Good Clinical Practice Workshop for Clinical Investigators

Guest Speaker

Prof. Gerhard Fortwengel, PhD, MPH

Head of Clinical Research, University of Applied Sciences and Arts Hannover, Germany

Venue: *Abdul Razzak Auditorium*

Faculty of Medicine, Kuwait University

Date: May 21st 2011

Time: From 8.30 AM to 4.30 PM

KIMS CME Reg. No: 332/IMO/May11

CME/CPD Credits: 8 Credits; Category 1

Program Schedule

Time	Topic	Practical Exercises / Corner Discussions / Group Work
8.00 - 9.00 AM	***Registration***	
8.50 – 9.00 AM	**Opening & Introduction**	
9.00 – 9.55 AM	History of Clinical Trial Legislation *CFR, Decl. of Helsinki, ICH, Regulatory Bodies, Summary*	-
9.55 – 10:10 AM	***Coffee Break***	
10:10 – 11.50 AM	ICH – GCP : *Overview, Roles and Responsibilities, EC/IRB, Investigator, Sponsor, Study Protocol and Amendments, Investigator Brochure, Summary*	Corner Discussion Related to Protocol Violations
11.50 – 1.00 PM	***Lunch Break***	
1.00 – 1.30 PM	Advertisement and Subject Recruitment	Practical Exercise: Material Review
1.30 – 2.15 PM	Informed Consent Process	Practical Exercise: Role Play on Consenting a Patient
2.15 – 3.00 PM	Safety in Clinical Trials	Corner Discussion Related to Safety Case Assessments
3.00 – 3.15 PM	***Coffee Break***	
3.15 – 3.40 PM	Investigational Product Handling at Site	-
3.40 – 4.20 PM	Essential Documents, Documentation and Archiving	Group Work: Electronic Documents as Medical Source
4.20 – 4.30 PM	**Discussion & Closing Ceremony**	

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