



**JSS Academy of Higher Education and Research,  
Mauritius**

# **Master of Pharmacy (Regulatory Affairs)**

**Programme Document**

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## **A. Programme Information**

Regulatory Affairs (RA) is a vital unit in a pharmaceutical company that successfully drives the Research & Development (R&D) efforts of the company to the market. The regulatory program works with a focus to get products to the market with a commercially viable label, in the least possible time and expense. In view of this program increasing global competitiveness among pharmaceutical companies, the key to success lies in obtaining timely marketing approval from the Regulatory agencies of the region where the drug is to be sold. This programme will help the students to expertise in this area and help the pharmaceutical firms to comply with a set of stringent rules and guidelines in the manufacturing process in order to ensure the safety and effectiveness of the medication in humans.

The process of drug development is a long, complicated and extremely expensive, although necessary, process. In order to register the medication and thus sell the drug, pharmaceutical firms have to use all the data collected during the research and production periods. Regulatory affairs play a critical role in this highly controlled environment, not only as the interface with health agencies and as a link between various departments in the business, but also as the leading department to provide strategic advice on extremely difficult decisions throughout the life of a drug. The graduates from this programme shall have through knowledge on various import and export regulations of drugs from different countries and can help the local government to regulate the cost of import of pharmaceuticals at the best cost.

The programme is also meant for the students coming from the Indian Ocean and African region including countries such as South Africa, Zambia, Zimbabwe, Uganda, Kenya, Ghana, Ethiopia, Tanzania, Rwanda, Nigeria, Namibia, India, Sri Lanka, and Nepal.

Our training needs analysis is based on desk research, thorough study of published research papers and the need for qualified pharmacy work force, especially in African region (e.g., **Annex b**).

It is noted that most African countries import 90% of their drug requirements. This is a strain on their economies and as such it is expected that the pharmaceutical industry is bound to grow in Africa. In fact, it is expected to grow between USD 50-70 Billion by 2030 and regulatory experts play a key role in getting import approvals for imported drugs to Mauritius as well as export drugs from.

There will be need for qualified pharmacy workforce to support the creation of this regulatory division, be it for the manufacture of nutraceutical and of pharmaceutical products, medical devices, or high-tech products

## **B. Programme Aim**

The M Pharm Regulatory Affairs is to equip students with advanced knowledge, skills and comprehensive education in the important aspects of Regulatory and Quality Compliance in the pharmaceutical industry including Pharmaceutical Regulatory Affairs, National and International Drug Approvals and also to embark on future regulatory research.

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### **Some of the Job Prospects include:**

1. Regulatory Affairs Consultants
2. Regulatory Affairs Assistants / Associates / Specialist
3. Regulatory Affairs Head / Director
4. Regulatory Administrator
5. Regulatory Compliance Manager
6. Medical Information Associates
7. Drug Inspector / Drug Controller
8. Drug Safety Specialist / Regulatory Food Safety Scientist
9. Quality Operations / Quality Control / Quality Assurance
10. Academics
11. Regulatory Food Safety Scientist

### **C. Programme Objectives**

This program provides an overview of the regulatory affairs profession and offers an in-depth look at premarket regulatory work related to drugs, biologics, and medical devices.

The programme objectives are to equip the students with:

1. Adequate scientific information regarding emerging concept in regulatory affairs, quality assurance GLP, GMP & Validation,
2. Ability to understand drug Regulatory Affairs, Intellectual Property Rights & Bioethics, Pharmaceutical Biostatistics & Computer Applications;
3. Knowledge and skills for Laboratory and Research which includes:
  - a. International Regulatory Systems Lab, Clinical Trials & Healthcare Policies Lab,
  - b. National Regulatory Affairs Lab, Emerging Concept in regulatory Affairs Lab,
  - c. Pharmaceutical Regulatory Affairs Lab, National & International Drug Approvals & Bio-ethics Lab;
  - d. Students are motivated and advised to find interest in respective area of research from start of semester.

