29 October 2018, Monday
3:30 - 5:00 pm, Ambassador A (La Plaza)

Creating a Culture of Collaboration:
Inspire, Innovate & Participate in Consensus Standards Development
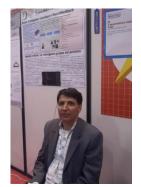
Christopher Scully, _Research Biomedical Engineer,_ Division of Biomedical Physics, Office of Science and Engineering Laboratories, **FDA Center for Devices and Radiological Health (CDRH)**

*Development and Use of Consensus Standards for Medical Devices.
*How Standards Can Aid in the Computational Evaluation of Physiologic Closed-loop Controlled Medical Devices.

Paper: _"Applying a Computational Model Credibility Framework for Physiological Closed-Loop Controlled Medical Device Testing"_

Luigi Bianchi, _Researcher and Assistant Professor,_ **University of Rome, Tor Vergata**

Built the first wearable BCI (Brain Computer Interface) system in the world.
Bianchi et.al., **Developing Wearable Bio-Feedback Systems: The BF++ Framework Approach**.
1st International IEEE EMBS Conference on Neural Engineering, March 2003.

*How the Adoption of a Standard model Can be Used to Better Describe a **BCI System** and its Performance
*Standardized File Formats in BCI Research Allows Data Sharing Among Labs and Manufacturers

Paper: _"Brain-Computer Interface Systems: Why a Standard Model is Essential"_

Carole C. Carey, _Medical Device Regulatory Consultant_, Former FDA CDRH, Senior Scientific Reviewer and International Advisor, **C3-Carey Consultants, LLC**

*IEEE Standards Development Process Overview and How to Participate in Standards Development & Standards Activities
*Engaging in Consensus, Open Standards Development is a Collaborative Process

Session Chair/ Moderator
IEEE EMB Standards Committee Chair

Luis Kun, _Distinguished Lecturer_, **EMBS (Engineering in Medicine and Biology) and SSIT (Society on Social Implications of Technology)**

Editor in Chief - Journal of Health & Technology - Springer Nature - IUPESM- WHO
IFMBE Chair Global Citizen Safety and Security WG, Member Developing Countries WG
IEEE Society on Social Implications of Technology (SSIT) - Board of Governors
IEEE EMBS /CS, Editorial Board - Transactions on NanoBioscience, Steering Committee
IEEE - Computer Society Adhoc Public Policy Committee - Healthcare Transformation Chair 2016

Lecture: "_Information Sharing of Electronic Health Records through Standards, Integration and Interoperability key for Adverse Preventable Errors, better Bio-surveillance and Healthcare outcomes_"

Pradeep Balachandran, Technology Consultant in the area of e-health and is based out of **Bangalore, India**

15 years of industry experience in design and development of health information systems, speech and language technologies and e-governance.
Secretary, IEEE P2650 Mobile Prescreening Audiometry Standards WG. He is also a member of IEEE P1752 Open Mobile Health Standards Working Group, IEEE P2673 Intelligence Augmentation for Medical Imaging Standards WG and IEEE Virtual Reality and Augmented Reality Advisory Board.

Paper: "_Collaborative Model for Stakeholder Engagement in Consensus Standards Development_"