

UNIVERSITY OF MUMBAI

No. UG/ 25 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. 4.4 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 Advanced Diploma Course in Clinical Studies and Data Management (Add-on-Course) has been introduced from the academic year 2012-2013.

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 5902 and 5903 and Regulations 8218, 8219, 8220, 8221, 8222 and 8223** including syllabus for the Advanced Diploma Course in Clinical Studies and Data Management (Add-on-Course) is as per Appendix and that the same has been brought into force with effect from the academic year 2012-2013.

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./4.4/20/11/2009

M.C./26/11/2009

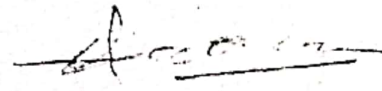
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11th February, 2010

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)

no.2/-



UNIVERSITY OF MUMBAI



ORDINANCES, REGULATIONS
AND
SYLLABUS FOR THE
ADVANCED DIPLOMA COURSE
IN
CLINICAL STUDIES
AND
DATA MANAGEMENT
(Add-on course)

(Introduced from the academic year 2012-2013)

**CAREER ORIENTED ADD ON ADVANCED DIPLOMA
COURSE IN CLINICAL STUDIES AND DATA
MANAGEMENT**

(W. e. F. the Academic Year 2012-2013)

O 5902 Title

Advanced Diploma Course in Clinical Studies and Data Management

O 5903 Eligibility

A Candidate seeking admission to the Advanced Diploma Course should have passed the Career Oriented Add-on Certificate and Diploma Course in Clinical Studies and Data Management of 40 Credits

R 8218 Duration

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

R 8219 Fee

Rs. 10,000/-

R 8220 Seats

30 Students Per Batch

R 8221 Theory

12 Credits (180 Hours)

R 8222 Practical & Project

8 Credits (120 Hours)

R 8223

Total Marks

Examination

: 200 Marks

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.
- 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	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]

Data definition, forms and data base design in clinical trials, data acquisition, CRF printing and vendor selection, Clinical Data Management (CDM) presentation at investigator meetings, data storage, computers in clinical trials, hardware, operating systems, data base management.

UNIT 2

[45 hrs]

Database base validation, programming and standards, data entry and data processing, laboratory and other external data, safety data management and reporting, data entry and distributed computing, measuring data quality, assuring data quality, database closure, clinical trial patient registration.

PAPER II

UNIT 1

[45 hrs]

Software tools for trial data management: SPSS/SAS

UNIT 2

[45 hrs]

Development of life skills: Task management, Business ethics, (Strength, Weakness, Opportunities, Threats (SWOT) analysis. Medical writing.

Books and References:

1. SAS Programming In The Pharmaceutical Industry by Jack Shostak SAS Publishing
2. Data Analysis with SPSS (version16) by Carver, Thomson Business Information

List of Practicals

[120 hrs]

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|---|----------|
| 1. Computer processing of clinical data using special softwares like SPSS/SAS | 60 hours |
| 2. On site visits | 10 hours |
| 3. Internship or project work using secondary data | 20 hours |
| 4. Medical writing | 30 hours |
| • Basics of medical writing | |
| • SOP writing | |
| • Design of protocol | |
| • Understanding of Research designs | |
| • Clinical trial protocol writing | |
| • Clinical Research report writing | |

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