GHC Global Harmonization Center

Website

Training on
ICH Guideline 2026

2026. 10. 1(Thu) - 10. 2(Fri) I EL Tower, Seoul

Hosted by GHC Global Harmonization Center

Ministry of Food and Drug Safety
National Institute of Food and Drug Safety Evaluation

Organized by KoBIA Korea Biomedicine Industry Association

Supported by IFPMA International Federation of Pharmaceutical Manufacturers & Associations

KPBMA

[GHC] 2026 ICH Guideline Training Program

DAY 1 - Oct 1 (Thu)				
Time			**Session Title**	**Speaker**
09:00-09:25	30'		Registration	
09:25-09:30	5'	Opening	Opening Remarks	**Seokyeon Kang** NIFDS/MFDS
09:30-10:00	30'	ICH	Introduction to Korea's ICH Activities and Guideline Implementation Status	**Heesung Kim** NIFDS/MFDS
Session 1. PQS (Pharmaceutical Quality System) - Case-Based				
Chair: Kyungnam Kim / Novartis Korea				
10:00-10:40	40'	Q2(R2) /Q14	Opportunities and Challenges of ICH Q2(R2) and Q14 for the Analytical Lifecycle	**Jean-Francois Dierick** GSK
10:40-11:20	40'		ICH Q2(R2) and Q14: The Enabler for Analytical Procedure Lifecycle, Ensuring Robustness of Analytical Procedures Across a Drug's Lifetime	**Bryan Castle** Eli Lilly
11:20-11:30	10'		**Break**	
11:30-12:30	60'	Q12	Connecting Drug Substance Development and Lifecycle Management to the Core Foundations of Risk Management and the Pharmaceutical Quality System as Part of a Modern Regulatory Approach to Supply Chain Resilience	**Joseph Kutza** Eli Lilly
			From Foundations to Practice: Case Studies Applying Risk Management and the Pharmaceutical Quality System to Drug Substance Variations and PACMPs* for Supply Chain Resilience * Post-Approval Change Management Protocols	**Brix Bayuga** Eli Lilly
12:30-14:00	90'		**Lunch**	
14:00-14:30	30'	Q8/Q9/Q10	A Case Study in QbD-Based Product Development: From an Overturned Risk Assessment to a Rebuilt Control Strategy	**Myungmo Lee*** Novartis Korea
14:30-15:00	30'		ICH Q9, Q10 Introduction and Implementation	**Seunghyun Kim** * Dong-A ST
15:00-15:10	10'		**Break**	
Chair: Hyeryeon Bang / AstraZeneca Korea				
15:10-15:40	30'	Q13	ICH Q13 Guideline: Application and Trends in Continuous Manufacturing of Finished Drug Products	**Haewoo Lee** K-MEDI hub
15:40-16:10	30'		Introduction to Continuous Manufacturing for Biological Products and Case Studies	**Sunghun Jung** Samsung Biologics
16:10-16:30	20'		**Break**	
Session 2. ICH EWG Special Session - Focus on Global Trends				
16:30-17:10	40'	Q1 EWG	ICH Q1 EWG Stability Testing for Drug Substances and Drug Products	**Ashutosh Rao*** FDA
17:10-17:50	40'	M4Q(R2) EWG	M4Q(R2) Overall Development and Overall Control Strategy	**Sheila Inada*** AstraZeneca

* Current and Former ICH Working Group Members

DAY 2 - Oct 2 (Fri)				
Session 1. Safety & Efficacy - Case-Based				
Chair: Sun-Young Jung / Chung-Ang University				
Time			**Session Title**	**Speaker**
09:30-10:00	30'	M14	Understanding and Applying the ICH M14 Guideline: Key Principles, Practical Case Examples, and Future Directions	**Hojoon Lee** Amgen
10:00-10:30	30'		Applying the ICH M14 Guideline to Vaccine Safety Studies: Real-World Data for Regulatory Decision-Making	**Bongkyoo Choi*** GC Biopharma Corp.
10:30-10:40	10'		**Break**	
10:40-11:10	30'	E2D(R1)	Beyond Individual Case Reporting: From ICH E2D(R1) and E2C(R2) to Real-World Evidence	**Minkyung Shin** SeltaSquare
11:10-11:50	40'		Brief Introduction to ICH E2D (R1)	**Yuan (Isaac) Meng** TJ Biopharmaceutical
11:50-13:00	70'		**Lunch**	
13:00-13:30	30'	E14/S7 B Q&A	Implementing ICH E14/S7B in Practice: An Integrated Nonclinical and Clinical Approach to Cardiac Safety Assessment	**Jean-Pierre Valentin*** EFPIA
13:30-14:00	30'		ICH E14/S7B : Case-Based Q&A	**Dong-Seok Yim** The Catholic University of Korea
14:00–14:10	10'		**Break**	
Chair: Chang Sun Lim / KCDA (Korea Clinical Development Association)				
14:10–14:40	30'	M15	Model-Informed Drug Development (MIDD) I	**Malidi Ahamadi*** Sanofi
14:40-15:20	40'		Model-Informed Drug Development (MIDD) II	**Shelly Wang*** Gilead Sciences
15:20–15:50	30'		Model-Informed Drug Development (MIDD) III	**Seunghoon Han** The Catholic University of Korea
15:50–16:00	10'		**Break**	
Session 2. ICH EWG Special Session - Focus on Global Trends				
16:00-16:40	40'	E20 EWG	Overview of the ICH E20 Guidance on Adaptive Designs in Clinical Trials	**Vladimir Dragalin*** Johnson & Johnson
16:40-17:20	40'	E21 EWG	Participation of Pregnant and Breastfeeding Women in Clinical Trials	**Corinne de Vries*** EMA
17:20-17:50	30'	E22 EWG	ICH E22: Introduction to New Guideline and General Considerations for Patient Preference Studies	**Young Su Noh*** Hanmi Pharm
17:50-17:55	5′		Closing Remarks	**Heesung Kim** NIFDS/MFDS

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