### **D. Overall Programme Learning Outcomes**

This programme will enable students to:

1. describe the government processes within the national and international health care systems and provincial formularies
  2. master the compiling and publishing of large regulatory application for submission for both APIs in different countries, commonly called, as dossiers
  3. acquire skill to access scientific and technical resources
  4. expertise knowledge and support in terms of local regulatory authority
  5. expert solutions to FDA and other regulatory agencies' queries
  6. describe international harmonization of regulations and the impact on manufacturing and the submission process and demonstrate effective interviewing and negotiating skills in managing a clinical study
  7. think logically and solve the problems, develop an ability to conduct, analyse and interpret data gathered from different regulatory bodies
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8. visualize and work on multidisciplinary tasks. They will be able to demonstrate necessary skills (e.g., working independently, time management and organizational skills). They will demonstrate an adaptable, flexible, and effective approach towards organizational development.

## E. Entry Requirements

**Candidates must be:**

***Graduates of a recognised university or any other institutions of higher education with at least a second-class B. Pharm degree or equivalent***

### Overseas Candidates

Overseas candidates whose first language is not English and who do not hold a B Pharm degree or equivalent qualification taught in English, will be required to produce evidence of their competence in English.

## F. Fees Structure

The extract of fee structure and breakdown refund policy are given below;

<b>Programme M Pharm (Regulatory Affairs)</b>	<b>MUR</b>	<b>USD</b>
<b>Tuition fee per annum (F/T)</b>	200,000	5300
<b>Tuition fee per annum (P/T)</b>	150,000	4000
<b>Other Fees</b>		<b>Amount (MUR)</b>
Application Fees	Non-refundable	1,000 One off
Registration Fees	Non-refundable	5,000 One off
Administrative Fees	Non-refundable	5,000 per annum
Library Fees	Non-refundable	5,000 per annum
Library Deposit	Refundable	5,000 One off
Laboratory Fees	Non-refundable	5,000 per annum
Examination Fees	Non-refundable	5,000 per annum
Marks card fees	Non-refundable	1,000 per annum
Convocation Fees	Non-refundable	2,000 One off

### Hostel Fees:

Accommodation Charges	Non-refundable	45,000 per annum
Food Charges	Non-refundable	40,000 per annum
Caution Deposit	Refundable	15,000 One Off

### Refund Policy:

Tuition fees are not refundable except in special circumstances on a limited number of grounds, which are as follows:

1. A refund of full tuition fees paid is considered for students having for some reasons

made the wrong choice or who realise that they are unable to cope with the regime of higher studies, provided that the application for refund is made to the Management within the first ten working days of the start of the programme.

2. A refund of 50% of the full semester tuition fees is considered on medical, family or other acceptable grounds if full fees for the semester have been paid, provided the request is received before the fifth week of the semester. No refund will be made if a lesser amount has been paid.
3. There is no refund for the accommodation charges. Food charges may be refunded on a pro rata basis by giving one-month notice. Caution deposit is refundable at the end of the stay.

### G. Programme Mode and Duration

(i)	<b>Delivery mode</b>	Full Time, Part Time and Online/Distance
(ii)	<b>Delivery Type</b>	Face to face/contact Face to face and distance with an online learning platform
(iii)	<b>Duration (minimum and maximum) in terms of years, and contact hours per year</b>	<b>Full time (Face to face and online mode):</b> Minimum 2 years– Maximum 4 years <b>Part-time:</b> Minimum 3 years - Maximum 6 years
(iv)	<b>Number of semesters</b>	<b>Full time (Face to face and online mode):</b> Minimum 4 Semesters – Maximum 8 Semesters <b>Part-time:</b> Minimum 6 Semesters – Maximum 12 Semesters

### H. Teaching and Learning Strategies

The teaching and learning are based on explicit learning outcomes which are consistent with programme/course aims and objectives. The programme consists of a wide variety of teaching methods, including lectures, individual or group projects, assignments, presentations, workshops, seminars, laboratory practical's, problem-based learning, independent learning and research projects and case studies. The programme also consists of class tests, structured discussions, self-development activities. Self-learning is a key feature of the programme, enabling students to explore, investigate and research in various issues related to pharmacy.

Positive learning outcomes reflect an interplay between the teaching activities and learning environment provided by JSSAHERM and the skills, knowledge, attitudes and behaviour of its students. The institution has brought forward a few principles to help ensuring that the quality of teaching and learning is always respected and to guide excellence in learning and teaching practices, while recognising that effective learning and teaching involves a partnership between students and the institution.

