

GOOD CLINICAL PRACTICE (GCP) WORKSHOP

7th to 9th October 2025
 (Tuesday, Wednesday & Thursday)

UCSI Hospital,
 No 2 Avenue 3 Persiaran
 Springhill, Port Dickson

Day 1 : 8.00 AM-5.15 PM (Online session)

Day 2 : 8.00 AM-5.00 PM (Online session)

Day 3 : 8.00 AM-1.00 PM (Physical)



SPEAKERS



Tan Sri Dato' Seri Clinical Professor Dr Haji Noor Hisham Abdullah
 Chairman of UCSI Healthcare Group, Consultant Breast and Endocrine Surgeon



Asst. Prof. Dr. Deepali Sharma
 Consultant Radiologist & Senior Director Healthcare Group Strategy Office & Medical Education Centre, UCSI Hospital



Dr Nik Nur Eliza Binti Mohamed
 Deputy Head of Unit, Clinical Research Center (CRC), Hospital Kuala Lumpur



Dr Tay Ju Fan
 Manager, Clinical Research Center (CRC), Hospital Selangor



Mr Lucas Khiew
 Clinical Study Manager, Roche Malaysia



Ms Zakiah Bakar Ali
 Investigational Product Evaluation & Safety Evaluator, National Pharmaceutical Regulatory Agency (NPRA)



Ms Sherena Razaly
 Coordinator, Center for Medical Education & Training (CMET), UCSI Hospital



Prof Dr Shamala Devi Sekaran
 Organising Chairman, GCP Programme, Adjunct Professor, FMHS, UCSI University

- Principal investigators of clinical trials
- Clinical physicians involved in clinical trials
- Nurses
- Allied health professionals
- Clinical research associates
- Clinical trial statisticians
- Pharmacists
- Postgraduate students
- Experienced research personnel who are interested in updating their knowledge about clinical trials

WHO SHOULD ATTEND

PROGRAMME FEE:

UCSI

- UCSI Postgraduate students and post-doctoral fellow
- UCSI University and UCSI Hospital staff

RM 400

RM 500

NON-UCSI

- External Participant

RM 550

ADDITIONAL

- GCP Certification Only (must provide proof of Attendance at a previous GCP Workshop)
- Group Registration Discount (5 persons)

RM 200

10%

REGISTRATION:



Scan QR Code to register and RSVP by **30.09.2025**

Limited to the **first 60 registrations** only

For enquiries, please contact CMET Coordinator at 012-2185 813

Email: cmet@ucsihospital.com | Tel: +606-648 8888 (ext.7247)

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ONLINE

- DAY 1**
- 7.30 AM : Registration & Introduction by **Ms Sherena Razaly**
 - 8.00 AM : **Welcome Speech** by **Assistant Professor Dr Deepali Sharma**
 - 8.10 AM : **Strengthening Clinical Research in Malaysia Through Good Clinical Practice (GCP) Certification** by **Tan Sri Dato' Seri Clinical Professor Dr Haji Noor Hisham Abdullah**
 - SESSION 1 : Introduction to GCP & Ethics of Clinical Research**
 - 8.25 AM : **Clinical Research In Malaysia** by **Dr Nik Nur Eliza Binti Mohamed**
 - 8.45 AM : **Overview of ICH/GCP (GCP Chapter 2)**
 - 9.45 AM : **ICH/GCP and Malaysian GCP Guideline Compared**
 - 9.45 AM : Morning Break
 - 10.15 AM : **Overview of Ethics of Clinical Research, Ethical Principles & Requirements (Helsinki Declaration)** by **Dr Nik Nur Eliza Binti Mohamed**
 - 11.15 AM : **Independent Ethics Committee (GCP Chapter 3)**
 - 11.45 AM : **Ethical Problems in Clinical Research**
 - 1.15 PM : Lunch
 - 2.15 PM : **Clinical Trial Protocol & Investigator's Brochure (GCP Chapter 6 & 7)** by **Dr Tay Ju Fan**
 - 2.45 PM : **Informed Consent (GCP Section 4.8)**

ONLINE

- DAY 2**
- 7.30 AM : Registration
 - SESSION 2 : Investigator's Responsibility**
 - 8.00 AM : **Investigator's Responsibility (GCP Chapter 4)** by **Dr Tay Ju Fan**
 - 10.30 AM : Morning Break
 - 11.00 AM : **Investigator's Responsibility (GCP Chapter 4, continued)** by **Dr Tay Ju Fan**
 - 12.00 PM : **Group Exercise : Role and Responsibilities or Investigator, IRB/IEC and Sponsor**
 - 1.00 PM : Lunch
 - SESSION 3 : Sponsor's Responsibility**
 - 2.00 PM : **Sponsor's Responsibility (Section 5 & 6)** by **Mr Lucas Khiew**
 - 4.00 PM : **Group Exercise: Adverse Event**

PHYSICAL

- DAY 3**
- 8.00 AM : Registration & Breakfast
 - SESSION 4 : Conducting Research in Malaysia**
 - 8.30 AM : **Regulatory Aspects of Clinical Trials in Malaysia** by **Ms Zakiah Bakar Ali**
 - 9.30 AM : **GCP Inspection – Trial Site, Sponsor/CRO, Phase 1 Unit, BE & EC**
 - 10.30 AM : Morning Break
 - 11.00 AM : **GCP CERTIFICATION EXAMINATION** by **Ms Sherena Razaly, Coordinator**
 - 12.00 PM : Lunch

NOTE: Attendance on all 3 days is MANDATORY to be eligible to sit for the GCP Certification Examination

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