

## **IEEE Region 2 Women In Engineering Coordinator**

### **Ms. Carole Carey**

**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, an International Advisor and as Director of International Staff. As a Senior Reviewer and peer-reviewed Expert Regulatory Review Scientist, she led multidisciplinary teams to evaluate safety and effectiveness data of highly complex, innovative cardiovascular devices. In this capacity, she was actively involved in the development of industry consensus device standards both at the national and international levels.

She served for 2 years as a Mansfield Fellow where she conducted technical exchanges 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). Carole worked on regulatory device issues, scientific matters concerning device safety and effectiveness, the recognition of international standards, medical devices global harmonization initiatives, and bilateral agreements with other countries. In addition, she conducted capacity building device regulatory workshops in Europe, Asia and Latin America. Currently, she is a regulatory consultant and founded C3-Carey Consultants, LLC. The consultancy provides advice and strategic approaches in premarket submissions, investigational device clinical trials and postmarket compliance issues. Carole earned her Bachelor's in Engineering degree from Johns Hopkins University and Master in Engineering Science Loyola University of Maryland with concentration in Computer Engineering.