Biography

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Dr. Hsien-Yi Lin received his Ph.D. in 1996 from the Stony Brook University in the United States. After receiving the degree, he completed his postdoctoral training at Princeton University and had 7 years of work experiences with the Biomedical Engineering Research Laboratory of the Industrial Technology Research Institute. In 2007, Dr. Lin switched to the field of regulatory affairs. Since then, he has been working in this field for more than 9 years, including 2 years with the Division of Medical Devices, Center of Drug Evaluation (CDE) and 5 years with the Division of Medical Device and Cosmetics, Taiwan Food and Drug Administration (TFDA). He transferred to the Division of Medicinal Products of TFDA in 2015. Within his career in regulatory affairs, he had experiences in reviewing medical device clinical trials and pre-market applications, consultation, guideline drafting, and international cooperation.

Since 2012, Dr. Lin has been actively participating in the Regulatory Harmonization Steering Committee (RHSC) of APEC Life Science Innovation Forum (LSIF) and playing a role in the planning of international conferences such as APEC Advanced Workshop of Good Review Practice on Medical Products and APEC-AHC-AHWP Joint Workshop on Medical Device Combination Products in 2012, International Forum on Good Submission Practices and International Forum on Medical Device Combination Products in 2014, and International Good Submission Practice Workshop on Pharmaceuticals in 2015. In addition, he was a member of RHSC working group drafting the Good review practices: guidelines for national and regional regulatory authorities from 2013 to 2014. Dr. Lin has been on the APEC Good Registration Management Regulatory Science Center of Excellence Program Committee since 2016.