

No : IASMED/9430/GCP/XII/2023/v/c



# CERTIFICATE OF COMPETENCE

This certificate is awarded to

***dr. KIRANA ANGGRAINI, MKM***

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 8-9 December 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)**

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- ☐ 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)
- ☐ Clinical Trial Design & Protocol



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