UNIVERSITY OF MUMBAI
No. UG/74 of 2015-16

CIRCULAR:-

The Principals of affiliated Colleges in Science and the Heads of the recognized Science Institutions concerned are hereby informed that the recommendation made by the Faculty of Science at its meeting held on 7th May, 2015 has been accepted by the Academic Council at its meeting held on 29th May, 2015 **vide** item No. 4.37 and subsequently approved by the Management Council at its meeting held on 27th June, 2015 **vide** item No.05 and that in accordance therewith, in exercise of the powers conferred upon the Management Council under Section 54 (1) and 55(1) of the Maharashtra Universities Act, 1994 and the Ordinances 6209 and 6210 and Regulation 8935,8936,8937,8938 and 8939 relating to the Post Graduate Diploma in Regulatory Affairs is introduced, which is available on the University's web site (www.mu.ac.in) and that the same has been brought into force with effect from the academic year 2014-15.

REGISTRAR

MUMBAI–400 032
15th September, 2015

To,

The Principals of affiliated Colleges in Science.

A.C/4.37/29/05/2015
M.C/05/27/06/2015

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No. UG/74 -A of 2015-16 MUMBAI-400 032 15th September, 2015

Copy forwarded with compliments for information to :-

1) The Dean, Faculty of Science,
2) The Professor-cum-Director, Institute of Distance and Open Learning (IDOL),
3) The Director, Board of Colleges and University Development,
4) The Controller of Examinations,
5) The Co-Ordinator, University Computerization Centre.

16/9/15

REGISTRAR

.PTO

UNIVERSITY OF MUMBAI

Post Graduate Diploma in Regulatory Affairs

(With effect from the academic year 2014-15)

O 6209	**Title**	**:**	Post Graduate Diploma in Regulatory Affairs
O 6210	**Eligibility**	**:**	B.Pharm, B.Sc (Botany, Zoology, Chemistry, Biochemsitry, Biotechnology, Microbiology, Life Sciences), PhD's and Pharmaceutical Professionals
R 8935	**Duration of the Course**	**:**	1 Year
R 8936	**Fee Structure**	**:**	Rs. 20,000/-
R 8937	**Intake Capacity**	**:**	40 Students
R 8938	**Teacher Qualifications**	**:**	B.Pharm, M.Pharm, Science Graduate, Post graduate, PhD's and Pharmaceutical Professionals
R 8939	**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.

Syllabus for Post Graduate
Diploma in

Regulatory Affairs

Scheme of Examination

Paper	TITLE OF PAPER	MAXIMUM MARKS	MINIMUM MARKS	Credits	PAPER CODE
I	Regulatory Affairs	300	150	24 Credits	PGDRA001
II	Regulatory Affairs	300	150	24 Credits	PGDRA002
	Total	**600**	**300**	**48 Credits**	

Syllabus for Post Graduate Diploma in Regulatory Affairs

Important to Regulatory Affairs in Pharma Industry

- Basic regulatory framework with respect to Regulated and Non-regulated market practices and procedures.
- Global Pharmaceutical Industry Scenario.

Paper I **24 Credits**

Basic ICH Requirement

ICH Topics

Q1 -Stability

Q2 -Analytical Validation

Q3 –Impurities

Q4 –Pharmacopoeia

Q6 –Specifications

Q7 –GMP API

Q8 –Pharmaceutical Development

Q9 –Quality Risk Management

Q10 –Pharmaceutical Quality System

Q11 –Development and manufacture of drug

Regulatory Filing systems for Active Pharmaceutical Ingredients in different countries.

- EU - ASMF, CEP, EU DMF
- US – DMF application, preparation and annual report.
- Semiregulated Markets- Requirement of API.
- Genotoxic Impurities, Elemental Impurities, Polymorphic form and characterization.
- Various types of DMF
- CTD –Module 1,2,3
- Quality Overall Summary (QOS)
- Quality by design concept applicable to API
- Post approval changes and handling deficiencies

Regulatory Filing systems in Europe.

- EMEA Procedures –Centralized, Decentralized, Mutual recognition and national procedure.

- CTD-Module 1, 2, 3, 4, 5 (including QOS, quality design concept and bioequivalence).
- Variation and Renewals
- Query-Response .

Paper II **24 Credits**

Regulatory Filing systems in US.

- Various Types of application - IND, NDA and ANDA.
- CTD- Module1, 2, 3 and CTD Overall summary -Module1, 2, 3 including quality overall summary and Quality by design CTD module. Module 4 and 5 (including Bioequivalence).
- Post approval changes.

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Registration procedures in various countries:

- Australia
- New Zealand
- Canada
- South Africa/Africa
- Latum
- DCGI(India)
- Asia
- Russia/CIS

Pharmacovigilance in EU/US

- Interviews for Regulatory Opening.
- Case study for both US and EU

AUDIT Checklist

- Prior Approval Inspections (PAI)
- Out of Specifications (OOS), Inspection and Audits, Deviations and Change Controls
- Annual Product Reviews (APRs) for Pharmaceuticals

References:

- Stability Testing of New Drug Substances and Products Q1A(R2)
- Validation of Analytical Procedures: Text and Methodology Q2(R1)
- Impurities in new drug substance Q3A(R2)
- Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances (Q6A)
- Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients (Q7)
- Organization of the Common Technical Document For the Registration of Pharmaceuticals for Human Use M4
- DISSOLUTION Guidance (USP pharmacopoeia Chapter 711)