

## 2019 ICH Guideline Training

- Date : September 4 (Wed) ~ 5 (Thu), 2019
- Venue : Grand Hilton Seoul Hotel (Seodaemun-gu, Seoul)
  - ※ Day1: Emerald Hall (3F) / Day2: Convention Hall (4F)

Day 1 Agenda [Multidisciplinary]		4th September, 2019
9:00-9:30	Registration	
*9:30-9:40	Opening Remarks	NiFDS
*9:40-9:50	Photo Time	
9:50-11:00	ICH M3(R2): Nonclinical Safety Studies for IND and NDA	Donghwan Kim (KYU)
11:00-11:20	Coffee Break	
11:20-12:30	ICH M3(R2) Questions and answers (Q&A) with case studies	Richard Haworth (GSK)
12:30-14:00	Lunch	
14:00-15:20	General principles of ICH M7	Joomi Kim (Dong-A ST)
15:20-15:40	Coffee Break	
15:40-17:00	ICH M7 Addendum: Derivation of compound-specific acceptable intakes/ Permissible Daily Exposures for impurities in pharmaceuticals	Patricia Parris (AstraZeneca)
17:00-17:20	Q&A	
17:20-	Closing	

\*Only In Convention Hall (4F)

Day 2 Agenda [Efficacy]		5th September, 2019
9:00-9:30	Registration	
9:30-10:30	Implementation of E2B(R3)	Yukie Yamaguchi (PMDA)
10:30-10:50	Coffee Break	
10:50-11:50	ICH E2B(R3) Guideline of China	Stella Xu (Dmed)
11:50-13:20	Lunch	
13:20-14:00	ICH E2B(R3) Implementation in Korea	Yubin Lee (MFDS)
14:00-15:00	ICH E2A – Clinical Safety Data Management: Definitions and Standards for Expedited Reporting	Gerald Dal Pan (FDA)
15:00-15:20	Coffee Break	
15:20-16:20	Inspection Readiness Through Internal Audits	Moin Don (PVCON)
16:20-17:20	A summary of the key messages in ICH E9, an introduction to Estimands and the Addendum to ICH E9.	David Wright (AstraZeneca)
17:20-	Closing	