Good Clinical Practice (GCP)

Synopsis
Based on the ICH GCP E6(R2) guidelines and incorporating local regulatory requirements, the GCP course seeks to equip participants with basic knowledge and understanding of how GCP principles may be applied to the conduct of clinical trials.

Experienced speakers from various clinical research-related sectors will deliver a series of lectures covering the following broad elements:

- Core principles of Good Clinical Practice and ethical research;
- Local regulatory requirements and legal framework for clinical trials;
- Responsibilities of the sponsor and investigator;
- Procedures related to the operationalisation and conduct of clinical trials.

AGENDA

Date	Time	Topic
Day 1	0900 - 0945	[1] History of Research Ethics
	0945 - 1030	[2] Introduction to Drug Development Process
	1030 - 1100	Tea Break
	1100 - 1215	[3] Regulatory Requirements for Clinical Trials and Clinical Research Materials
	1215 - 1300	[4] Clinical Trial Safety
	1300 - 1400	Lunch
	1400 - 1500	[5] Investigational Products
	1500 - 1545	[6] What to Organise and How to Maintain the Investigator File
	1545 - 1615	Tea Break
	1615 - 1700	[7] Fraud and Misconduct
	1700 - 1745	[8] Overview of DSRB Review Process
Day 2	0900 – 1000	[1] Responsibilities of a Principal Investigator
	1000 - 1115	[2] Informed Consent
	1115 - 1145	Tea Break
	1145 - 1230	[3] GCP Inspections
	1230 - 1315	[4] Quality Assurance in the World of Clinical Trials
	1315 - 1415	Lunch
	1415 - 1515	[5] Overview of Legal Framework for Clinical Trials and CTAs
	1515 - 1600	[6] Legal Risk Management for Clinical Research
	1600 - 1645	[7] Responsibilities of a Sponsor

Note: Information is accurate at time of print. Agenda is subject to changes without prior notice.

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