Vidya Prasarak Mandal's

Advanced Study Centre

Syllabus for

Programme : P. G. Diploma

Course : Drug Regulatory Affairs

With effect from academic year

2017 - 2018

POST GRADUATE DIPLOMA IN DRUG REGULATORY AFFAIRS

Course Details:
Duration : One Year
Eligibility : B. Sc. / B. Pharm.
Timings : 6.30 pm to 8.30 pm (Fridays & Saturdays)

Regulatory Affairs (RA), also called Government Affairs, is a profession within regulated industries, such as drugs, pharmaceuticals, and medical devices. These industries are most highly regulated in the country. As India is growing very rapidly in all these sectors, there is a growing need of regulatory affairs professionals to cater the current needs of industries for the global competition. Regulatory Affairs Officers are the crucial link between their company, its products and worldwide regulatory authorities including Indian FDA, USFDA, EMEA. They ensure appropriate licensing, marketing and legal compliance of pharmaceutical and medical products. They combine scientific knowledge, legal and business issues and co-ordinate the approval and registration of pharmaceuticals, veterinary medicines, complimentary medicines, active pharmaceutical ingredients etc. Our course is designed as per FDA requirements to cater the need of expertise in the field of pharmaceutical regulatory affairs.

SYLLABUS AND QUESTION PAPER PATTERN OF

COURSE :DRUG REGULATORY AFFAIRS

Course Code	Course Title	No. of lectures	Credits
ASCDRA01	Paper I	36	3
ASCDRA02	Paper II	36	3
ASCDRA03	Paper III	36	3
ASCDRAP1	Dissertation	40	4
ASCDRAP2	Industrial Visits	40	4
Total Credits			17

Course Code: ASCDRA01	Course Title Paper I	No. of lectures
Unit I: Drug Regulatory Affairs – General		**12**
Unit II:Drug Licensing Application, Renewal and Filing Procedures		**12**
Unit III:Drug Master Files		**12**

Course Code: ASCDRA02	Course Title Paper II	No. of lectures
Unit I: Introduction to Quality Control & Quality Assurance		**12**
Unit II:SOPs and Good Laboratory Practices Basic Principles and Methods		**12**
Unit III:International Conference on Harmonization - (ICH Guidelines)		**12**

Course Code: ASCDRA03	Course Title Paper III	No. of lectures
Unit I: USFDA Guidelines		**12**
Unit II:European Guidelines and Rules Governing Medicals Product – EMEA		**12**
Unit III:Therapeutic Goods Administration Australia (TGMP)		**12**

Course Code: ASCDRAP1	Course Title Dissertation

Duration: 3 months
Based on any subtopic from the syllabus or related to Drug Regulatory Affairs under the guidance of expertise from within or outside the institution.

Guidelines for Dissertation:

1. Students have to select their topic in consultation with the guide, who can be any faculty teaching the course or expert in the subject. (If the expert is not a teaching faculty of the course, biodata of expert is to be submitted in Advanced Study Centre and approval to be taken from Head, Advanced Study Centre.)
2. The outline of the dissertation (about 2/3 pages – 400/600 words) signed by the student & guide to be submitted on or before 31st December to Advanced Study Centre.
3. The student has to collect the data, relevant information, photographs, references in consultation of guide.
4. The dissertation in the hard bound format based on this data has to be submitted on or before 31st March to Advanced Study Centre.
5. Dissertation book should have certificate page signed by their respective guides and coordinator of the course.
6. Final power point presentation should be given by students at the time of examination.
7. Dissertation will comprise 75 Marks

Format for submission of outline for dissertation

Front page

Title of the topic:

Place of work: VPM's Advanced Study Centre.

Name of the student:

Name of the guide:

Date of submission:

Sign of guide Sign of student

Details: Introduction, Review of Literature, Material & methods, Hypothesis, Results & Discussions, Conclusions, References.

Course Code: **ASCDRAP2**	**Course Title** **Industrial visits**

Students will have to bear their own expenses for the Industrial visits.
Industrial visit: Note book -
Students have to maintain Industrial visit- note book along with the photos at places visited. The observations have to be noted in Industrial visit- note book/ register. Diagrams/ drawings can be drawn or photographs can be stuck. Industrial visit- note book has to be presented at the time of practical examination.
Examination based on which viva voce will be conducted. (25 marks)

Industrial Visits/ Training that can be taken from among following or such similar places:

1. Tata Institute of Fundamental Research, Mumbai.

Evaluation Scheme:

Theory Examination: Suggested format of Question paper

Duration: 3 hours **Total Marks: 100**

- **All questions are compulsory**

Q. 1	Based on unit I	25
	OR	
Q. 1	Based on unit I	25
Q. 2	Based on unit II	25
	OR	
Q. 2	Based on unit II	25
Q. 3	Based on unit III	25
	OR	
Q. 3	Based on unit III	25
Q. 4	Based on unit I, II, III	25
	OR	
Q. 4	Based on unit I, II, III	25

Each question may consists of sub questions of following types

Full length question: 15 Marks
Short answer question: 10 Marks
Short note questions: 5 Marks
Objectives: 2 Marks

Total marks of Theory Examination:

Course Code	Maximum marks
ASCDRA01	100
ASCDRA02	100
ASCDRA03	100
TOTAL	**300**

Practical Examination:

Course Code	Details	Total
ASCDRAP1	Dissertation	75
ASCDRAP2	Industrial visit: Note book	25
	TOTAL	**100**

Total of Theory Examination: 300Marks

Total of Practical Examination: 100 Marks

Grand Total: 400 Marks

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