Academic Council 25/05/2011
Item No. 4.71

UNIVERSITY OF MUMBAI

Syllabus for Clinical Studies
Program: Diploma
Course: Post Graduate Diploma
in
Clinical Studies, Data Management & Medical Writing

(Introduced as per Credit Based Semester and Grading System with effect from the academic year 2011–2012)

O	***Title***	:	Post Graduate Diploma in Clinical Studies, Data Management and Medical Writing
O	***Eligibility***	:	Bachelor Degree in Life Science or Biotechnology or Chemistry or Statistics
R	***Duration of the Course***	:	One Year (Full Time/)
R	***Fee Structure***	:	Rs. 30000/-
R	***Intake Capacity***	:	40 Students
R	***Teacher Qualifications***	:	Completed Course in Clinical Studies and Experts from Clinical Research or Pharma industry
R	***Standard of Passing***	:	

a. Candidate who secures minimum 50% marks in each paper be declared to have passed the examination in that subject.

b. A candidate who fails to secure 50% marks in a paper will be allowed to reappear in that paper.

c. Candidate can carry forward at his/her option the marks in the paper in which he/she has passed, in such a case student is entitled for award of class.

d. Candidate who secures a minimum of 50% marks in each paper and an aggregate of 60% and above marks on the whole shall be declared to have passed the examination in the First Class.

e. Candidate who secures a minimum of 50% marks in each paper and an aggregate of 70% and above marks on the whole shall be declared to have passed the examination in First Class with Distinction.

Medium of Instruction	:	English
Field Visit	:	Clinical Research Organizations

Syllabus for Post Graduate Diploma

in
Clinical Studies, Data Management and Medical Writing
Scheme of Examination

PAPER	TITLE OF PAPER	MAXIMUM MARKS	MINIMUM MARKS	Credits	PAPER CODE
I	Clinical Pharmacology	100	50	8 Credits	PGDCS001
II	Good Practices & Regulations	100	50	8 Credits	PGDCS002
III	Clinical Trial Process	100	50	8 Credits	PGDCS003
IV	Drug Safety & Pharmacovigilance	100	50	8 Credits	PGDCS004
V	Data Management & Medical Writing	100	50	8 Credits	PGDCS005
VI	Management Skills	100	50	8 Credits	PGDCS006
	TOTAL	600	300	48 Credits	

(All papers include theory, viva, project and case studies)

Syllabus for Post Graduate Diploma

in
Clinical Studies, Data Management and Medical Writing

Paper I	:	Clinical Pharmacology
Paper II	:	Good Practices & Regulations
Paper III	:	Clinical Trial Process
Paper IV	:	Drug Safety & Pharmacovigilance
Paper V	:	Data Management & Medical Writing
Paper VI	:	Management Skills

Paper I : Clinical Pharmacology *8 Credits*

1. **Pharmaceutical Industry & globalization** –Overview, Opportunities & Career options in Clinical Research
2. **Pharmacy** - Physico-Chemical properties of drugs, different drug dosage forms, Formulation development and manufacture of drugs.
3. **Therapeutics** - Principles of Management & Drug Therapy
4. **Pharmacokinetics** - Absorption, bioavailability, distribution, metabolism protein binding, excretion, placental and blood brain barrier
5. **Pharmacodynamics** - Mechanism of drug action, receptors, agonists, antagonists, side effects and adverse events
6. **Toxicology** - Acute, Sub-acute and Chronic Toxicity, Mutagenicity, Teratogenecity, Oncogenicity and effects on fertility
7. **BA/BE Studies** - Bioavailability and Bioequivalence - Methods and Procedures, regulatory requirements, planning & design, Protocol/ CRF outline, QA & QC, Drug accountability

Paper II : Good Practices & Regulations *8 Credits*

GMP
GLP
ICH GCP
Ethics in Clinical Research
Regulation in India : Drugs and Cosmetics Act, Schedule 'Y', Quality in Regulatory Context, Patent laws
USFDA : History, Structure & Function, Code of Federal Regulation
EMEA : History, Structure & Function, Regulations
JAPAN : History, Structure & Function
ICMR : Overview

