## IEEE-NIH 2016 Special Topics Conference
## on Healthcare Innovations & Point-of-Care Technologies
## Mexico, November 9-11, 2016

### SPECIAL SESSION - PANEL

### "Moving Discoveries from the Bench to Product Realization in the Marketplace: Standards and Regulatory Considerations"

The intersection of engineering, health and medicine with rapidly evolving new technologies in wireless communications, sensors, "smart" devices and so on have further stimulated cutting-edge product development, entrepreneurship, and commercialization of innovative medical devices. Specific areas of interest include imaging, biomaterials, Nano applications, neuroprosthetics, brain-computer interface and many others. The cross-functional collaborations drive innovations and clinical solutions that have foreseeable impact in commercial healthcare products globally. For society to benefit from the breakthroughs in biomedical engineering and enabling technologies, they must be translated into practical clinical applications in the form of devices, drugs or other products. Converting these discoveries, however, can be very challenging -- issues such as safety, manufacturability, cost, patients' acceptance, protection, licensing, and marketing.

This session will bring together professionals who will share case studies and translational engineering experience from idea creation to commercialization. The panel will also discuss the role of standards and provide an understanding of the medical devices premarket regulatory requirements, as the legal gateway to commercialization in the U.S. marketplace.

**DATE:** November 10, 2016 (Thursday)
**TIME** 11:00-12:00PM

**SESSION CHAIR:** Carole C. Carey

**Carole C. Carey, M.Eng**
Affiliation**: C3-Carey Consultants, LLC**
Carole Carey is an IEEE senior member and a member of the IEEE Eta Kappa Nu Honor Society. She currently serves as chair of the EMBS Standards Committee, liaison to the IEEE Standards Association, and was recently selected as a recipient of the 2016 IEEE-SA Standards Medallion Award. She is a former U.S. FDA official in the Center for Devices and Radiological Health (CDRH) with over 23 years of regulatory science experience as a Scientific Reviewer and International Advisor. As a Reviewer, she was team leader of highly complex, innovative cardiovascular devices and a peer-reviewed expert regulatory review scientist. In this capacity, she was also active in the

development of industry consensus standards in her areas of specialization, both at the national and international levels. As a Mansfield Fellow, she trained side-by-side and collaborated with regulatory counterparts in Japan's Ministry of Health, Labour and Welfare (MHLW) and its scientific review arm, the Pharmaceutical and Medical Devices Agency (PMDA) — on regulatory device issues, scientific matters concerning device safety and effectiveness, the recognition of international standards and global harmonization initiatives. Later, she served as Director of International Staff in FDA CDRH. Furthermore, she conducted device regulatory workshops in Europe, Asia and Latin America. Currently, she is a regulatory consultant providing advice and strategic approaches in premarket submissions, investigational device clinical trials and postmarket issues for regulated industry. Carole earned her engineering degrees from Johns Hopkins University and Loyola University of Maryland.

Presentation: "**Understanding the FDA Medical Device Premarket Regulatory Process Helps Streamline the Path to Commercialization"**

*Abstract* – The FDA regulates all products that meet the definition of a medical device defined in Section 201(h) of the U.S. Federal FD&C Act. Entrepreneurial medical device firms face many translational challenges, including regulatory issues. Device classification determines the appropriate type of premarketing application and the regulatory requirements for new medical devices. Understanding the risk-based regulatory paradigm in premarket evaluation, FDA's device classification system, and conforming level of control should improve the outlook of commercial success in the introduction of novel devices in the U.S. market.

**Emilio Sacristan, PhD.**

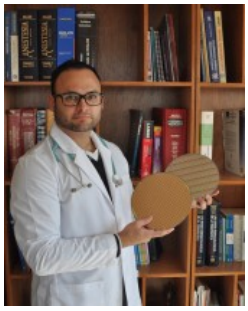
Affiliation: CI3M, UAM-Iztapalapa, Mexico City

Dr. Sacristan is a respected Mexican Researcher, Inventor and Entrepreneur in the field of medical technology. He holds a Ph.D. in Biomedical Engineering and is Professor and Director of the National Center for Medical Instrumentation and Imaging Research, CI3M, at the UAM-Iztapalapa, Mexico, and founder of 7 medical technology startups. His research focuses on instrumentation for anesthesia and critical care as well as Magnetic Resonance Imaging, and is author of over 70 research articles and 22 international patents. Dr. Sacristan is also an active entrepreneur seeking to translate medical innovations to the market, having served as founder/CEO/CSO of Enviva Corp. (MA), Innovamedica (Mexico), Abdeo Medical (Mexico and CA), Critical Perfusion Inc. (CA), and currently serves as Chief Science Officer of Nervive, Inc.(OH). He is the Inventor of the VITACOR UVAD artificial heart, the aspiration condenser for anesthesia, the gastric impedance monitor for critical care, the VITALFLOW magnetic stimulator for stroke therapy, among other medical devices. He is an Endeavor entrepreneur since 2004 and he was honored as American Express Entrepreneur of the Year 2006.

