ASC Course: 02

Vidya Prasarak Mandal's

Advanced Study Center

Syllabus for

Programme: P. G. Programme

Special Programme: Drug Regulatory Affairs

[Initiated in2010-2011, 1st update 2017 – 2018, 2nd update 2019 - 2020]

3rd update: from Academic Year 2020-2021

Course will be conducted on online mode

POST GRADUATE PROGRAMME IN DRUG REGULATORY AFFAIRS

Preamble

Preamble:

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.

Marketing the pharma products in Indian as well as global markets is a challenge and it requires to go through all regulatory formalizes before getting the license. The legalities in India and abroad differ and thus multinational companies require the regulatory affair officers who are knowledgeable in both.

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. It includes all regulations as per the requirements of FDA, USFDA and EMEA thus making a person suitable for job in multinational Pharma companies.

Duration: 9 Months (Two days five hours a week)

Course Details:

Duration : One Year

Eligibility : B. Sc. / B. Pharm./LLB

Timings : 6.30 pm to 8.30 pm (Fridays & Saturdays)

Specific Programme will be conducted in online mode.

Programme Outcome

- The programme will fill the gap of knowledge as per requirement of industry.
- The programme will provide global level advanced and skill oriented deep knowledge to the learners for survival in global competition.
- The knowledge will improve the employability of the learner which can fetch good job opportunity.
- For those who are already in service will provide a good platform to upgrade their skills.
- The learner will get practical experience and will be updated about recent knowledge in the field.
- The programme is also designed for making the learner capable for self-employment or startups and own consultancy.

Programme Specific Outcome

- Understanding the basics of Drug Regulatory affairs.
- Getting the in depth knowledge of different laws related to drug regulations.
- Understanding the laws in different countries like in India, European countries, Australia.
- Developing the basic requirements for marketing drugs.
- Understanding the basic requirements of pharma industry,

SYLLABUS AND QUESTION PAPER PATTERN OF

Specific Programme : DRUG REGULATORY AFFAIRS

Course Code	Course Title	No. of lectures	Credits
ASCDRAT1	Paper I	45	4
ASCDRAT2	Paper II	45	4
ASCDRAT3	Paper III	45	4
ASCDRAP1	Dissertation	40	4
ASCDRAP2	Industrial Visits	40	4
Total Credits			***20***

Course Code: ASCDRAT1	Course Title Paper I	Credits 4	No. of lectures
Course Outcome:- • Learner will understand the Basic concept of Drug Regulatory Affairs. • Learner will get the knowledge about IPR, Patents • Learner will understand how to apply for the License • Learner will get the knowledge of renewal of License and filing procedure • Learner will understand what is drug maintenance file and types of files. • Learner will know the maintenance of Drug master file.			
Unit I: Drug Regulatory Affairs – General			**15**
Unit II: Drug Licensing Application, Renewal and Filing Procedures			**15**
Unit III: Drug Master Files			**15**

Course Code: ASCDRAT2	Course Title Paper II	Credits 4	No. of lectures
Course Outcome:- • Learner will get introduced to Quality control and Quality assurance. • Learner will understand requirements of US FDA • Learner will know good laboratory practices • Learner will understand about International Conference on Harmonization - (ICH Guidelines) • Learner will understand Analytical Method of Validation and Process Validation • Clinical Safety and clinical trial design			
Unit I: Introduction to Quality Control & Quality Assurance			**15**
Unit II: SOPs and Good Laboratory Practices Basic Principles and Methods			**15**
Unit III: International Conference on Harmonization - (ICH Guidelines)			**15**

Course Code: ASCDRAT3	Course Title Paper III	Credits 4	No. of lectures
Course Outcome: - • Learner will understand USFDA Guidelines. • Learner will know about Centre for Drug Evaluation • Learner will understand about Centre for Biological Evaluation and Research • Learner will know about European Guidelines and Rules Governing Medicals Product • Learner will know the Inspection procedure. • Learner will understand the Therapeutic Goods Administration Australia. • Learner will know about Global Harmonization Task Force Guidelines			
Unit I: USFDA Guidelines			**15**
Unit II: European Guidelines and Rules Governing Medicals Product – EMEA			**15**
Unit III: Therapeutic Goods Administration Australia (TGMP)			**15**

Course Code: ASCDRAP1	Course Title Dissertation	Credits 3	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 to Head, Advanced Study Centre for approval.)
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 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	Credits 3

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)

Evaluation Scheme

- **Evaluation will be based on External and Internal examination in the ratio of 60:40 (External 60% weightage and Internal 40% weightage)**
- **External:**
- **Theory Examination: Suggested Format of Question paper ***
- **Duration: 2.30 Hours** **Total Marks: 60**
- **All questions are compulsory**

Q. 1	Based on Unit I	15
	OR	
Q. 1	Based on Unit I	15
Q. 2	Based on Unit II	15
	OR	
Q. 2	Based on Unit II	15
Q. 3	Based on Unit III	15
	OR	
Q. 3	Based on Unit III	15
Q. 4	Based on Unit I, II, III	15
	OR	
Q. 4	Based on Unit I, II, III	15

Each question may have following subquestions

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

Internal Examination: The internal examination will consist of various assignments which will include presentation of given topic, seminar on given topic, writing the given assignment, attending and reporting seminars and conferences, field experience. And many such types. There will be one assignment on each unit of each course and need to be submitted in the given time limit. Each assignment will be of 10 marks and total marks of assignments will be converted to 40% marks.

Total marks of Theory Examination:

Course Code	External	Internal	Maximum marks
ASCDRAT1	60	40	100
ASCDRAT2	60	40	100
ASCDRAT3	60	40	100
TOTAL			**300**

Practical Examination:

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

Total of Theory Examination **300 Marks**

Total of Practical Examination **100 Marks**

Grand Total **400 Marks**

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