Wednesday, July 18 8:00am –9:30am Meeting Room 304AB

Developing Open Standards Facilitates Technology Commercialization

Organizers:
Carole C. Carey, Former U.S. Food and Drug Administration
Esteban J. Pino, Universidad de Concepcion

Rapid changes in medical technology and innovation in medical devices require a general guidance to ensure their usefulness to benefit public health as well as improved quality of life. This is what standards are for. Standards provide a general framework on what is expected, a common language to describe these new technologies and minimal performance requirements, to ensure repeatable and reliable results. The need for standardization is evident in order to produce quality, safe, reliable products as well as low costs. IEEE Standards Association participants drive the development of IEEE international standards in an open environment. IEEE-SA brings together experts from academia, government and companies to find consensus and promote the development of new solutions in diverse areas. The purpose of this special session is to present the work of current initiatives and engage people to collaborate or propose new areas where standards are needed.

Panel Speakers

A. *Carole C. Carey, C3-Carey Consultants, LLC, carolecarey@mac.com*

"Overview of the IEEE Standards Development and Participation in WGs"

Carole is Chair of the IEEE EMB Standards Committee and Liaison to IEEE Standards Association Standards Board. She is former Senior Scientific Reviewer and Regulatory Scientist at FDA Center for Medical Devices and Radiological Health.

B. *Jose Contreras-Vidal, University of Houston, jlcontr2@Central.UH.EDU*

"Industry Connections Program in Neuro-Technologies for Brain-Machine Interfacing"

Jose "Pepe" is Hugh Roy and Lillie Cranz Cullen Distinguished Professor and Director, Noninvasive Brain-Machine Interface Systems Lab, Department of Electrical & Computer Engineering, University of Houston.

C. *Esmaiel Jabbari, University of South Carolina, JABBARI@cec.sc.edu*

"NanoBioTechnology Commercialization"

Esmaiel is a tenured Full Professor of Chemical and Biomedical Engineering at the University of South Carolina. He directs the Biomaterials, Tissue Engineering, and Drug Delivery Laboratory that specializes in 3D tissue models for bone and cartilage tissue engineering and targeted drug delivery to cancer stem cells.

D. *Young Lae Moon, Chosun University, ylm2103@gmail.com*

"IEEE Standardization Projects in 3D-Based Medical Device Applications – Visualization, Data Management, 3D Simulation, Bio-CAD Format for 3D Printing"

Young Lae the Chair of IEEE-SA 3D Medical Application Work Group, a Member of Additive Manufacturing, ISO-TC 261 and Medical team head, Kia professional baseball team. He is a practicing Orthopedic doctor and Professor in the Orthopedic Dept. Chosun University and Director of Chosun Medical Research Center.

E. *Esteban Pino, University of Concepcion, epino@ieee.org*

"Importance of Standards Education in Biomedical Engineering Programs"

Esteban is an associate professor at the Universidad de Concepción. He was head of the Biomedical Engineering program from 2010 to 2016. He is a member of the EMBS TC on Translational Engineering for Healthcare Innovations.

F. *Colleen Lee, US Food and Drug Administration (FDA), Colleen.Lee@fda.hhs.gov*

"The CDRH Standards and Conformity Assessment Program"

CAPT Colleen Lee is a Senior Standards Advisor at the Center for Devices and Radiological Health at the Food and Drug Administration covering multiple device areas including cardiology, neurology, and physical medicine.