UNIVERSITY OF MUMBAI

Post Graduate Diploma

in Regulatory Affairs

(With effect from the academic year 2014-15)

O 5894	**Title**	**:**	Post Graduate Diploma in Regulatory Affairs
O 5895	**Eligibility**	**:**	B.Pharm, B.Sc (Botany, Zoology, Chemistry, Biochemsitry, Biotechnology, Microbiology, Life Sciences), PhD's and Pharmaceutical Professionals
R 8196	**Duration of the Course**	**:**	1 Year
R 8197	**Fee Structure**	**:**	Rs. 20,000/-
R 8198	**Intake Capacity**	**:**	40 Students
R 8199	**Teacher Qualifications**	**:**	B.Pharm, M.Pharm, Science Graduate, Post graduate,PhD's and Pharmaceutical Professionals
R 8200	**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)