The following principles aim to guide excellence in learning and teaching practices, while recognising that effective learning and teaching involves a partnership between students and the institution:

- Creating an engaging, motivating, and intellectually stimulating learning environment and experience.
- Encouraging the spirit of critical inquiry and creative innovation informed by current research.

- Emphasising the importance, relevance and integration of theory and knowledge with professional practice to develop solutions to real world issues.
- Providing learning experiences that develop inter-culturally capable graduates who can make a difference as socially and ethically responsible global citizens.
- Valuing and recognising individual and cultural diversity through the provision of an inclusive context of support and respect for all students.
- Enhancing student engagement and learning through effective curriculum design, pedagogy, and assessment strategies.
- Continuously improving teaching practice through academic staff professional development, and critical reflection informed by a range of evaluation approaches.
- Conducting evaluation (feedback) exercises, through which the students will be encouraged to give their view and rate the teaching quality of each lecturer – The feedback survey forms would be analysed, and reports would be generated. Appropriate measures would be taken to eliminate weaknesses and shortcomings; all feedback survey forms would be securely kept for verification and consultation as and when required; the feedback exercise will be conducted every semester before the end of courses to ensure that students' views are appropriately taken care prior to their sitting for examinations.
- Conducting Performance Appraisal exercises for all teaching and non-teaching staff members; This exercise allows the institution to find room for improvement, evaluate the staff's opportunities for promotion and to channel staff members for training and development as learning is an on-going process not only students but for lecturers and other staff members also.

#### **I. Program Committee:**

- Every post graduate program shall have a Program Committee constituted by the HOD in consultation with all the Course Teachers of the corresponding program.
- The composition of the Program Committee shall be as follows: Among the faculty member one will be the Chairperson; Teacher of all courses of the corresponding program; Student Adviser and two student representatives of the program (one in I year and other in II year), nominated by the Head of the Department.
- Duties of the Program Committee:
  - i. Reviewing periodically the progress of the classes.
  - ii. Discussing the problems concerning curricula, syllabi and the conduct of classes.
  - iii. Providing consultation of the Course Teachers on the nature and scope of assessment for the course, this shall be announced, to the students at the beginning of respective semesters.
  - iv. Communicating its recommendation to the Head of the Department on academic matters.
  - v. The Program Committee shall meet at least thrice in a semester preferably at the end of each internal continuous assessment tests and before the final end semester exam.

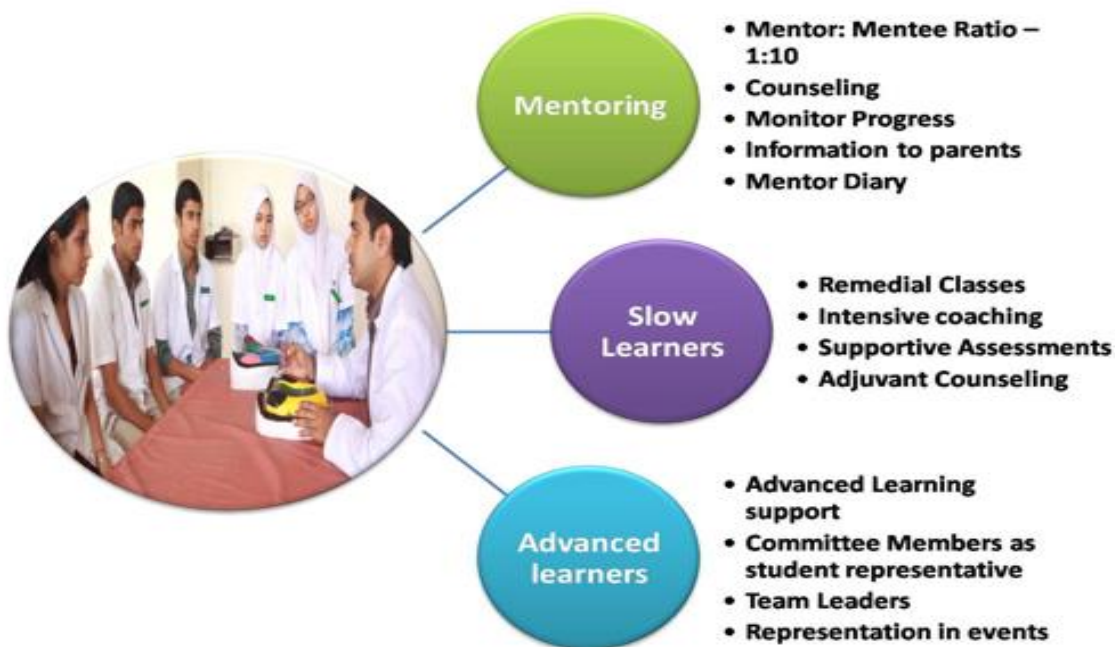
#### **J. Student Support and Guidance**

