Medical Imaging Devices Forum

08:30-12:00, September 12

Co-Chair: Ms. Liu Xiaoyan
Director of Evaluation Division I of Center for Medical Device Evaluation, CFDA.

Co-Chair: Ms. Tran Quan
Executive, Quality Assurance & Regulatory Affairs, GE Healthcare Asia Pacific & China.

08:30-08:35 Introduction of the Co-Chairs

08:35-09:15 Common Questions for Technical Evaluation of Ultrasonic Instruments and Thinking about New Ultrasonic Technology
Guo Zhaojun, Review for Evaluation Division I of Center for Medical Device Evaluation, CFDA, with the responsibility for technical evaluation of ultrasonic instruments, Member of Medical Ultrasonic Instruments Standardization Technical Sub-Committee of National Technical Committee on Medical Electrical Equipment of Standardization Administration of China. She has been involved in compilation of Guide for Technical Evaluation of Diagnostic Imaging Ultrasonic Instrument Registration.

09:15-09:45 IEC 60601-1 – Experiences and Expectations
Wolfgang Leetz, Head of Technical Regulation and Standards, responsible for the management of Technical Regulations and Standards of Siemens Limited China and based in its Headquarters in Beijing. When he came to Siemens years ago, his initial responsibility was data privacy and information security for products of the Healthcare Sector. Then he became the Standards and Regulations Manager of the Healthcare Sector with worldwide responsibility for the appropriate staffing of relevant committees and for the overall standardization strategy. During this time he actively influenced the structure of standards for medical devices, including software which is a medical device in IEC TC 62 and ISO TC 215.

09:45-10:15 Basic introduction of clause 14 of IEC60601-1 3rd edition
Wang Shunmin, Responsible for medical device and medical laboratory equipment certification services, having more than 13 years relevant experience. He is qualified UL final reviewer for relevant product, 510(k) and EU CE MDD technical file reviewer. Familiar with international regulatory requirements, risk management, quality system, software evaluation, is one of the most experienced engineer in UL health science department.
10:15-10:25 Tea Break

10:25-11:00 Differences and Similarities about EMC Standards of International and Domestic Medical Device
Meng Zhiping, Director of EMC Lab, Beijing Quality Supervision and Testing Center for Medical Device, CFDA, Senior Engineer, with his focus on medical device EMC test and improvement technology research. He is a member of B-Branch of International Special Committee on Radio Interference.

11:00-11:30 UDI–Japanese Medical Imaging Industry Perspective
Tatsuo Heki is Senior Expert at Fujifilm Healthcare Business Development Office. He is the member of International Committee, Japan Medical Imaging and Radiological Systems Industries Association (JIRA). He is a representative from Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association (DITTA) to the Unique Device Identification (UDI) Working Group of the International Medical Device Regulators Forum (IMDRF). He has been working on standards since the Advanced Photographic System, which is the last photographic film system in its history.

11:30-12:00 The Significant Change of European Medical Devices Directives in 2014
Lian Hongwen, North region Manager of Beijing Branch of TÜV SÜD Group China, holding responsibility for medical device system certification and CE product certification. She once worked in Quality and Standard Department of China National Medical Equipment Industry Corporation and Standard Division of Quality Department, SFDA. Her responsibility includes development of medical device national standard and industrial standard, harmonization work for China Secretariat of IEC/TC62 of International. Besides, she was once appointed to be responsible for product certification, manufacturing license, and product registration review at Medical Device Department of SFDA.

Co-Chairs: Mr. Wang Jianjun
Deputy Head for Liaoning Medical Device Test Institute, Professor of Engineering, involved in standard formulation and test research of medical x-ray diagnostic instrument.

Co-Chair: Ms. Feng Yan
Vice-chairman of COCIR in China. She is also a member of AHWP and has been working in the field of healthcare equipment regulatory affairs for many years, being responsible for various regulatory affairs, such as the standards of healthcare equipments, registration and certification, quality monitoring, security regulation. She has extensive experience in the field of global standards, law and regulatory systems for different countries in the healthcare equipment industry. Currently, she is the director of quality, regulatory and government affairs department of Philips Healthcare China.

