to medical device, pharmaceutical & biotechnology companies including consulting & innovative educational programing, creative regulatory strategy & compliance regulatory intelligence, regulatory submission design, FDA presentation preparation & defense, brain-storming sessions, prototype design, product development, benchtop & animal testing, clinical trial design, recruitment, clinical acceptance, software development & technology assessment.

Dr. Drues received his B.S., M.S., and Ph.D. degrees in Biomedical Engineering from Iowa State University in Ames, Iowa. He has worked for and consulted with leading medical device, pharmaceutical and biotechnology companies ranging in size from start-ups to companies with over 100 employees. He also works on a regular basis for the U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the Centers for Medicare and Medicaid Services (CMS) and other regulatory and governmental agencies around the world.

Dr. Drues is an internationally recognized expert and featured keynote speaker on cutting- edge medical technologies and regulatory affairs. He conducts seminars and short-courses for medical device, pharmaceutical and biotechnology companies, the U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the US Centers for Medicare and Medicaid Services (CMS) and other regulatory and governmental agencies around the world.

Finally, as an Adjunct Professor of Regulatory Science, Medicine, Biomedical Engineering & Bioethicology, Dr. Drues teaches graduate courses in Regulatory Affairs, Clinical Trials, Clinical Trial Design, Medical Device Regulatory Affairs & Product Development, Combination Products, Bioethicology, Medical Technology & Bioethicology at several universities & medical schools on ground & on-line.

Dr. Robert Klitzman

Dr. Robert Klitzman is a Professor of Clinical Psychiatry in the College of Physicians and Surgeons and the Joseph Mailman School of Public Health and the Director of the Masters of Bioethics Program at Columbia University. He co-founded and for five years co-directed the Center for Bioethics, and for 15 years directed the Ethics and Policy Core of the HIV Center. He has conducted research and written about a variety of ethical issues in medicine and public health to promote public and professional education concerning these issues. He has written eight books, and authored or co-authored over 130 articles, already on qualitative as well as quantitative methodologies. His work has appeared in the New England Journal of Medical Association, Science, and other scientific journals and reviews for the New York Times, Newsweek, The Nation, and other publications. He has received several awards for his work, including the Outstanding Teacher Award, Outstanding Service Award, Distinguished Service Award, Fulbright Foundation, the Robert Wood Johnson Foundation, the Rockefeller Foundation and the Commonwealth Fund. He is a gubernatorial appointee to the NY State Stem Cell Commission, and a member of the Research Ethics Advisory Panel of the Gates Foundation. He has been interviewed about these issues and quoted by the media, including the New York Times, The Wall Street Journal, the Washington Post, NPR, PBS, CNN, CBS, NBC, ABC, the BBC and others.

Yong Lin Kong

Yong Lin Kong is an Assistant Professor of the Department of Mechanical Engineering at the University of Utah (2018 – Present). He received his Ph.D. in mechanical engineering and materials science from Princeton University in 2016. He was a postdoctoral associate at the Massachusetts Institute of Technology (2016–2017) working with Professor Robert Langer. His research focuses on fabrication of biomedical devices and printing of nonmaterials based functional devices. Yong Lin Kong is an inventor of 30 granted active electronic materials and devices, 3D printed multifunctional hybrid devices and structures, and gastric resident electronics. He is a recipient of the MIT Technology Review Innovators Under 35 Asia Award, SRC DCS Rising Researchers and DRAC Rising II. Power Junior Faculty Enhancement Award, Materials Research Society Graduate Student Award, The Daniel & Florence Guggenheim Foundation Fellowship, Sayre Graduate Prize, and the HKUST Academic Achievement Medal.

Ravi Patel

Ravi Patel, PharmD is the Lead Innovation Advisor at the University of Pittsburgh School of Pharmacy where he helps lead the Innovation Lab. In this role, he work with students, faculty, and partners to find what's new and useful in pharmacy practice and education. He explores new technology includes review of technology to see how it more apply to pharmacy (ex. Google Home, Amazon Alexa) and implementations of different technologies through out pharmacy practice. Additionally, he explores how technology can be an hospital delivery model. Looking at the challenges of understanding and motivating change in behavior is a vast problem and opportunity for healthcare which he is most passionate about through the lens of technology.

Alfred Poor

Alfred Poor is an independent technology industry analyst, freelance writer, and professional speaker based in Pennsylvania, specializing in wearable and display technologies. He brings to his work strong communication skills, a broad background covering a wide range of technologies, more than 30 years of experience with the technology markets, and the ability to make complex concepts accessible to non-technical people, especially business professionals. He holds a BA in Biology from Harvard College, and PhD from Union Graduate School.