JSSAHERM provides career counselling, remedial coaching, bridge courses, soft skill development, personal counselling and guidance for competitive examinations besides improving their communication and language skills to improve their employability as well as build human values in their personality. The institution strongly believes that its primary stakeholders are students. The institution tries to realize its vision and mission centering on student empowerment,

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inclusive practices, and knowledge – skill – competence development. Accordingly, the institution has implemented suitable supporting steps and facilities for the benefit of students. Towards this, the institution has a provision for counsellors/ mentors /advisors for each class or group of students for academic and personal guidance.

The various student support mechanisms are summarised in the Figure 2 below:



<b>Mentoring</b>	<ul style="list-style-type: none"> <li>• Mentorship - Mentor, Batch teacher, Class teacher</li> </ul>
<b>Support &amp; Progression</b>	<ul style="list-style-type: none"> <li>• Scholarship</li> <li>• Health Care &amp; Insurance</li> <li>• Placement Cell</li> <li>• Alumni</li> <li>• Support for competitive exams</li> <li>• Student Support Centre</li> <li>• Skill development</li> <li>• Personality Development</li> </ul>
<b>Activities</b>	<ul style="list-style-type: none"> <li>• Cultural</li> <li>• Sports</li> <li>• Magazine</li> <li>• Outreach</li> </ul>
<b>Professional Bodies</b>	<ul style="list-style-type: none"> <li>• Local Branch</li> <li>• Student Charter</li> <li>• Institutional Society</li> </ul>



Each cohort of the programme is allocated a Programme Coordinator who will act as a liaison officer between the students and the institution. The programme coordinator will also provide support for academic management of the programme

Student support and guidance at JSSAHERM include

1. Tutoring
2. Access to library / E-library
3. Access to IT workshop
4. A variety of student welfare activities
5. Workshop and Laboratories

### **K. Attendance Requirement**

The students must secure a minimum of 80% attendance in each subject to become eligible to take term end examination. All students must attend every lecture, tutorial and practical classes except for approved leave like medical emergencies etc. Each course of the semester shall be treated as a separate unit for calculation of the attendance. A student, who does not satisfy the attendance requirement, mentioned as above, shall not be eligible to appear for the examination of that semester and not promoted to higher semester. The student shall be required to repeat that semester along with regular students later by paying the prescribed fee as per the regulations of JSSAHERM.

### **L. Credit System**

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly, the credit associated with any of the other academic, research activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

<b>Total Number of Credits – Full Time</b>	
<b>Semester</b>	<b>No. of Credits</b>
I	<b>26</b>
II	<b>26</b>
III	<b>21</b>
IV	<b>16</b>
<b>Total</b>	<b>89</b>
<b>Total Number of Credits – Part Time</b>	
<b>Semester</b>	<b>No. of Credits</b>
I	<b>14</b>
II	<b>16</b>
III	<b>14</b>
IV	<b>12</b>
V	<b>17</b>
VI	<b>16</b>

<b>Total</b>	<b>89</b>
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## **M. Student Progress and Assessment**

The regulations for assessment, evaluation and grading of student performance are as follows:

1. The evaluation of performance of the student is based on the marks obtained in each module. Semester Grade Point Average (SGPA) and Cumulative Grade Point Average (CGPA) are calculated to determine their final awards at the end of their programme of study.
2. Modules are assessed through written examinations of duration of 3 hours.
3. All modules are normally assessed over 100 marks, except for project/dissertation which will be assessed over 200 marks.
4. The overall pass mark for a module shall be 50%, subject to the students submitting their continuous assessment within set deadlines.
5. All modules must be passed in the examinations, coursework and other forms of assessment.

