

## SURAT TUGAS

Nomor : 2061-R/UNTAR/PENUNJANG/VIII/2022

Rektor Universitas Tarumanagara, dengan ini menugaskan kepada saudara:

**SIUFUI HENDRAWAN, dr., M.Biomed., Dr.**



Untuk melaksanakan kegiatan penunjang dengan data sebagai berikut:

Judul Kegiatan/Aktifitas	:	Berperan serta aktif dalam pertemuan ilmiah Course & Workshop on Applied Good Clinical Practice (GCP)
Tingkat	:	Nasional
Peran	:	Anggota
Periode/Tahun/Tanggal	:	Genap/2022/17-18 Juni
URL/Repository	:	-

Demikian Surat Tugas ini dibuat, untuk dilaksanakan dengan sebaik-baiknya dan melaporkan hasil penugasan tersebut kepada Rektor Universitas Tarumanagara

10 Agustus 2022

**Rektor**



**Prof. Dr. Ir. AGUSTINUS PURNA IRAWAN**



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No : IASMED/8442/GCP/VI/2022/v/c



# CERTIFICATE OF COMPETENCE

This certificate is awarded to

***Dr. dr. SIUFUI HENDRAWAN, M.Biomed***

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 17-18 June 2022**

  
***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