Harald Schmidt, PhD, MA

Harald Schmidt, PhD, MA, is an Assistant Professor at the Department of Medical Ethics and Health Policy, and a Research Associate at the Center for Health Incentives and Behavioral Economics, both at the Perelman School of Medicine, University of Pennsylvania. His research centers around personal responsibility for health, public health ethics and priority setting. His principal research focus is on the ethics of lower medication adherence monitoring technologies. He is particularly interested in understanding on what grounds patients might be obliged to use such approaches, and how behavioral economics and behavioral nudges can be maximized. Ongoing empirical research in this area focuses on postransplant patients, HIV-positive women who are pregnant or post-partum, and substance patients. The overall goal of his research is to combine robust conceptual and empirical work to contribute to more evidence-based, equitable and efficient health care policy and practice.

Before coming to Penn, Harald was a Commonwealth Fund Harkness Fellow in Health Care Policy and Practice at the Harvard School of Public Health, and for seven years served as Assistant Director of the U.K's Nuffield Council on Bioethics in London. He completed his Ph.D. and MSc in Philosophy at the London School of Economics and Political Sciences LSE Health, and previously studied Philosophy at the universities of Bremen, Oxford and Munster.

Judd Sheets

Judd Sheets has been a consulting engineer in analog, RF, & microwave systems for nearly 30 years. He helped bring the E-Cap Film Sensor to a reliable and practical system. He also led the development of the electric field sensor for the Gatorhome, the Gatorpod, the Gatorpack, the Gatorbrain, the Gatorbrain Cap, the Gatorhead Cuffins, developing commercial avionics equipment. He then spent several years in the Washington area designing surveillance receivers for the US intelligence community. As the founder of Odin Engineering Company, he has developed a wide variety of equipment and dozens of wireless communications systems, including four successful spaceflight experiments. Other projects include a CSVRs Satcom band up/down converter system, a C band miss-distance indicator and phase measurement processors for NASA Ka-band ground station and operational RADAR systems. He has existing and pending patents, including a digital VCM bearing conversion algorithm and pinlest circuit board design technique.

Mr. Sheets graduated from the University of Florida with a Bachelor of Science in Electrical Engineering. He is a senior member of the world's largest technical professional organization for the advancement of technology, the Institute of Electrical and Electronics Engineers.

Harry J. Travis

Harry J. Travis is a senior healthcare executive with over 30 years' experience in all aspects of pharmaceutical distribution channel management. This includes multibillion-dollar specialty and non-specialty pharmacy operations, health plan pharmacy benefit design and pharmaceutical wholesale operations. Currently, Mr. Travis is the President and CEO of electiq, Inc. electiq has developed an innovative digital pill system that incorporates a tiny ingestible sensor into a capsule, which transmits a signal to a wearable reader and then to a smartphone-based app and secure cloud- based server to reliably and safely indicate when a patient has taken their medicine.

Mr. Travis has held senior leadership positions with Express Scripts, Caremark, Cardinal Health, AccroMedica and Aetna where he served as the VP of Aetna's Specialty and Home Delivery Pharmacy Business. He is a nationally known speaker on the topics of the disruptive impact of digital technologies on the practice and business of pharmacy.

He holds a BS in Pharmacy from the University of Pittsburgh, School of Pharmacy and an MBA from The Darden School at the University of Virginia.

Venue

USP Meeting Center
12601 Twinbrook Parkway
Rockville, MD 20852-1790, USA
See transportation directions and parking options.

What To Know Before You Go
If you need to secure hotel accommodations near the USP Meeting Center in Rockville, MD; then please visit the USP local hotel and special offer opportunities:
https://www.usp.org/help/ieee-information

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Attendee Registration Fee Schedule

Registration fee includes the following:

- One full day of learning, networking and contributing towards solutions
- Breakfast, lunch, and reception
- Discount credit of $50 towards a one-year membership in the IEEE-SA Global Wireless Platform Development Lab
- Opportunity to contribute to the workshop's industry outcomes report

	Early Savings Fee *before 8 Nov 2019*	Standard Fee *after 8 Nov 2019*
General Attendee	$190	$290
IEEE Member or USP Volunteer *An assigned 10% discount code will be provided to both groups which must be entered at the time of registration.*	$179	$269

Registrations

IEEE Member Rate	Event Ended
Price	US$179
TOTAL	US$179

USP Member Rate	Event Ended
Price	US$179
TOTAL	US$179

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This workshop is presented in collaboration with USP.

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For questions on current and future workshop programs, technical standards activities and/or the overall WAMII initiative, please write to:

Marco Palombini
Director of Communities and Opportunities Development, Life Sciences Practice | m.palombini@ieee.org

If you would like to be notified of event and initiative developments, **subscribe to the WAMII Interest list**

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