The modules will be assessed as follows:

- End semester examinations contributing to 70% of the total marks for theory and 60% for practical
- Continuous assessment carrying 30% of total marks for theory and 40 % for practical of total marks. Continuous assessment can be based on attendance, national/international conference attended by the students, research/review papers published in indexed journal and other activities

In order to pass in a module, a minimum of 50% should be attained in:

- Continuous assessment, and in
- End semester examination

### **Continuous Internal Assessment (CIA)**

- The Continuous Internal Assessments may be in the form of a combination of periodical tests, % of attendance and other research activities carried out.
  - The assessment procedure to be followed for each course shall be approved by the Program Committee and announced to the students at the commencement of each semester by the Course Teacher.
  - Such schedule for continuous assessment procedure will be displayed on the notice board in the beginning of the semester.
  - The course teacher shall intimate the internal marks of the candidates and their attendance detail to the student through notice board.
  - The HOD/Dean will send the internal assessment marks together with attendance secured by each candidate and forward to Controller of Examinations office. Based on these details the Controller of Examinations will issue hall ticket (admit cards) for end semester examination, through HOD/Dean.
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Scheme for awarding Continuous mode marks:

Criteria	Maximum Marks
Attendance (A)	4
Academic and Research activities (B)	
1. Participation in National Level Seminar/ Conference/ Workshop/ Symposium/ Training Programs/Webinar (related to the specialization of the student)	1
2. Participation in international Level Seminar/ Conference/ Workshop/ Symposium/ Training Programs (related to the specialization of the student)	2
3. Research / Review Publication in National/ International Journals (Indexed in Scopus / Web of Science)	2
4. Academic Award/Research Award from International Agencies	1
<b>Total (A + B)</b>	<b>10</b>

#### Guidelines for the allotment of marks for attendance

Percentage of Attendance	Marks
95 – 100	4
90 – 94	3
85 – 89	2
80 – 84	1
Less than 80	0

Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the institute. The scheme of question paper for theory and practical sessional examinations is given below. The average marks of two sessional exams shall be computed for internal assessment.

#### Question paper pattern for theory sessional examinations

I. Long Answers (Answer 1 out of 2)	=	1 x 10	=	10
II. Short Answers (Answer 4 out of 5)	=	4 x 5	=	20
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		Total	=	<b>30 marks</b>
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#### Question paper pattern for practical sessional examinations

I. Synopsis	=	05		
II. Experiment	=	30		
III. Viva voce	=	05		
		-----		
		Total	=	<b>40 marks</b>
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### Scheme for internal assessments and end semester examinations

Subject	Assessment				End Semester Exams		Total Marks
	Continuous Mode	Sessional Exams		Total	Marks	Duration	
		Marks	Duration				
Theory	10	20	1 Hr	30	70	3 Hrs	100
Practical	10	30	4 Hrs	40	60	4 Hrs	100

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given below;

Postgraduate			
Overall Marks	Grade	Grade point	Performance
$90 \leq X \leq 100$	O	10	Outstanding
$80 \leq X < 90$	A	9	Excellent
$70 \leq X < 80$	B	8	Very Good
$60 \leq X < 70$	C	7	Good
$50 \leq X < 60$	D	6	Satisfactory
$X < 50$	F	0	Fail
Absent	AB	0	Fail

The calculation of the semester grade point average (SGPA) and the cumulative grade point average (CGPA) is shown below.

#### Calculation of Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called ‘Semester Grade Point Average’ (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C<sub>1</sub>, C<sub>2</sub>, C<sub>3</sub>, C<sub>4</sub> and C<sub>5</sub> and the student’s grade points in these courses are G<sub>1</sub>, G<sub>2</sub>, G<sub>3</sub>, G<sub>4</sub> and G<sub>5</sub>, respectively, and then students’ SGPA is equal to:

$$\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4 + C_5G_5}{C_1 + C_2 + C_3 + C_4 + C_5}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F grade awarded in that semester. For example, if a learner has a F grade in course 4, the SGPA shall then be computed as:

$$\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4 * \text{ZERO} + C_5G_5}{C_1 + C_2 + C_3 + C_4 + C_5}$$

## Calculation of Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

$$\text{CGPA} = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4 + C_5S_5 + C_6S_6 + C_7S_7 + \dots + C_nS_n}{C_1 + C_2 + C_3 + C_4 + C_5 + C_6 + C_7 + \dots + C_n}$$

where C<sub>1</sub>, C<sub>2</sub>, C<sub>n</sub>,... is the total number of credits for semester I,II,...,n, and S<sub>1</sub>,S<sub>2</sub>, S<sub>n</sub>,...is the SGPA of each semester I,II,,,n.

