

UNIVERSITY OF MUMBAI

No. UG/27 of 2010

CIRCULAR:-

The Directors/Heads of the recognized Science Institutions concerned and the Principals of the affiliated colleges in Science are hereby informed that the recommendation made by the Ad-hoc Committee appointed by the Academic Council to advise it on all matters relating to the B.Sc. and M.Sc. degree course in the subject of Biotechnology at its meeting held on 19th September, 2009 has been accepted by the Academic Council at its meeting held on 20th November, 2009 vide item No. 4.2 and subsequently approved by the Management Council at its meeting held on 26th November, 2009 vide item No. 21 and that, in accordance therewith, the Certificate Course in Clinical Studies and Data Management (Add-on-Course) has been introduced from the academic year 2010-2011.

Further, that in exercise of powers conferred upon the Management Council under Section 54(1) and Section 55(1) of the Maharashtra Universities Act, 1994, it has made **Ordinances 5898 and 5899 and Regulations 8206, 8207, 8209, 8210 and 8211** including syllabus for the Certificate Course in Clinical Studies and Data Management is as per Appendix and that the same has been brought into force with effect from the academic year 2010-2011.

MUMBAI-400 032

11th February, 2010

PRIN.K.VENKATARAMANI
REGISTRAR

To,

The Directors/Heads of the recognized Science Institutions concerned and the Principals of the affiliated colleges in Science.

A.C./4.2/20/11/2009

M.C./26/11/2009

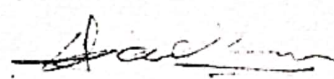
No. UG/27-A of 2010,

MUMBAI-400 03

11th February, 2010

Copy forwarded with compliments for information to:-

- 1) The Dean Faculty of Science,
- 2) The Controller of Examinations,
- 3) The Co-Ordinator, University Computerization Centre.


(D. N. Jadhav)

I/c. Deputy Registrar
(UG/PG Section)

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UNIVERSITY OF MUMBAI



ORDINANCES, REGULATIONS

AND

SYLLABUS FOR THE
CERTIFICATE COURSE

IN

CLINICAL STUDIES
AND
DATA MANAGEMENT
(Add-on course)

(Introduced from the academic year 2010-2011)

**CAREER ORIENTED ADD ON CERTIFICATE COURSE
IN CLINICAL STUDIES AND DATA MANAGEMENT**
(W.E.F. the Academic Year - 2010-2011)

O 5898 Title

Certificate Course in Clinical Studies and Data Management

O 5899 Eligibility

XII (Science) Pass

R 8206 Duration

- Minimum 1 Year
- 20 Credits (Total 300 Hours)

R 8207 Fee

Rs. 5000/-

R 8208 Seats

30 Students Per Batch

R 8209 Theory

12 Credits (180 Hours)

R 8210 Practical & Project

8 Credits (120 Hours)

R 8211

Total Marks

Examination

: 200 Mark

Theory

Paper I

: 50 Marks

Paper II

: 50 Marks

Practical & Project

Practical

: 50 Marks

Project & Presentation

: 50 Marks

Passing Criteria

40% Marks in Theory and Practicals

Students can be given Grades

A Grade

Above 75%

B Grade

60-74%

C Grade

40-59%

Eligibility, No. of Seats, Distribution of Credits to theory, practical & projects, Passing and grading criteria are according to the guidelines given by UGC in the XIth Plan

• **Infrastructure Requirement:**

- Well equipped lecture room
- Library with relevant books
- CPSEA certified animal house
- Computer Lab
- Internet Connectivity
- Laptop
- LCD Projector
- Licensed Softwares (SPSS/SAS)

Staff Requirement

- A coordinator who will be responsible for the smooth conduct of the course. Co-ordinator of the course may be paid an Honorarium of Rs. 5000/- per year out of the seed money.
- A Lectures and practical can be conducted by the core faculty or visiting faculty having expertise in concerned field. Guest Faculty/Internal Faculty may be remunerated @ Rs. 250/- per lecture of 1 hr. duration.
- Faculty must possess atleast a Bachelors Degree with a expertise in respective field.
- Faculties from industry and research institutes

Unitized question Paper Pattern

Theory Question Paper Pattern

Question 1	From Unit 1	10 marks
Question 2	From Unit 1	10 marks
Question 3	From Unit 2	10 marks
Question 4	From Unit 2	10 marks
Question 5	From Unit 1 and Unit 2	10 marks
	Total	50 Marks

Course Name	Total Hours	Credits
Certificate in Clinical Studies and Data Management	300 hrs	20 Credits

Course Name	Theory Duration	Practical Duration	Objective
Certificate in Clinical Studies and Data Management	180 hrs	120 hrs	Introduction of Indian clinical environment, concepts of clinical studies and research, knowledge of clinical trials, soft skills for clinical research associates.

Course Name	Contact Hours			Credits		
Name	Theory	Practical	Total	Theory	Practical	Total
Certificate in Clinical Studies and Data Management	180 hrs	120 hrs	300 hrs	12	8	20

PAPER I

UNIT 1 [45 hrs]

Introduction to Clinical studies and research: Definition, types and scope of clinical studies and research, careers in clinical research. Concept of research methodology (data handling, data processing, information seeking methods, data collection, processing, interpretation, applications).

UNIT 2 [45 hrs]

Preclinical and research: Understanding the concept of pharmaceutical research, number and types of experiments animals used for pre clinical research, CPCSEA rules, recognition of animal house, food and diseases of experimental animals, understand protocols for pre clinical and clinical studies, clinical trials, phases of clinical trials, importance of these investigations, post market surveillance, importance of ethical committee, protocol design, documentation in clinical trials.

PAPER II

UNIT 1 [45 hrs]

Basic Statistics: Central tendency, dispersion, variance, testing of hypothesis, tests of significance, regression and correlation.

Computer skills: MS-Office: Introduction to MS-Office, Introduction to Word, Excel, Power point, Internet search engines.

UNIT 2 [45 hrs]

Development of life skills: Reading and scientific writing skills, use of techniques of acquisition of information from various sources, development of assertive skills, leadership training, stress management, decision making, conflict resolution, task completion.

Books and References:

1. Research in education by J W Best and J V Khan Prentice Hall of India, New Delhi.
2. Pharmaceutical Statistics by Sanford Bolton, Marcel Dekker, New York, USA.
3. Elementary Statistical quality control, I W Burr, Marcel Dekker, New York, USA.
4. Managing the clinical drug development process, C. Nardi, Marcel Dekker, New York, USA.
5. Basic managerial skills for all by E H Mcgrath, Prentice Hall of India, N.Delhi.
6. Organization behavior by Pearson Education Asia, Tata Mc Graw Hill, N.Delhi.
7. Clinical Research Environment In India by Umakanta Sahoo, Faiz Kermani, Icfai University Press

List of Practical's**[120 hrs]**

1. MS-Word	05 hours
2. MS-Excel with special reference to statistical applications	15 hours
3. MS-Power point	05 hours
4. Internet usage	05 hours
5. Laboratory Animal Handling	30 hours
6. Case studies	20 hours
7. Project work	20 hours
Presentations	20 hours

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