13:30-13:35 Introduction of the Co-Chairs
13:35-14:15 Introduction to Guide for Medical Magnetic Resonance Imaging System
Yang Pengfei, Reviewer of Division I of Evaluation, Center for Medical Device Evaluation, CFDA.
Holding responsibility for technical review of imaging instruments including magnetic resonance imaging system. He holds a Doctor degree in engineering.

14:15-14:45 TC210 WG on ISO13485
Marcelo Antunes, CEO of SQR Consulting, Medical Imaging & Technology Alliance (MITA) Brazil representative. More than 10 years of experience in medical device consulting, which specializes in areas of expertise such as risk management (ISO 14971), quality systems (ISO 13485, GMP), regulatory systems (CE mark, ANVISA) and testing and standardization (IEC 60601 series). He is also a professor of Medical Device Design and Development at the Biomedical Engineering Department of the Pontificia Universidade Catolica de Sao Paulo as well as teaching Medical Device Regulatory Affairs at the Instituto Nacional de Telecomunicacoes. He is the Chairman of the Brazilian mirror groups to ISO TC 210 (Quality Management and general aspects of medical devices) and IEC TC 66 (laboratory equipment). He is also the convener of several working groups of the Brazilian mirror committees to IEC TC 62 (Medical Electrical Equipment) and ISO TC 215 (Health Informatics). At an international level, Marcelo is the Brazilian-appointed expert to all TC 210 working groups, as well as the IEC TC 62, IEC TC 66 and ISO TC 215 working groups.

14:45-15:15 GCP & GDP in Medical Device Clinical Trials
Randall Sanabria, M.D. Director, Clinical Affairs Operations, GE Healthcare. He graduated from the Autonomous University of Central America Medical School (Costa Rica) where he earned his M.D. degree. Working as an attending physician in a rural clinic he was responsible for managing local preventative medicine campaigns and providing care to the growing community. He also established a series of 9 remote clinics. He was a Clinical Project Manager at Boston Scientific-Neuromodulation, he managed clinical studies for their pain management division. Prior to GE, Randall worked as Director of Clinical Affairs for NeuroSystec Corporation where he was responsible for the Global Clinical Research department. In this function he developed and provided oversight to the team, establishing standard operating procedures and adopting a clinical database system.

15:15-15:30 Tea Break

15:30-16:00 International Good Clinical Practices Requirements for Medical Devices Clinical Trials (TC194 WG4 for ISO 14155)
Danielle Giroud, RN, MBA, Founder, WMDO & MD-CLINICALS. With over 25 years of experience, Ms. Giroud is founder and senior faculty board member of the World Medical Device Organization (WMDO), an independent professional organization dedicated exclusively to serving the professional development and educational needs of medical device professionals from around the world. She is also currently convener for the expert group on clinical investigations; TC 194 WG4 for the ISO 14155 as well as liaison with the EU Commission - CIE (Clinical Investigation and Evaluation) task force.

16:00-16:30 Introduction on medical device post-market administration
Paul van Zeijst, Program Director Medical Technology at the Dutch Health Care Inspectorate.
16:30-17:00 Remanufactured Medical Systems: A Global Perspective on Regulation and Access
Gail Rodriguez, MITA’s Executive Director. She has worked in the nuclear medicine industry for eighteen years in various sales, marketing, training and management roles. Gail has been involved in imaging policy since 2008 when she served as policy and membership director for the Institute for Molecular Technologies. She has a Ph.D. in political science from the University of Kansas with an emphasis on health policy.

17:00-17:30 Medical X-ray Diagnostic Instruments
Ding Hongbin, Senior Engineer, working for Liaoning Medical Device Test Institute, main involved in electromagnetic compatibility including large laboratory project design, EMC laboratory design and EMC test and research.

