Co-hosts DIA | China Center for Food and Drug International Exchange

2020 ICH E2 Guidelines Workshop

September 20 - 21, Beijing Tangla Hotel

ICH Recognised Training Programme

In order to enhance the transformation and implementation of ICH E2: Pharmacovigilance guideline in China, China Center for Food and Drug International Exchange (CCFDIE) and DIA China will jointly hold the 2020 ICH E2 Workshop on September 20 - 21 in Beijing.

The workshop will focus on the most frequently asked questions/concerns during the implementation of ICH E2 related among the drug development stakeholders of China, invite the PV and Drug Safety experts from ICH E2 EWG, China ICH Office, China CDE, China ADR and industrial professionals to share and discuss the China ICH E2 regulatory requirements, collected feedback, difficulties analysis and implementation strategies with the participants.

Program Committee

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Pfizer

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Agenda

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Day 1 | September 20 | Sunday

8:30 – 8:40	**Welcome**
8:40 – 9:00	**Overview of ICH E2 Guidelines** **Howe LI, MD, PhD** Founder and CEO, DeltaMed
9:00 – 10:00	**Interpretation of Post-Market PV System in "Drug Administration Law"** **Yue YANG, MD, PhD** Professor, Vice Dean, Drug Administration School, Shenyang Pharmaceutical University
10:00 – 10:15	Tea Break
10:15 – 11:00	**Post-market E2D Individual Case Safety Report (ICSR) Frequent Asked Questions** **Haibo SONG** ADR, NMPA
11:00 – 11:30	**The Collection and Reporting System of Adverse Drug Events – EMA's Perspective** EMA's Experience Sharing How to Encourage ADE Report ADE Reporting system and feedback
11:30 – 12:30	**China CDE's Experience on Reviewing of RMP** **Zhimin YANG** Acting Director, Drug Review Division II, CDE, NMPA
12:30 – 13:30	Lunchs
13:30 – 14:30	**Pharmacovigilance Planning: US Implementation of ICH E2E** **William Gregory** Senior Director, Worldwide Safety and Regulatory, Pfizer ICH E2B (R3) EWG
14:30 – 15:30	**How to Prepare and Write a Good RMP** **Gao GAO** Director, Safety Surveillance and Risk Management, Pfizer • ICH RMP Requirement • Hands-on Experience in RMP Development from MNC's perspectives
15:30 – 15:45	Tea Break
15:45 – 16:45	**Risk Management Plan** **Jan PETRACEK** Advisory Board, International Society of Pharmacovigilance • EMA's Practices • Industry's Perspective

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Day 2 | September 21 | Monday

8:40 - 9:00	**Introduction of ICH Periodic Safety Reporting Requirements**
	Julia ZHU, MD, PhD Executive Director, Drug Safety & Pharmacovigilance, Overland Pharma E2C (R2) – Periodic Benefit – Risk Evaluation Report E2F – Development Safety Update Report
9:00 – 10:00	**DSUR's Updates in China**
	Runyi MA Reviewer, CDE, NMPA
10:00 – 10:15	Tea Break
10:15 – 11:00	**E2C(R2): PBRER Guideline's Update and Implementation in China**
	China ADR Speaker Invited
11:00 – 12:00	**The Challenges and Key Practice for Implementing E2C(R2): PBRER Guideline – from Global Perspective**
	Tessy RUIJGROK Biogen
12:00 – 13:30	Lunch
13:30 – 14:30	**Difficulties and Key Points on Writing DSUR**
	Jia LIU Senior Director, PV & Drug Safety, dMed Medical • General Principles of DSUR Preparation • Data source and presenting of DSUR • Coordination and communication in the writing process of DSUR • DUSR connection and unification with other related documents
14:30 – 15:00	**Q&A**
15:00	End of the Workshop

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