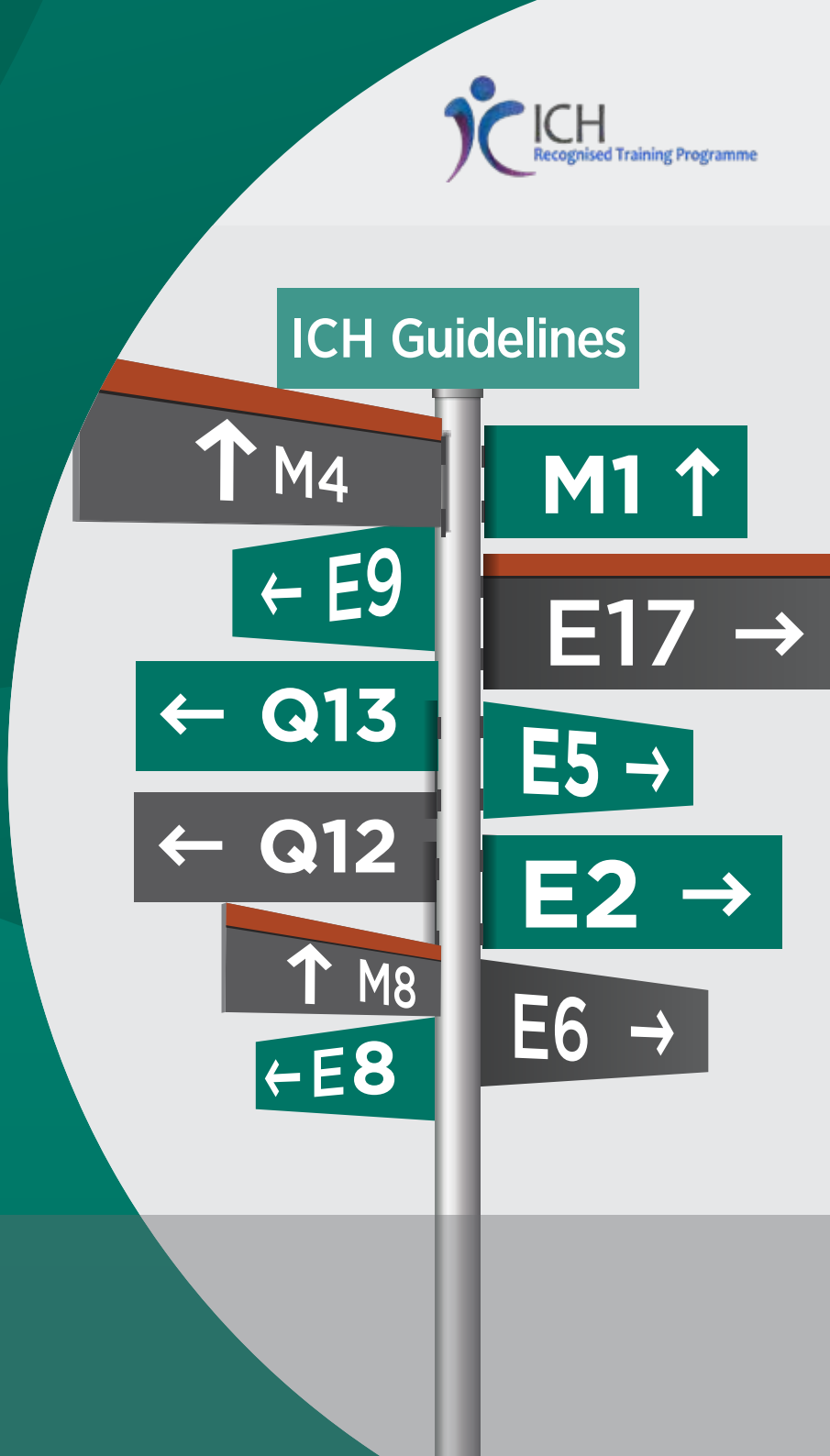
DIA CHINA

ICH Day

2022年12月8日 | 线上

December 8th, 2022

Virtual Meeting



Thursday | December 8th | ICH DAY

Since its inception in 1990, founded by the drug regulatory agencies of the US, EU, and Japan along with industry associations, to its reform and establishment of the non-profit, non-governmental legal entity under Swiss law in 2015, International Council for Harmonzation of Technical Requirements for Pharmaceuticals for Human Use (ICH) has successfully attracted regulators around the world to join and ensure greater coordination among the participating regulatory agencies. The purpose of ICH is to promote public health through international harmonization of technical requirements that contributes to the timely introduction of new medicines and continued availability of the approved medicines to patients, to the prevention of unnecessary duplication of clinical trials in humans, to the development, registration and manufacturing of safe, effective, and high quality medicines in an efficient and cost-effective manner, and to the minimization of the use of animal testing without compromising safety and effectiveness.

2022 is the 5th year since NMPA, China joined ICH Management Committee, to promote the ICH's global development strategy, DIA China 2022 ICH Day will invite the speaker from ICH core member countries to forward look the ICH's Further Initiatives from global perspectives, impact and updates for the new ICH Patient Focused Drug Development Guideline, as well ICH's Key Achievements and Implementation in China.

ICH Q series, S series, E9R1, E6R3, E8R1 and M4QR2 will be also covered.

Plenary

PROGRAM CO-CHAIRS

XU Xiaoqiang
Department of Drug Registration of NMPA

Zili LI, MD, MPH
Chair, DIA Advisory Council of China
Vice President and Head of Asia Pacific R&D, Janssen Pharmaceutical Company

8:30–8:35 **Welcome**

8:35–8:50 **Views of Different Stakeholders on How ICH Has Contributed to Better Health and ICH's Future Capacity Building Directions in the Next 5-10 Years**

Theresa MULLIN, PhD
Associate Director for Strategic Initiatives, FDA Center for Drug Evaluation and Research
Chair, ICH Management Committee

8:50–9:00 **PMDA Guidance on Patient Participation–PMDA's Consideration**

Junko SATO, PhD
Director, Office of International ProgramsPharmaceuticals and Medical Devices Agency (PMDA)
A Member of the ICH Patient Centricity Working Group

9:00–9:30 **ICH's Key Achievements and Implementation in China**

Siyuan ZHOU
Deputy Director, China CDE

9:30–10:00 **Tea Break**