Organizer: Clinical Trials Centre, The University of Hong Kong

Title: ICH E6(R3) GCP Guidelines in Action: From Clinical Trial Principles to On-Site Practice

Description:

“ICH E6(R3) GCP Guidelines in Action: From Clinical Trial Principles to On-Site Practice” is a six-session programme designed to help research professionals understand and apply the updated principles in day-to-day trial conduct. Each session will focus on key ICH GCP (R3) principles, practical sharing, and essential knowledge to support its implementation in research settings. A certificate of attendance will be awarded to participants who attended each session and CME accreditation for each session is pending.

This series is suitable for investigators, research staff, research pharmacists, study coordinators, and other clinical research professionals who would like a practical introduction to ICH E6(R3), along with useful insights and reminders for compliance and quality in clinical trial conduct.

Date	Topics	Description	Trainers
April 14, 2026	ICH GCP E6(R2) (R3) Overview & Principles Insight for Investigators & Study Site Personnel	Introduction to the core concepts in both ICH GCP (R2) & (R3), highlight of differences in (R3) and implementation to trial conduct at site level	Mr. Henry Yau
April 16, 2026	Study Site Records Management	Requirements of study site records management covering good documentation practices including organisation, maintenance, storage and archiving of essential study documents	Ms. Ada Chan
April 20, 2026	Safety Management in Clinical Trials	Assessment and reporting procedure of adverse events, or other safety information during real-life trials from the perspective of study operations team	Ms. Kitty Leung
April 22, 2026	Biospecimen and Investigational Product Management at Study Sites	Site workflows of biospecimen handling namely processing, labelling, storage, transport in addition to investigational product receipt, storage, preparation, dispensing with attention to protocol requirements	Mr. Leon Wan, Ms. Meena Au
April 28, 2026	Quality Management at Study Sites	Quality management approaches that support consistent, compliant, and well-controlled clinical trial conduct at study sites, examining how site teams can strengthen routine processes to maintain data integrity and support inspection readiness	Ms. Ada Chan, Ms. Olivia Hung
April 30, 2026	Informed Consent Principles & Practice	Highlight of how to carry out consent discussions properly in real-world site practice and ensuring the consent process follows regulatory requirements	Mr. Matthew Lou