### *Evaluation of Performance*

#### **a) Seminar/Assignment –**

The contact hours of seminars and assignments shall be treated as that of practical module. The contact hours shall be 30 for 1 credit.

In this module the latest developments, advancements and applications in the field of any one of the other modules, taken during the semester shall be assigned to a student and the student is supposed to work on the topic, do research and present the same in the form of power point presentation (50%) and submit the assignment in hard copy (50%) to the subject in charge for evaluation. The presentation evaluation will be done through a panel of three academic staff. The student is evaluated based on his/her extent of understanding of the subject, time management, communication skills etc. The assignment will be in the form of report of at least 3000-5000 words. The format for evaluation of seminar and assignment is given as **annexure IA & IC**

This module has no summative assessment.

#### **b) Journal Club:**

The journal club shall be considered as theory module of 1 credit. Each M Pharm student will be responsible for presenting at least one published research paper from peer reviewed refereed journals, in journal club meetings on a topic related to Regulatory Affairs or its subspecialties. The presentation evaluation will be done through a panel of three academic staff. This experience fulfils several goals of the research curriculum such that at its conclusion each student will be able to:

- Conduct structured critical appraisal
  - Understand the limitations of the application of evidence
  - Recognize and understand basic study design
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- Gain familiarity with basic methodologies
- Gain insight into a specific research problem
- Hone skills related to oral and written presentations

There will be no summative assessment for this module. The student will have to submit the paper selected to the faculty at least 10 days before the presentation and the later will circulate the paper to all of the students and interested faculties at least one week before the presentation.

The form for evaluation of journal club presentation is given as **annexure II**

### **c) Research/Project Work – Protocol preparation, hypothesis, methodology and proposal presentation**

The research work presentations and discussions with the supervisor shall be considered as theory module of 16 credits. In this module the student identifies the research topic related to the research problem and building up the hypothesis of the work. The student is supposed to prepare the protocol in consultation with research supervisor. The through literature survey is mandatory for finalizing the research proposal. Based on the research problem the tentative methodology to be prepared and submitted.

The steps involved in the research project include:

- 1) Developing a research question
- 2) Conducting a literature review
- 3) Building a model to analyze your question
- 4) Conducting appropriate analysis, and
- 5) Analyzing results and writing the research paper

The evaluation of research work in III semester is as follows;

#### **Evaluation of research work:**

<b>Dimensions</b>	<b>Percentage of Marks</b>
Identification of the problem	<b>50</b>
Literature search	<b>50</b>
Aim and scope of the work	<b>50</b>
Objective(s) of the work	<b>50</b>
Novelty of research/project work	<b>100</b>
Methodology to be adopted	<b>50</b>
Question and answers	<b>50</b>
Total	<b>400</b>

The format for evaluation of this module is given as **annexure III**

#### **d) Project dissertation/Final presentation**

The student should submit a research/project work at the end of the final semester of the programme supported by dissertation. The dissertation should be around 15000-20000 words and have to be defended in a viva-voce.

Four copies of the dissertation shall be submitted (typed & bound copy). The examiners appointed by the institution shall make the evaluation on the bases on the criteria given below;

#### **Evaluation of Dissertation and Presentation**

<b>Dimensions</b>	<b>Percentage of Marks</b>
Achievement of Objective(s)	<b>25</b>
Methodology	<b>75</b>
Results and Discussions	<b>100</b>
Conclusions and Outcomes	<b>50</b>
Question and answer skills	<b>50</b>
Presentation of work	<b>75</b>
Communication skills	<b>25</b>
Total	<b>400</b>

The format for evaluation of this module is given as **annexure IV**

#### **N. Award Classification**

The class shall be awarded on the basis of CGPA as follows:

<b>Classification of Award</b>	<b>CGPA</b>
Distinction	8.00 and above
Merit	7.00 to 7.99
Pass	6.00 to 6.99
No Award	less than 6.00

