Japanese Clinical Engineers Visit

October 26, 2012

At the end of August, a team of clinical engineering professionals from Japan visited the Technical Services Partnership (TSP) at the University of Vermont in Burlington. This is the second visit by clinical engineers from Japan with the first occurring in 2006. The purpose of their visit was to understand the profession in the US, visit TSP – a best practices leader with all clinical engineers certified (CCE) by the Healthcare Technology Certification Commission, and to research US requirements for medical device Instructions for Use (IFU) documents – what is required, what is the content, how are they used, etc.? In Japan, it is required to provide the IFU document called “Tempu Bunsho” with the device separately from the full operator’s manual. This usually 4-5 page document consists of the information such as warnings, contraindications, usage and operations, specifications, etc. The team wants to improve the document as it is far from user-friendly. As clinical engineers are key professionals regarding this aspect of medical device regulation in Japan, funding was provided from the Japanese Ministry of Health for the trip. The contingent included Minoru Hirose, Ph.D., Professor, Clinical Engineering, Kitasato University, Takashi Kano, Ph.D., Professor, Clinical Engineering, Saitama Medical University, Teruhiko Takakura, Director, Department of Clinical Engineering, Kameda Medical Center, Fumika Aoki, Japanese Pharmaceuticals and Medical Devices Agency, and Atsuko Kakehi, Overseas Operations Manager, Taisho Biomed Instruments Co. who served as the interpreter.

In Japan, clinical engineers are individuals who operate life support equipment such as cardio-pulmonary bypass units, dialysis equipment, and ventilators in addition to being responsible for the testing, maintenance and management of medical devices. Their training includes intensive education in medical sciences and clinical procedures along with technical and engineering studies.

During their visit to the Technical Services Partnership in Vermont, TSP arranged a conference call with the FDA, toured the university’s Clinical Simulation Center, Fletcher Allen Health Care, UVM campus, and the Burlington area. As the American College of Clinical Engineering (ACCE) International Committee was having its monthly conference call during their visit, the group joined via WEBEX to introduce themselves and to discuss clinical engineering in Japan.

TSP Director, Tobey Clark is a member of the international committee. The group was very appreciative of the donations and support provided by ACCE membership to the Japan Association for Clinical Engineering Technologists following the earthquake and tsunami disaster in 2011. The Japanese association hopes to establish a relationship with ACCE in the future.

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