REGISTRATION INFORMATION

Category	Before 28th February 2017	Before 7th April 2017
MOH	RM 800.00	RM 880.00
Non-MOH	RM 900.00	RM 980.00

CANCELLATION

- Any cancellation must be made in writing to the organizers
- Full refund for cancellation at least 2 weeks before date of the workshop
- 50% refund for cancellation within 1 week
- No refunds for cancellation less than 1 week or no show
- We reserve the right to cancel this course without liability other than return of the course fee
- Cancellation with no payment made less than 2 weeks need to find replacement or payment is compulsory

PAYMENT

Please check with secretariat that your registration is confirmed before making payment. Payment must be submitted at least 2 weeks **(latest by 7th April 2017)** before the workshop. Cheque / bank draft / local order / postal order / ATM transfer / online transfer to be payable to:

LOGOS BIOMED SYSTEMS SDN BHD
c/o Clinical Research Centre (CRC),
Sarawak General Hospital ,
93586 Kuching, Sarawak
Reg No: 863019-H
Account No: **21114600014339**
RHB Jalan Simpang Tiga

CONTACT PERSONS:

Ms. Shirley Tan Siang Ning or Dr. Tiong Xun Ting
email address: crcsgh.gcp@gmail.com

CLINICAL RESEARCH CENTRE
SARAWAK GENERAL HOSPITAL

TEL: 082-276820 / 082-276666 (ext 1074)
FAX: 082-276823

REGISTRATION FORM

Name: Prof/Dr/ Mr/ Ms

_____

IC / Passport No:_____
(Please print full name in capital letters and identification card/ passport clearly for preparation of certificates)

Department: _____

Institution: _____

Designation: _____

Contact Address: _____

_____

_____

Contact No (Compulsory):_____

Email: _____

Office: _____

Mobile: _____

Fax: _____

Signature: _____

Meal Request:
Vegetarian Non-vegetarian

Sponsor:
Government (LPO)

Private
Company name: _____
Contact person: _____
Contact no: _____

Self

GOOD CLINICAL PRACTICE (GCP) CERTIFICATION WORKSHOP

DATE : 22nd-24th April 2017
(Saturday-Monday)
VENUE : Imperial Hotel,
Boulevard Mall, Kuching

LIMITED TO 50 SEATS ONLY!!!

ORGANISED BY:

CRC
MINISTRY OF HEALTH MALAYSIA
Research that matters to patients

IN COLLABORATION WITH:

LOGOS BIOMED

Attendance is compulsory for the entire duration of the course to be entitled to sit for the exam

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 trials are protected.

OBJECTIVES

1. To understand the principles underlying GCP and its specific rules of conduct.

2. To provide experience in the key skills required through simulation in classroom settings.

3. To provide some of the resources required to design and to conduct GCP trial.

4. To achieve an overall understanding on how to conduct GCP compliant clinical trial.

COURSE CONTENTS

Overview of ICH/GCP and Malaysian GCP

Clinical trials design and protocol development

Ethics and regulation of clinical trials

Role of IRB/IEC

Informed consent

Safety monitoring and reporting

Investigator's responsibility (study initiation, patient recruitment, CRF completion and source documents, drug accountability, role of site coordinator, essential documents, archiving at site)

Working with sponsor (selection of investigator/site, agreement including finance

Legal aspects of clinical trials including research agreement

Financial aspects of clinical trials

IT for clinical trials

GXP (good clinical data management practice, good statistical practice, good laboratory practice, good documentation practice)* *(*optional)*

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 doctors 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.

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 GCP