



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

A blue ink signature of Dra. Endang W. Hoyaranda, written over a faint, stylized IASMED logo.

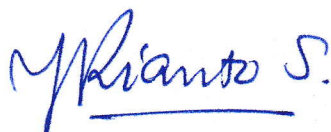
Dra. Endang W. Hoyaranda

President of the IASMED Executive Board

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 Clinical 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