

Good Clinical Practice Workshop

24 – 26 September 2010, Ho Chi Minh City – Vietnam.

Why you cannot miss this workshop?

The Good Clinical Practice (GCP) represents the operational standards in Clinical Drug Development and ensures that clinical trials meet ethical and scientific standards.

In this 3-days GCP workshop,

- Exposure to the theoretical and operational aspects of core Clinical Trials Management activities
- Participants will get a step by step understanding of the clinical trial management process, from drug discovery to the conduct of a clinical trial.
- Ethical issues involved and potential problems faced in clinical trials will be covered through mind-stimulating and interactive discussion based on examples and exercises.
- Participants will put what they are learning to use, and they will be evaluated on their knowledge through a GCP Test. Participants who pass the test will receive a certificate exclusively issued by GleneaglesCRC Pte. Ltd, endorsed by Murdoch University, Western Australia.

**LIMITED SPOT
AVAILABLE**

**Venue: Oscar Saigon Hotel
68A Nguyen Hue Ave,
District 1, HCMC,
Vietnam.**

Date: 24-26 September 2010

BOOK EARLY

Who should attend?

- ✓ Clinical research professionals in the pharmaceutical and biopharmaceutical industry, clinical research organizations, and research institutions.
- ✓ Clinical Research Associates
- ✓ Clinical Research Coordinators
- ✓ Clinical Research Managers
- ✓ Medical Directors
- ✓ Project Team Leaders/ Coordinators
- ✓ Investigators
- ✓ Clinicians, nurses and pharmacists, who are currently engaged or interested in the conduct of clinical trials
- ✓ Experienced research personnel, and Business Development Executives who are interested in networking with other clinical research professionals
- ✓ Statisticians and Database Managers.

Workshop Highlights:

- Introduction to Clinical Research.
- Understand the Principles of ICH-GCP.
- Elements of Informed Consent.
- The Responsibilities & Golden-Rules of Sponsor, Investigators and Study Coordinator.
- Clinical Trial Protocol & Protocol Amendments.
- Safety Monitoring and Reporting.
- Handling & Accountability of Clinical Trial Material.
- Quality Assurance in Clinical Trial: Fraud and Misconduct.

Learning Objectives:

- Key concepts in Good Clinical Practice and Clinical Research.
- Essential Skills in running a Clinical Trial.

Organized by:



Approved by:



Endorsed by:



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Agenda

Introduction to Clinical Research

Session-1: From Molecules to Bedside: Basics of Drug Development

- Exploring the basics of drug development.
- Introducing new strategies in drug development which brought about advances in chemistry, molecular biology and translational medicine.

Session-2: Study Design and Phases

- Introducing the different Clinical Trials, Phases and Designs.
- It also highlights evolution of Clinical Trials, such as the demand for more Phase-IV Studies and adaptive Clinical Trials.

Session-3: History of Clinical Research

- Giving an overview of Clinical Research and the Development of Regulation in the industry.
- It also gives an overview of Institutions Regulatory bodies and Organizations that are involved in the industry, e.g: WMA, WHO, ICH, USFDA and EMEA.

Session-4: Clinical Trials in Vietnam

- An insight into the current Clinical Research Regulations and its Regulatory requirements for the conduct of Clinical Trials in Vietnam.

Session-5: Overview of Clinical Research Development in Vietnam.

Session-6: Principles of Good Clinical Practice

- Introducing to the Principles of Good Clinical Practice as outlined in the First-Part of the E6 Guideline of ICH-GCP.

Research Ethics

Session-1: The Role of the Ethics Committee

- Giving an overview of the responsibilities of the Ethics Committees as detailed in ICH-GCP.
- Giving insights on deficiencies of the Ethics Committees commonly found by Auditors.

Session-2: Elements of Informed Consent

- The Informed Consent Process is never straight forward and requires skill and training.
- Providing a Step-by-Step process of the Informed Consent Process.
- Examining approaches to the Informed Consent of vulnerable Subjects, e.g: in Pediatric Studies.

Session-3: Safety Reporting

- Safety reporting is critical for Clinical Trials.
- Introducing the Basics of Safety Reporting in accordance with ICH-GCP.

Players in Clinical Trials: The Golden Rules

Session-1: The Sponsor

Session-2: The Investigator

Session-3: The Monitor

- Introducing the Key-Player on the essentials as taken from ICH-GCP.

Starting a Study

Session-1: What makes a Good Clinical Trial Site?

- Choosing a Clinical Trial Site is critical for the success of the Study.
- Outlining the characteristics of a Clinical Trial Site that can conduct the Study according to expectations.
- Practical-Tips will also be provided for Site-Selection.

Session-2: Handling of Biological Specimens

- Giving the Practical Tips on handling dangerous goods and planning the clinical trial logistics

During Study

Session-1: Recruitment Strategies

- Giving best strategies for patient recruitment in general and as applied to specific therapeutic areas.

Session-2: Study Documentation

- Introducing the basic of Good Documentation Practice.

Special Topics: Introduction to Bioavailability and Bioequivalence Studies.

Workshops

(Participants are divided into Groups)

Session-1: Group Discussion of Current Clinical Research Infrastructure in Vietnam.

Session-2: Informed Consent Scenarios.

Session-3: Evaluation of Adverse Events

Session-4: Case Studies: Fraud and Misconduct in Clinical Trials.

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Registration Form

[] Prof. [] Dr. [] Mr. [] Ms.

PLEASE FILL IN THIS FORM WITH CAPITAL BLOCK

Please complete and return this form to:

+84-903 623 249

Email to:

letrinhmrc@yahoo.com.vn (Vietnam) or
deny_l@gleneaglescrc.com (outside Vietnam).

FIRST NAME _____ GIVEN NAME _____

ADDRESS _____

CITY _____ STATE _____

ZIP _____ COUNTRY _____

PHONE _____ FAX _____

EMAIL _____

MEAL : NON VEGETARIAN VEGETARIAN

WORKSHOP	REGISTRATION FEE	
	Participant from Vietnam	Participant from countries other than Vietnam
Good Clinical Practice (GCP) (3 days)	Free of Charge	USD 200

*The above registration fee is inclusive of coffee breaks, lunch, GCP certification endorsed by GleneaglesCRC and Murdoch University, Western Australia

** Accommodation and transportation are not inclusive in the registration fee and must be arranged by the participant

*** Should there be any cancelation, the registration fee is non-refundable

PAYMENT METHOD

- Transfer via following account:
Beneficiary : GleneaglesCRC Pte Ltd
Beneficiary account : 064-002920-7
Bank swift code : DBSSSGSG
Bank : DBS bank

Bank charges will be borne by participants

For further information, please contact: +84-903-623 249 letrinhmrc@yahoo.com.vn (Vietnam) or
+62-21-520 7739 deny_l@gleneaglescrc.com (outside Vietnam).

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