

No : IASMED/9112/GCP/VI/2023/v/c



CERTIFICATE OF COMPETENCE

This certificate is awarded to

apt. NURUL KUSUMAWARDANI, M. Farm.

Who has passed the Competency test of

Course & Workshop on
APPLIED GOOD CLINICAL PRACTICE (GCP)

Organized by

The Indonesian Association for the Study of Medicinals (IASMED)

Virtually provided on 16-17 June 2023


Dra. apt. Endang W. Hoyaranda
IASMED Chairperson

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)**

- ☐ The Principles of ICH-GCP & its Implementation in Clinical Trial
- ☐ The Roles of Ethical Committee/IRB
- ☐ Study Protocol & Study Protocol Amendments
- ☐ Investigator Brochure & Essential Documents
- ☐ The Roles of Principal Investigator in a Clinical Trial
- ☐ The Roles of Clinical Research Coordinator, Site Preparation and Drug Accountability
- ☐ The Roles & Responsibilities of Sponsor and CRO
- ☐ Adverse Event(s) & Serious Adverse Event(s) in Clinical Trial
- ☐ Clinical Trial Monitoring & Source Document Verification (SDV)



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