St.James College of Pharmaceutical Sciences St.James medical Academy River Bank, Chalakudy			
Programme:	PharmD	Sem.:	5th year
Name of Course: (*Subject*)	Clinical Research	Course Code:	1
Teaching faculty of the course	Maria George		

Summary of the Lecture Plan

Topic	Lectures	Hours
Drug development process	Drug discovery	6
	Preclinical trials	6
	IND application	2
	Drug characterization	2
Clinical development of Drug	Clinical trials	10
	ICH-GCP	14
	Regulatory environment in USA,Europe,India	8
	Roles and responsibilities of clinical trial personnel	14
	Designing of clinical study documents	10
	Data management and its components	4
	Safety monitoring in clinical trials	3

Major issues or Core aspects addressed/ covered:

Drug development process
Introduction to drug development
Drug discovery process-phases
Current methods in drug development process
Pre clinical testing
Pharmacological testing
Toxicological testing
Drug characterisation
Dosage form designing
IND application
Clinical development of drug
Introduction to clinical trials-planning and execution
Phases of clinical trials
Methods of post marketing surveillance
New Drug Application ,Abbreviated New Drug Application
ICH-GCP
History of ICH-GCP

Helsinki declaration, Nuremberg code ,Schedule Y, Vulnerable subjects
Principles and guidelines
Challenges in the implementation of ICH-GCP
CDSCO guidelines
Ethical guidelines/issues in biomedical research
Regulatory environment in USA, Europe, India
Clinical trial documents
Protocol
Case Report Form
Informed Consent Form
PIC
Roles and responsibilities of clinical trial personnel
Sponsor, Investigator
Clinical research associate,Auditor
Institutional Ethical Committee
Clinical research coordinator, Regulatory authority
Clinical Data Management
History of CDM,data management plan,drug review and validation,discrepancy management
Safety monitoring in clinical trials

Sample Questions from Lectures

Drug development process
Explain the DEVELOPMENT OF DRUG WITH a diagram
Approaches of Drug discovery process
Newer Techniques in drug development process
Pre clinical testing
Pharmacological approach in clinical research
Various types of Toxicological testing
Pharmacokinetic details in drug development
Bioavailability and bioequalence studies
Clinical development of drug
Explain the planning and execution of clinical trials
Compare the various Phases of clinical trials along with their objectives
Various methods of post marketing surveillance
New Drug Application
Abbreviated New Drug Application
ICH-GCP
Various milestones in the History of ICH-GCP
Describe the Principles of ICH-GCP

Various guidelines of ICH-GCP
Challenges in the implementation of ICH-GCP
CDSCO guidelines
Ethical issues in biomedical research
Helsinki declaration
Nuremberg code
Indian GCP
Schedule Y
Vulnerable subjects
Explain the Regulatory environment in India
Describe the clinical framework in USA
Explain the clinical trial in Europe
Roles and responsibilities of clinical trial personnel
Composition and role of Institutional Ethical Committee
Role of Investigator in clinical research
Responsibilities of Sponsor
Clinical research associate
Roles and responsibilities of auditor
Explain the duties and role of Regulatory authority in clinical trials
Clinical research coordinator
Clinical trial documents
Explain the lay out of Case Report Form
Designing of Informed Consent Form
Write note on PIC
Need of ICF in clinical trials
Note on Protocol designing