JSS ACADEMY OF HIGHER EDUCATION AND RESEARCH MAURITIUS

A degree awarding institution registered with the Higher Education Commission, Mauritius

JSS Academy of Higher Education and Research, Mauritius

Master of Pharmacy (Regulatory Affairs) Online

Programme Document

JANUARY 2026

Table of contents

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

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.

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

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 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. Programme Mode and Duration

(i)	**Delivery mode**	Online/Distance
(ii)	**Delivery Type**	distance with an online learning platform
(iii)	**Duration (minimum and maximum) in terms of years, and contact hours per year**	Minimum one and half years - Maximum three years
(iv)	**Number of semesters**	*Minimum 3 Semesters – Maximum 6 Semesters*

G. 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.

H. Programme Development and Review Committee:

- Every post graduate program shall have a Program Committee constituted by the Dean in consultation with all the Module in charges 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;
- Duties of the Program Development and Review 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 Development and Review Committee shall meet at least once in

a semester preferably before the final end semester exam.

The last comprehensive review of the M Pharm Regulatory Affairs programme was conducted in **December 2024**, during which several key recommendations were proposed to enhance the programme's accessibility, relevance, and alignment with institutional standards. The following decisions were made:

1. **Transition to Distance Learning Mode**
   It was resolved that the programme will be offered exclusively in **distance learning mode**. This decision was informed by two primary factors:
   - **Low Enrollment Numbers:** The programme has received a minimal number of applications, which has posed challenges in launching and sustaining it.
   - **Target Learner Constraints:** Despite the clear demand for Regulatory Affairs professionals, many prospective candidates are working pharmacists who are unable to enroll in a **full-time/part-time, on-campus programme** due to their professional obligations. Offering the programme in a flexible distance learning format will enable these professionals to upskill without compromising their employment.

   Furthermore, the nature of the curriculum—being primarily theoretical and regulatory in focus—does not involve wet-laboratory components, making it **ideally suited for distance delivery** without compromising on academic rigor or learning outcomes.

2. **Revision of Programme Duration**
   In alignment with the duration of other postgraduate offerings at JSS Academy of Higher Education & Research, Mauritius (JSSAHERM), the duration of the M Pharm (Regulatory Affairs) programme will be revised from the previous three years to 1.5 years for learners.
   This change will standardize the programme structure and make it more appealing and feasible for working professionals.
3. **Integration of Artificial Intelligence (AI) in Curriculum**
   To future-proof the programme and ensure alignment with global trends in pharmaceutical regulation, AI-integrated learning modules will be incorporated. These will focus on applications of AI in regulatory data analysis, submission automation, and policy decision-making—areas increasingly prioritized by global regulatory agencies.

I. 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, 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 below:

Mentoring
- Mentor: Mentee Ratio – 1:10
- Counseling
- Monitor Progress
- Information to parents
- Mentor Diary

Slow Learners
- Remedial Classes
- Intensive coaching
- Supportive Assessments
- Adjuvant Counseling

Advanced learners
- Advanced Learning support
- Committee Members as student representative
- Team Leaders
- Representation in events

Mentoring
- Mentorship - Mentor, Batch teacher, Class teacher

Support & Progression
- Scholarship
- Health Care & Insurance
- Placement Cell
- Alumni
- Support for competitive exams
- Student Support Centre
- Skill development
- Personality Development

Activities
- Cultural
- Sports
- Magazine
- Outreach

Professional Bodies
- Local Branch
- Student Charter
- Institutional Society

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

J. 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.

K. 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.

- **Credit System**
  - (i) 1 credit = 15 hours of lecture
  - (ii) 1 credit = 30 hours of practical/tutorials/seminars

Total Number of Credits	
Semester	**No. of Credits**
I	**20**
II	**24**
III	**18**
Total	**62**

L. 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 module in charge.
- Such schedule for continuous assessment procedure will be displayed on the notice board in the beginning of the semester.
- The module in charge 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.

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); Research / Review Publication in National/ International Journals (preferably Indexed in Scopus / Web of Science);	6

Academic Award/Research Award from National/ International Agencies	
Total (A + B)	**10**

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

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≤ X ≤100	O	10	Outstanding
80≤ X <90	A	9	Excellent
70≤X<80	B	8	Very Good
60≤X<70	C	7	Good
50≤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 C1, C2, C3, C4 and C5 and the student's grade points in these courses are G1, G2, G3, G4 and G5, 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:

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

where C1, C2, Cn,…. is the total number of credits for semester I,II,…n, and S1,S2, Sn,….is the
SGPA of each semester I,II,,,,n.

Evaluation of Performance

a) 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 8 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 analyse your question
4) Conducting appropriate analysis, and
5) Analysing results and writing the research paper

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

Evaluation of research work:

Dimensions	Percentage of Marks
Identification of the problem	**20**
Literature search	**10**
Aim and scope of the work	**10**
Objective(s) of the work	**10**
Novelty of research/project work	**20**
Methodology to be adopted	**20**
Question and answers	**10**
Total	**100**

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

b) 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 12,000 to 15,000 words (excluding figures, tables and references) have to be defended in a viva-voce. The examiners appointed by the institution shall make the evaluation on the bases on the criteria given below;

Evaluation of Dissertation and Presentation

Dimensions	Percentage of Marks
Achievement of Objective(s)	**10**
Methodology	**20**
Results and Discussions	**30**
Conclusions and Outcomes	**15**
Question and answer skills	**15**
Presentation of work	**5**
Communication skills	**5**
Total	**100**

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

M. Award Classification

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

Classification of Award	**CGPA**
Distinction	8.00 and above
Merit	7.00 to 7.99
Pass	6.00 to 6.99
No Award	less than 6.00

N. Programme Organization and Management

Programme Coordinator:

Name : Prof Dr Ashish Wadhwani
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O. Programme Structure

Master of Pharmacy (M Pharm) – Regulatory Affairs - Online

Module code	Modules	Hrs/Wk L/P	Credits
Year 1 - Semester I			
MPRA101T	Good Regulatory Practices	4	4
MPRA102T	Documentation and Regulatory Writing	4	4
MPRA103T	Clinical Research Regulations	4	4
MPRA104T	International Pharmaceutical Regulations - I	4	4
MPRA105P	Pharmaceutical Regulatory Affairs Practical I	8	4
		Total	**20**
Year 1 - Semester II			
MPRA201T	International Pharmaceutical Regulations - II	4	4
MPRA202T	Regulatory Aspects of Herbals and Biologics	4	4
MPRA203T	Regulatory Aspects of Medical Devices	4	4
MPRA204T	Regulatory Aspects of Food and Nutraceuticals	4	4
MPRA205P	Pharmaceutical Regulatory Affairs Practical II	8	4
		Total	**20**
Year 2 - Semester III			
MPRA301T	Advanced Research Methodology and Biostatistics	4	4
MPRA302T	AI in Pharmacy: Regulatory Science & Pharmaceutical Compliance	4	4
MPRA303PW	Research/Project Work – Protocol preparation, hypothesis, methodology and proposal presentation	4	2
MPRA304PW	Research/Project work – Dissertation / Final presentation	20	10
		Total	**20**

Semester wise credits distribution – Distance Learning

Semester Credit Points	Semester Credit Points
I	**20**
II	**20**
III	**20**
Total	**60**