Presentation: **"Development of the VitalFlow® Magnetic Stimulator of the Facial Nerve as an Early Treatment for Stroke"**

*Abstract*— Magnetic stimulation of the facial nerve has been shown to dilate cerebral arteries. We began proof-of-concept testing of a magnetic stimulator as an early clinical treatment for stroke in 2010. In 2014 we founded Nervive, Inc. to develop a commercial clinical

device we called the VitalFlow, which is currently undergoing clinical trials, under FDA oversight, toward a PMA clearance. The VitalFlow story is presented as a case study in moving discovery from bench to market, and how regulatory considerations influence the R&D process**.**



**Jose Fernandez Villasenor, M.D.**
Affiliation: NXP Semiconductors
Dr. José Fernández-Villaseñor has been a practicing physician for over 15 years and is concurrently the Healthcare Business Development Manager for NXP Semiconductors Silicon Valley Center. Prior to his current role, he worked with Freescale Semiconductor, Inc., headquartered in Tokyo, Japan, spanning different operational areas such as sales, applications engineering, product marketing, R&D. He co-authored a book based on RTOS and biomedical applications and has been awarded patents for semiconductors applied to biomedical sensing; MSG Excellence Award (2010) and the Outstanding Achievement Award (2011). Dr. Fernandez-Villasenor's interests focus on how to use technology to shift the paradigm from therapeutic medicine to preventative medicine and how to achieve a more efficient healthcare sector through commoditization in the healthcare industry and its services. He earned his degrees in Bachelor of Systems and Electronics Engineering, Bachelor of Medicine and Bachelor of Surgery, holds Master's Degree and Residency in Aesthetic and Cosmetic Surgery. Most recently, he completed an interchange program with China Europe International Business School (CEIBS) on entrepreneurship and emerging new business models in China, and graduated Magna Cum Laude from his MBA at Tokyo specializing in finance, entrepreneurship and Japanese-style management.

Presentation: **"How Tech Companies are helping to Innovate and Define Standards for Medical Innovations"**
*Abstract* – Semiconductor companies are helping define the standards in hardware and software security, processing algorithms, and high power computing yet power-efficient microcontrollers and applications processors to drive innovation in the healthcare and medical markets. By designing them and creating easy to use enablement boards, reference designs and testing/validation procedures we reduce our customers' R&D investment and time to market, shortening time to revenue and increasing the accuracy/reliability for easy market adoption and regulation approval. By collaborating with OEMs and ODMs Semiconductor companies will help drive innovation in the market.

**Esamaiel Jabbari, PhD**
Affiliation: University of South Carolina
Dr. Jabbari is a tenured Full Professor of Chemical and Biomedical Engineering and the Director of Tissue Engineering and Drug Delivery at the University of South Carolina. He earned his Ph.D. from Purdue University in Chemical Engineering. He began his independent career as an Assistant Professor in the Departments of Biomedical Engineering

and Orthopedic Research at Mayo Clinic upon completion of his post-doctoral training at Monsanto and Rice University. Dr. Jabbari's research focuses on the engineering of 3D model culture systems for selection of stem cells and the effect if micro-environmental factors on maintenance of stem cells, in particular cancer stem cells. He received the Berton Rahn Award from the AO Foundation in 2012 and the Stephen Milam Award from the Oral and Maxillofacial Surgery Foundation in 2008. He was elected to the College of Fellows of the American Institute for Medical and Biological Engineering (AIMBE) in 2013. He has published >200 books, book chapters, peer-reviewed journal articles, and conference proceedings, and presented >250 seminars at national and international conferences on tissue engineering and drug delivery. He currently serves as the Chair of Bionanotechnology Technical Committee of EMB Society, Editor of International Journal of Biomaterials, special issue Editor of Gels, and North America Editor of Journal of Biomaterials and Tissue Engineering. He has published >200 books, book chapters, peer-reviewed journal articles, and conference proceedings, and presented >250 seminars at national and international conferences on tissue engineering and drug delivery.

Presentation: **"Regulatory Challenges in Commercialization of Novel Biologics for Tissue Regeneration"**

*Abstract* – It is predicted that the number of retrieval spinal fusion surgical operations will exceed the number of primary spinal fusion operations by year 2020. Metallic/plastic cages filled with autologous or allogeneic bone are commonly used in interbody spinal fusion. The persistence of residual stresses in non-resorbable cages, cage migration and slippage, and failure to integrate with the surrounding osseous tissue leads to localized chronic immune response, inflammation, nerve compression, long-term pain and graft failure in patients. This presentation will discuss FDA requirements for commercialization of a revolutionary CortiaMic device as a spinal fusion cage that provides the strength and stability of current plastic and metal products and is ultimately displaced by the patient's own bone tissue. Unlike current spinal fusion devices, CortiaMic is resorbable thus eliminating the long-term complications associated with persistence of non-resorbable metallic or plastic products in the patient after implantation.