



Wednesday 06 August 2008

- 0800-0830 Registration
- 0830-0845 Welcome address by Ms. Angeline Lim
Senior Clinical Research Manager
GleneaglesCRC Pte. Ltd, Singapore
- 0845-0915 Overview of Drug Development & Clinical Research
Prof Robert Coltrona, Dean, School of Pharmacy,
Murdoch University, Perth, Australia
- 0915-0945 Overview of ICH-GCP Guidelines
Prof Robert Coltrona, Dean, School of Pharmacy,
Murdoch University, Perth, Australia
- 0945-1030 Exercise 1: ICH-GCP Guidelines
- 1030-1045 Coffee Break
- 1045-1130 Ethics in Clinical Research and Role of Ethics Committee
Ms. Angeline Lim, Senior Clinical Research Manager,
GleneaglesCRC Pte. Ltd, Singapore
- 1130-1215 Regulatory Requirements of Clinical Trials in Indonesia
drs. Hary Wahyu
Badan Pengawas Obat dan Makanan Republik Indonesia
- 1215-1300 Networking Luncheon
- 1300-1345 Informed Consent Process
Ms. Angeline Lim, Senior Clinical Research Manager,
GleneaglesCRC Pte. Ltd, Singapore
- 1345-1445 Exercise 2: Informed Consent
- 1445-1505 Sharing of Experience : Conducting International Clinical Research in Indonesia
Prof. dr. Menaldi Rasmin, Sp.P(K), FCCP
Pulmonologist and principal investigator of WG2006/7 study
- 1505-1535 Intellectual Property and Governance by Sites
Prof Robert Coltrona, Dean, School of Pharmacy,
Murdoch University, Perth, Australia
- 1535-1605 Handling and Accountability of Clinical Trial Material
Fabiola C. R. Hutabarat, Senior Clinical Research Associate
GleneaglesCRC (Indonesia) Pte Ltd
- 1605-1620 Coffee Break
- 1620-1650 Q & A
- End of Session



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- A vertical decorative graphic element on the left side of the page, resembling a DNA double helix with various colored segments (blue, green, red, yellow) and a purple outline.
- 0815-0830 Registration
 - 0830-0915 Clinical Research in Indonesia
drs. Hary Wahyu
Badan Pengawas Obat dan Makanan Republik Indonesia
 - 0915-1000 Role and Responsibilities of the Sponsor and Site Study Monitor
Mr Rodmar Pulido, Country Manager
Gleneagles Clinical Research International Pte. Ltd, Philippines
 - 1000-1015 Coffee Break
 - 1015-1100 Role and Responsibilities of Investigator
Ms. Angeline Lim, Senior Clinical Research Manager,
GleneaglesCRC Pte. Ltd, Singapore
 - 1100- 1145 Exercise 3: Roles and Responsibilities
 - 1145- 1230 Good Documentation and Archiving
Mr Rodmar Pulido, Country Manager
Gleneagles Clinical Research International Pte. Ltd, Philippines
 - 1230-1315 Quality Assurance in Clinical Trials: Fraud and Misconduct
Mr Rodmar Pulido, Country Manager
Gleneagles Clinical Research International Pte Ltd, Philippines
 - 1315-1400 Networking Luncheon
 - 1400-1445 Safety Monitoring and Reporting
Ms. Angeline Lim, Senior Clinical Research Manager,
GleneaglesCRC Pte. Ltd, Singapore
 - 1445- 1515 Q & A
 - 1515-1530 Closing Remarks by Ms. Angeline Lim,
Senior Clinical Research Manager
GleneaglesCRC Pte. Ltd, Singapore
 - 1530-1545 Coffee Break
 - 1545-1700 Multiple choice question examination for certification
 - 1700-1730 Participants Evaluation
- End of Session

