

Registration Fee	
Category	Registration Fee
MOH staff / Student	RM 800.00
Non-MOH Staff	RM 900.00

This course fee includes workshop materials, refreshments, lunches and registration to sit for the examination

Payment Details
<i>Payment can be remitted via CDT / ATM transfer / Online Banking / Cheque / Local Order latest by 5th April 2019 made payable to:</i>
LOGOS BIOMED SYSTEMS SDN BHD Company Reg ID: 863019-H
Receiving Bank: RHB Bank Berhad (Jalan Simpang Tiga Branch)
Beneficiary A/C no: 21114600014339

We reserve the rights to cancel the workshop without liability other than the return of your registration fee

Contact Person & Enquiry
Forward your registration or enquiries to; Mr Sim Kian Tong or Puan Zuriah Sarkawi simktg.crc@gmail.com zuriah.crc@gmail.com
Clinical Research Centre Sarawak General Hospital 93586 Kuching, Sarawak
Tel: 082 - 276820 (Direct line) 082 - 276666 (Hospital ext. 1074) Fax: 082 - 276823

REGISTRATION FORM		
Title : Prof / Dr / Mr / Ms / Mdm / Miss <i>(please circle)</i>		

<i>Please print full name clearly as in your identification card or passport for your examination registration</i>		
IC / Passport No : _____		
Designation / Post : _____ Grade: _____		
MMC Number: _____ <i>(Doctor only for MMA-CPD point)</i>		
Department / Unit / Ward : _____		
Institution / Hospital / Clinic : _____		
Contact Details: <i>(* Required & please write clearly your email)</i>		
*Mobile (hp) no. : _____		
* Email Address : _____		
Mode of payment <i>(please tick ✓)</i>		
<input type="checkbox"/>	Cash (Fund Transfer / Online Banking / Cheque)	
<input type="checkbox"/>	LPO <i>(Approval given by Supervisor or HOD)</i>	
Meal request:		
<input type="checkbox"/>	Normal	<input type="checkbox"/> Vegetarian
Signature:		
For Secretariat use: Date received:	Registration No: GCP e-handbook: Quotations:	Status/Remarks:
Acknowledgement:	Receipt/Invoice:	Calling Letter:

GOOD CLINICAL PRACTICE (GCP) CERTIFICATION WORKSHOP (1/2019)

Date : 20th – 22nd April 2019
(Saturday - Monday)

Venue : Imperial Hotel Kuching
Level 5, Boulevard Mall
93250 Kuching, Sarawak.

Limited to 50 candidates only

Organiser



In collaboration with



Attendance is compulsory for the entire duration of the workshop to be eligible to sit for the examination

OVERVIEW

Good Clinical Practice (GCP) is a set of rules and regulation that is provided by International Conference on Harmonisation (*ICH*), an international body that regulates clinical trials involving human subjects. It is a standard for the design, conduct, performance, monitoring, auditing, recording, analyse and reporting of clinical trials that provides assurance that the;

- Data and reported results are credible and accurate, and
- Rights, integrity and confidentiality of trial subjects are protected.

WHY GCP?

In clinical trials, the protection of the subject is paramount especially when untested therapy is used. There must also be assurance about the conduct of clinical trials in terms of elimination of cheating, fraud or accidental error. Problems of poor study design must be avoided. Adherence to GCP is vital otherwise, subjects participating in the trials may be put at risk or the clinical trial data submitted may be rejected by health authorities and the scientific committee, if found to be unreliable. Also, the research credibility of the researcher and the research institution may be damaged. Malaysia adopted GCP in 1999 and since then health professionals are required to undergo training on GCP leading to certification prior to participation in clinical trials. This course is specifically designed to meet this requirement.

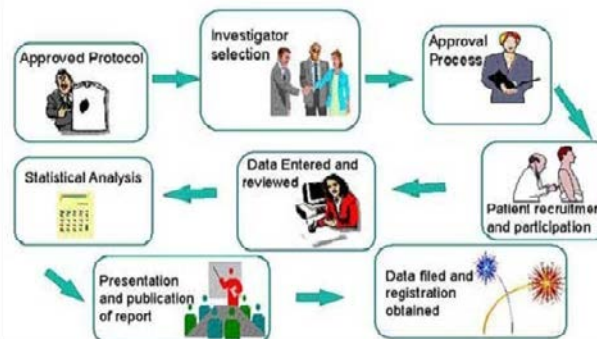
OBJECTIVES

- To understand the principles underlying GCP and its specific rules of conduct.
- To provide experience in the key skills required through simulation in classroom settings.
- To provide some of the resources required to design and to conduct GCP trial.
- To achieve an overall understanding on how to conduct GCP compliant clinical trial.

WHO SHOULD PARTICIPATE?

- Clinicians, nurses and allied health professionals involved with research
- Research Associates and Study Coordinators
- Biomedical and research scientists
- Statisticians and database managers
- Experienced research personnel who are interested in updating their knowledge regarding Good Clinical Practice

Clinical Trials - Design & Manage



COURSE CONTENTS

- Introduction to Good Clinical Practice
- Clinical Research in Malaysia and Role of Clinical Research Centre
- Overview of ICH/GCP and Malaysian GCP guidelines compared.
- Overview of ethics of clinical research, ethical principles & requirements
- Independent Ethics Committee (IRB/IEC)
- Informed Consent
- Case studies and ethical problems in clinical research & research misconduct
- Clinical Trial Protocol & Investigator's Brochure
- Investigator's responsibility
- Sponsor's responsibility
- Adverse event reporting & Safety surveillance
- Regulatory Aspects of Clinical Trials in Malaysia
- GCP Inspection – Trial site, sponsor/CRO, Phase 1 unit, BE & EC
- *Oversight and Funding for clinical research in MOH: Role of NIH, MOH guidelines for clinical research, MREC and MOH Research Grant
- *GXP (good clinical data management practice, good statistical practice, good laboratory practice, good documentation practice) * (*optional modules*)