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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No. UG/ 25 -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)

...2/-

Enclosure to Item No. 4.4
20/11/200

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)

University of Mumbai

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 5215	Duration	• Minimum 1 Year • 20 Credits(Total 300 Hours)
R 5219	Fee	Rs. 10,000/-
R 5220	Seats	30 Students Per Batch
R 5221	Theory	12 Credits (180 Hours)
R 5222	Practical & Project	8 Credits (120 Hours)

R 5223

Examination

Total Marks		:	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 bu 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.
- ALectures 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

Total Duration: 300 hrs(One Academic Year) Theory: 180 hrs Practical: 120 hrs

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]

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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