17:30-18:00 Risk Management Implementation is the Only Way for Realizing Medical Device Safety
Chen Zhigang, Chairman of Beijing Hua Guang Certification of Medical Devices Co., Ltd., National Senior Auditor, Secretary-General for Beijing Society of Biomedical Engineering, Senior Engineer, Secretary-General of SAC/TC221. He was once appointed as deputy director of new medical device auditing department, SFDA, director of China Quality Certification Center for Medical Devices, leader for Beijing Institute for Medical Device Research.

08:30-12:00, September 13

Co-Chair: Ms. Shi Hui
Consulting Division of China Ceter for Pharmaceutical International Exchange

Co-Chair: Ms. Eva Reiter
Vice President Quality Management, Process Management & Regulatory Affairs, Healthcare Sector, Siemens AG. She has been with Siemens for nearly 15 years and has worked in Quality & Regulatory Affairs in particular for the standalone medical device software area. She has gained tremendous experience in a variety of medical device companies by executing regulatory audits (MDD, CMDCAS) for a European Medical Device Notified Body (DQS Med GmbH).

08:30-08:35 Introduction of the Co-Chairs

08:35-09:10 Safety Research on Medical Information Instruments
Liu Jiong, working for active test lab of Shanghai Testing & Inspection Institute for Medical Device.
09:10-09:40 Research on Trade Compliance in Domestic Medical Device Enterprises
Globalization—Introduction to US. And Hongkong Restraint of Trade
Yanhong Bai, Technical manager of Regulatory Affairs for Shenzhen Mindray Bio-Medical Electronics Co. Ltd. Many years of experience in the marketing clearance of medical device in China, America, Europe, Canada and other international areas.

09:40-10:10 Software Standards Update: FAQ Regarding IEC 62304:2006 & Update about the IEC 82304-1
Peter Linders, Director of Global Quality and Regulations for Philips Healthcare. He has been with Philips Healthcare for more than 25 years. He was involved in X-ray imaging R&D for over 14 years, in various management positions. In that period, he became increasingly involved in development of international standards for regulatory purposes. In 1999 he became director of development of standards and regulations at Philips Healthcare. Since then, he has been active in the development of standards and regulations at the European and international level. He is chair of CENELEC/TC 62 and is involved in technical committees of IEC and ISO. He is also active in European industry associations related to medical devices, in particular in COCIR, where he is chair of the Technical and Regulatory Affairs Committee. For DITTA, the international industry association set up by COCIR and other industry bodies, he participates in working groups of the International Medical Device Regulators Forum, IMDRF.

10:10-10:25 Tea Break

10:25-10:55 Medical Software Modification: Regulatory Requirements in Europe, US and Other Countries and Industry Examples
Eva Reiter, Vice President Quality Management, Process Management & Regulatory Affairs, Healthcare Sector, Siemens AG. She has been with Siemens for nearly 15 years and has worked in Quality & Regulatory Affairs in particular for the standalone medical device software area. She has gained tremendous experience in a variety of medical device companies by executing regulatory audits (MDD, CMDCAS) for a European Medical Device Notified Body (DQS Med GmbH).

Susumu Takahashi, Chairman of International Committee, Japan Medical Imaging and Radiological Systems Industries Association (JIRA) Member of the Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association (DITTA) Steering Committee Vice chairman of Committee on Electromedical Systems, Japan Electronics & Information Technology Industries Association (JEITA) Vice chairman of General Administration Committee, Japanese Association of Healthcare Information Systems Industry (JAHIS) Vice chairman of Asia sub-committee, The Japan Federation of Medical Devices Associations (JFMDA) Senior Staff, Planning Department, Toshiba Medical Systems Corporation Senior Staff, 3R (Refurbishment/Reuse/Recycle) Promotion Department, Toshiba Medical Systems Corporation.

11:25-12:00 Basic Requirements on Registration Application of Medical Device Software
Peng Liang, Review of Evaluation Division I of Center for Medical Device Evaluation, CFDA, Doctor of Engineering, mainly responsible for technical evaluation of medical device software. He is the Chinese Representative of IMDRF SMDS Working Group.