No : IASMED/10638/GCP/V/2025/v/c

CERTIFICATE
OF COMPETENCE

This certificate is awarded to

HELDA KHUSUN, STP., M.Sc., PhD

Who has passed the Competence test of

Course & Workshop on

APPLIED GOOD CLINICAL PRACTICE (GCP)

Based on International Council for Harmonisation Good Clinical Practice E6(R3)

Organized by
The Indonesian Association for the Study of Medicinals (IASMED)
Virtually provided on 2-3 May 2025

Dra. Endang W. Hoyaranda
President of the IASMED Executive Board

This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors

Course & Workshop on

APPLIED GOOD CLINICAL PRACTICE (GCP)

Based on International Council for Harmonisation Good Clinical Practice E6(R3)

- Introduction to Good Clinical Practice (GCP)
- Roles and Responsibilities of the Ethics Committee in GCP
- Information for Trial Participants & Informed Consent Process
- Roles and Responsibilities of Investigators in Clinical Trials
- Protocols and Protocol Amendments in Clinical Trial
- Safety Reporting in Clinical Trials
- Investigator's Brochure, Essential Records, and Investigational Product in Cl inical Trial
- Roles and Responsibilities of the Sponsor in Clinical Trials
- Role of Study Coordinator and Trial Site Readiness
- Monitoring, Audits, and Quality Assurance and Quality Control in Clinical Trials

Prof. Dr. dr. Rianto Setiabudy, Sp.FK
Advisor of GCP Course Program