Paper III : Clinical Trial Process *8 Credits*

1. **Responsibilities of Stakeholders** : Sponsors, Investigators, CROs, Monitors
2. **Clinical Trial Design**
3. **Clinical Trial Phase I**
4. **Clinical Trial Phase II**
5. **Clinical Trial Phase III**
6. **Clinical Trial Phase IV**
7. **Essential Documents in Clinical Trials** : SOP, Protocol , Investigator Brochure, Master Files, Informed Consent Forms, Case Record Form
8. **Managements of Clinical Trials** - Investigator's Meeting, Project management, Patient Recruitment & Retention, Trial Monitoring, Drug Resource and supplies
9. **Trial Budget, Audit and Inspection**

Paper IV : Drug Safety & Pharmacovigilance *8 Credits*

1. **Principles of Pharmacovigilance :** Importance; National & International Programs; Methods
2. **Principles of Pharmacovigilance :** ADR; Assessment; Medication errors, Signal detection; Risk assessments
3. **Drug Dictionaries**: Coding & Tools
4. **Regulatory Guidelines :** ICH, EMEA, USFDA, Sch. 'Y'
5. **Drug Safety** : PSURs; Package inserts

Paper V : Data Management & Medical Writing *8 Credits*

1. **Bio-Statistics : Descriptive Statistics :** Data Types; Collection; Sampling, Compilation; Tables & Graphs, Measures of Central Tendency, Measures of variation
2. **Bio-Statistics : Analytical Statistics :** Overview, hypothesis testing in CR
3. **Clinical Data Management** : Principles of CDM, Data Entry, Queries & Data Clarification, Softwares in CDM
4. **Medical Writing :** Literature Search & Medical Articles, Contract writing, Publication, Abstracts, Bibliography, Clinical Study Reports

Paper VI Management Skills *8 Credits*

1. **Principles of Management**
2. **Management & relevance to CR**
3. **Introduction to Organization behavior**
4. **Introduction to Marketing**
5. **Introduction to Business environment**
6. **Aptitude Tests**

   Language & Vocabulary

   Spelling

   Comprehension

   Numerical

   Reading
7. **Effective communication skills**
   - Process
   - Types/Barriers
   - Business Language writing
   - E-mail writing
   - Report writing
8. **Public speaking**
9. **Presentation skills**
10. **Self Management & People Skills**
    - SWOT, Self Motivation
    - Emotional Intelligence

- Being Assertive
- Working together- team member
- Time management
- Managing conflicts
- Developing Leadership skills
- Creativity & Innovation
- Cross cultural skills

11. **Corporate etiquettes & workplace behavior**
12. **Developing Personal Impact**
13. **Interviews Skills and etiquettes & mock sessions through FAQs.**
14. **Group Discussions**
15. **Writing compelling CV and covering letter**

List of Reference Books :

1. Research in education by J W Best and J V Khan Prentice Hall of India, New Delhi (1995).
2. Pharmaceutical Statistics by Sanford Bolton, Marcel Dekker, New York, USA, Informa Healthcare; 4 edition (October 17, 2003).
3. Elementary Statistical Quality Control, Volume 25, Burr, I. W. (1979), New York: Marcel Dekker, Inc.
4. Managing the clinical drug development process, C. Nardi, Marcel Dekker, New York, USA (1991).
5. Basic managerial skills for all by E H Mcgrath, Prentice Hall of India, N.Delhi (2002).
6. Organizational Behavior, John W Newstrom, Keith Davis, Tata McGraw Hill, New Delhi (2002)

7. Clinical Research Environment in India by Umakanta Sahoo, Faiz Kermani, ICFAI University Press (2008).
8. Clinical Trials. Lelia Duley and Barbara Farrell (eds), BMJ Books, London, 2002.
9. Handbook for good clinical research practice WHO Library Catalogue.
10. Artciles: ICH-GCP, Schedule Y, US FDA guidelines, WHO Guidelines.
11. Bioavailability and Bioequivalence in pharmaceutical technology by Tapan Kumar and Ganeshan M, CBS publishers and distributers(2006).
12. Design of experiments. A realistic approach by V L Anderson and Robert Mclean, Marcel Dekker, New York, USA (1974).
13. Fundamentals of Clinical Research: Bridging Medicine, Statistics and Operations, Antonella Bacchieri and Giovanni Della Cioppa, Springer (2007)