UNIVERSITY OF MUMBAI

Post Graduate Diploma

in Regulatory Affairs

(With effect from the academic year 2014-15)
<table>
<thead>
<tr>
<th><strong>O 5894 Title</strong></th>
<th>Post Graduate Diploma in Regulatory Affairs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>O 5895 Eligibility</strong></td>
<td>B.Pharm, B.Sc (Botany, Zoology, Chemistry, Biochemistry, Biotechnology, Microbiology, Life Sciences), PhD’s and Pharmaceutical Professionals</td>
</tr>
<tr>
<td><strong>R 8196 Duration of the Course</strong></td>
<td>1 Year</td>
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<td><strong>R 8197 Fee Structure</strong></td>
<td>Rs. 20,000/-</td>
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<tr>
<td><strong>R 8198 Intake Capacity</strong></td>
<td>40 Students</td>
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<tr>
<td><strong>R 8199 Teacher Qualifications</strong></td>
<td>B.Pharm, M.Pharm, Science Graduate, Post graduate, PhD’s and Pharmaceutical Professionals</td>
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<td><strong>R 8200 Standard of Passing</strong></td>
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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

<table>
<thead>
<tr>
<th>Paper</th>
<th>TITLE OF PAPER</th>
<th>MAXIMUM MARKS</th>
<th>MINIMUM MARKS</th>
<th>Credits</th>
<th>PAPER CODE</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Regulatory Affairs</td>
<td>300</td>
<td>150</td>
<td>24 Credits</td>
<td>PGDRA001</td>
</tr>
<tr>
<td>II</td>
<td>Regulatory Affairs</td>
<td>300</td>
<td>150</td>
<td>24 Credits</td>
<td>PGDRA002</td>
</tr>
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<td></td>
<td><strong>Total</strong></td>
<td><strong>600</strong></td>
<td><strong>300</strong></td>
<td><strong>48 Credits</strong></td>
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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.
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.

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)