#### **O. Programme Organization and Management**

Programme Coordinator:

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Email : [vishalkumargupta@jssuni.edu.in](mailto:vishalkumargupta@jssuni.edu.in)

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## P. Programme Structure

### *Masters of Pharm (M. Pharm) – Regulatory Affairs – Full time*

Module code	Modules	Credits
<b>Year 1 - Semester I</b>		
MPRA101T	Good Regulatory Practices	4
MPRA102T	Documentation and Regulatory Writing	4
MPRA103T	Clinical Research Regulations	4
MPRA104T	International Pharmaceutical Regulations - I	4
MPRA105P	Pharmaceutical Regulatory Affairs Practical I	6
MPRA106P	Seminar/Assignment – I	4
<b>Total</b>		<b>26</b>
<b>Year 1 - Semester II</b>		
MPRA201T	International Pharmaceutical Regulations - II	4
MPRA202T	Regulatory Aspects of Herbals and Biologics	4
MPRA203T	Regulatory Aspects of Medical Devices	4
MPRA204T	Regulatory Aspects of Food and Nutraceuticals	4
MPRA205P	Pharmaceutical Regulatory Affairs Practical II	6
MPRA206P	Seminar/Assignment – II	4
<b>Total</b>		<b>26</b>
<b>Year 2 - Semester III</b>		
MPRA301T	Advanced Research Methodology and Biostatistics	4
MPRA302T	Journal club	1
MPRA303T	Research/Project Work – Protocol preparation, hypothesis, methodology and proposal presentation	16
<b>Total</b>		<b>21</b>
<b>Year 2 - Semester IV</b>		
MPRA401P	Research/Project work – Dissertation / Final presentation	16
<b>Total</b>		<b>16</b>

### Semester wise credits distribution

Semester Credit Points	Semester Credit Points
<b>I</b>	<b>26</b>
<b>II</b>	<b>26</b>
<b>III</b>	<b>21</b>
<b>IV</b>	<b>16</b>
<b>Total Credit Points</b>	<b>89</b>



*Masters of Pharm (M Pharm) – Regulatory Affairs – Part-time*

Module code	Modules	Credit points
<b>Year 1 - Semester I</b>		
MPRA101T	Good Regulatory Practices	4
MPRA102T	Documentation and Regulatory writing	4
MPRA103T	Clinical Research Regulations	4
MPRA106P	Seminar/Assignment – I	2
<b>Total</b>		<b>14</b>
<b>Year 1 - Semester II</b>		
MPRA104T	International Pharmaceutical Regulations - I	4
MPRA201T	International Pharmaceutical Regulations - II	4
MPRA105P	Pharmaceutical Regulatory Affairs Practical I	6
MPRA106P	Seminar/Assignment – I	2
<b>Total</b>		<b>16</b>
<b>Year 2 - Semester III</b>		
MPRA202T	Regulatory Aspects of Herbals and Biologics	4
MPRA203T	Regulatory Aspects of Medical Devices	4
MPRA204T	Regulatory Aspects of Food and Nutraceuticals	4
MPRA206P	Seminar/Assignment – II	2
<b>Total</b>		<b>14</b>
<b>Year 2 - Semester IV</b>		
MPRA301T	Advanced Research Methodology and Biostatistics	4
MPRA205P	Pharmaceutical Regulatory Affairs Practical II	6
MPRA206P	Seminar/Assignment – II	2
<b>Total</b>		<b>12</b>
<b>Year 3 - Semester V</b>		
MPRA302T	Journal club	1
MPRA303T	Research/Project Work – Protocol preparation, hypothesis, methodology and proposal presentation	16
<b>Total</b>		<b>17</b>
<b>Year 3 - Semester VI</b>		
MPRA401P	Research/Project work – Dissertation / Final presentation	16
<b>Total</b>		<b>16</b>

**Semester wise credits distribution**

Semester Credit Points	Semester Credit Points
<b>I</b>	<b>14</b>
<b>II</b>	<b>16</b>
<b>III</b>	<b>14</b>
<b>IV</b>	<b>12</b>
<b>V</b>	<b>17</b>
<b>VI</b>	<b>16</b>
<b>Total Credit Points</b>	<b>89</b>