St.James College of Pharmaceutical Sciences St.James medical Academy River Bank, Chalakudy			
Programme:	MASTER OF PHARMACY	Sem.:	1ST
Name of Course: (*Subject*)	CLINICAL RESEARCH	Course Code:	MPP 104 T
Teaching faculty of the course	DEEPTHI C DENNY		

Summary of the Lecture Plan

Topic	Lectures	Hours
Drug development process	Submission Ethics in Biomedical Research	2
	Ethical committee	1
	Challenges in implementation of ethical guidelines	2
	Drug Safety Reporting.	1
Types and Designs used in Clinical Research	Planning and execution of clinical trials	1
	Various Phases of clinical trials	2
	Bioavailability and Bioequivalence studies	2
	Randomization techniques	2
	Time Sequences	2
	Sampling methods	2
	Health outcome measures	2
Clinical Trial Study team	Investigator	1
	Study Coordinator	1
	Sponsor	1
	Monitor	1
	Contract Research Organization	1
Clinical trial Documents	Protocols	1
	Investigator's Brochure	1
	Informed Consent Form	1
	Case report forms	1
	Contracts and agreements	1
	Dairy Cards	1
Clinical Trial Start up activities	Site Feasibility	1
	Pre-study visit	1
	Clinical trial agreement execution	1
	Ethics committee document	2
Investigational Product	Procurement and Storage of investigation product	2
Filing procedures	Essential documents for clinical trial	2

	Site initiation visit	
	Clinical Trial Monitoring	1
	Review of source documents	1
	Accountability and reconciliation	2
	EC communications	1
	Safety reporting	1
	Close out visit	1
Quality Assurance and Quality Control in Clinical Trials	Audit	1
	Stakeholders in audit process	1
	FDA inspections	1
	Fraud and misconduct management	1
Management Infrastructure and System Requirement for Data Management	Electronic data capture	1
	Coding dictionaries	1
	Data migration and archival	1
Clinical Trial Data Management	Standard Operating Procedures	1
	Data management	1
	CRF & Database design considerations	1
	Study set-up	1
	Managing laboratory and ADR data	1
	Quality Control and Quality Assurance in CDM	1
	Data mining and warehousing	1

Major issues or Core aspects to be addressed/ covered:

Topic Title
Drug development process:
Introduction various approaches to drug discovery
Investigational new drug application
Ethical Issues in Biomedical Research
Principles of ethics in biomedical research
institutional review board - its constitution and functions
ICH GCP guidelines and ICMR guidelines in conduct of Clinical trials
Topic Title
Types and Designs used in Clinical Research:
Simple randomization, restricted randomization, blocking method and stratification
Experimental, Quasi experimental, and Observational methods
Prospective and Retrospective
Cohort study, case Control study and cross sectional study
Clinical & Physiological, Humanistic and economic
Topic Title
Clinical Trial Study team:
Roles and responsibilities Investigator
Roles and responsibilities Study Coordinator
Roles and responsibilities Sponsor
Roles and responsibilities Monitor
Roles and responsibilities Contract Research Organization

Topic Title
Clinical trial Documents:
Guidelines to the preparation of Protocols
Guidelines to the preparation of Investigator's Brochure
Guidelines to the preparation of Informed Consent Form
Guidelines to the preparation of Case report forms
Guidelines to the preparation of Contracts and agreements
Guidelines to the preparation of Dairy Cards
Topic Title
Clinical Trial Start up activities:
Studies
Site/Investigator selection
Investigator meeting
Ethics committee document preparation and submission
Topic Title
Investigational Product:
Procurement of investigation product
Storage of investigation product
Topic Title
Filing procedures:
preparation and maintenance of Trial Master File
preparation and maintenance of Investigator Site File
preparation and maintenance of Pharmacy File
Conduct, Report and Follow up Clinical Trial Monitoring
Preparation and conduct of monitoring visit
Review of CRF, ICF,IP storage
Study Procedures
Monitoring visit reporting and follow-up
Study related documents collection
Archival requirement
Investigational Product reconciliation and destruction
Close-Out visit report
Topic Title
Quality Assurance and Quality Control in Clinical Trials:
Types of audits
Audit criteria, Audit process & Audit follow up and documentation
Responsibilities of stakeholders in audit process
Preparing for FDA inspections
Topic Title
Management Infrastructure and System Requirement for Data Management:
Electronic data capture systems
Systems Selection and implementation of new systems
System validation and test procedures

Topic Title
Clinical Trial Data Management:
Data management plan, Data entry, Data cleaning
CRF tracking and corrections
Data transfer and data base lock

Sample Questions

Topic Title
Drug development process:
ICH GCP guidelines in conduct of Clinical trials
Investigational new drug application
Institutional review board - its constitution and functions
Types and Designs used in Clinical Research:
Types of study in Clinical Research
Designs in Clinical Research
Clinical Trial Study team:
Roles and responsibilities of Sponsor, Monitor, Contract Research Organization & Investigator
Clinical trial Documents:
Guidelines to the preparation of Informed Consent Form, Investigator's Brochure, Case report forms
Clinical Trial Start up activities:
Ethics committee document preparation and submission
Topic Title
Investigational Product:
Procurement & Storage of investigation product
Filing procedures:
preparation and maintenance of Trial Master File,
Conduct, Report and Follow up Clinical Trial Monitoring, Investigational Product reconciliation and destruction, Close-Out visit report
Topic Title
Quality Assurance and Quality Control in Clinical Trials:
Types of audits
Audit follow up and documentation
Preparing for FDA inspections, Responsibilities of stakeholders in audit process
Topic Title
Management Infrastructure and System Requirement for Data Management:
Electronic data capture systems, System validation and test procedures
Clinical Trial Data Management:
Data transfer and data base lock