

JSS ACADEMY OF HIGHER EDUCATION & RESEARCH, MYSURU
(Deemed to be University – Accredited 'A' Grade By NAAC)

JSS COLLEGE OF PHARMACY, OOTY

(An ISO 9001:2015 Certified Institution)
(Ranked 15th in India by NIRF - 2018)
(QS 3 Star in Pharmacy Program)



PHARMACEUTICAL REGULATORY AFFAIRS

Preamble

Pharmaceutical Regulatory Affairs (PRA) course was started in the year 2010 under the Department of Pharmaceutics. The PRA is a comparatively new & specialized profession, which has developed to protect public health, by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines. PRA department in a pharmaceutical company is a vital unit that drives the R & D efforts of the company to the market successfully. The regulatory department works with a focus to get products to the market with a commercially viable label, in the least possible time and expense.

Mission

"To make the JSS College of Pharmacy, Ooty a preferred destination to study Pharmaceutical Regulatory Affairs"

Vision

"To make available a pool of competent professionals in the area of Pharmaceutical Regulatory Affairs with fundamental knowledge on Various Good Regulatory Practices in the Healthcare and related industries".

Why PRA?

India is growing very rapidly in pharmaceutical sector; there is a need of PRA professionals to cater the current needs of industries as the global competition is increasing. Regulatory affairs professionals are the link between pharmaceutical industries and world-wide regulatory agencies. They are required to be well versed in the laws, regulations and guidelines as per different regulatory agencies. There is a growing need to incorporate the current requirements of pharmaceutical industries in the standard curriculum of pharmacy colleges to prepare the students with the latest developments to serve the industries.

Objectives

- * To prepare professionals for regulatory affairs positions in the pharmaceutical sector.
- * To facilitate the students knowledge with proper foundation in advancing them in the regulatory profession.
- * Provide fundamental basics as per industrial requirement in the field of regulatory affairs.
- * Keeping track of the ever-changing legislation in all the regions.
- * Update students with thorough and up-to-date knowledge of global laws and regulations, applicable in the various stages of drug development.
- * Theoretical and practical knowledge in preparing , compelling and submitting required documents as per industry and regulatory authority needs for the registration of healthcare products.

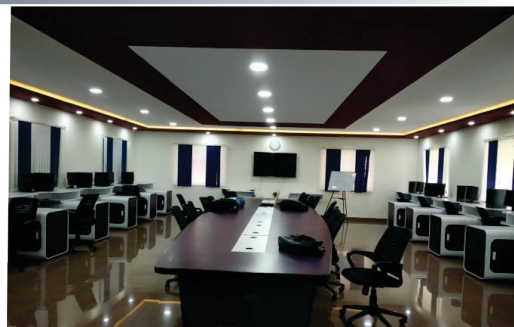
Why at JSS College of Pharmacy, Ooty?

- Pioneer institute in India to offer M-Pharmacy in Pharmaceutical Regulatory Affairs.
- State of the art infrastructure, video conferencing facilities, individual workstations, ebooks, journals, dedicated staff.
- Course in liaison with current pharmaceutical industry requirements.
- National and International PRA professionals roped in for delivering the course.
- Mission "To make the JSSCPO a preferred destination to study Pharmaceutical Regulatory Affairs"
- 100% placement through campus interview.

Infrastructure

Exclusive regulatory affairs suite with

- Individual work station.
- Completely Wi-Fi enabled.
- Video conferencing facility.
- Separate library for regulatory department.
- Smart class room facility.



Faculty Profile

The course is driven by eight teachers. Eighty percent of teachers are having more than 15 years of teaching and research experience.

SI No	Faculty	Qualification	Designation
1.	Dr. K. Gowthamarajan	M.Pharm, Ph.D.	Professor
2.	Dr. V Senthil	M.Pharm, Ph.D.	Professor
3.	Dr. R Suresh Kumar	M.Pharm, Ph.D.	Asst. Professor
4.	Dr. D NagaswamyVenkatesh	M.Pharm, Ph.D.	Asst. Professor
5.	Dr. G N K Ganesh	M.Pharm, Ph.D.	Asst. Professor
6.	Dr. N. Jawahar	M.Pharm, Ph.D.	Asst. Professor
7.	Dr. Karri V V S Narayana Reddy	M.Pharm, Ph.D.	Lecturer
8.	Mr. Arun R	M.Pharm, (Ph.D.)	Lecturer

Admission for PRA

Eligibility:

A candidate who has passed B. Pharm degree examination from any recognized University and has secured not less than 55% of the maximum marks (aggregate)

Selection Criteria:

Through Merit and written test/ personal interview

Intake capacity: Annual intake capacity is 15 seats

Program Duration Two years from the commencement of academic term.

Course system:

Credit based semester system

Delivery of Course:

The course consists of 4 semesters: (Includes internship during third and fourth semester for a period of 6 months in Pharmaceutical company.



FIRST SEMESTER:

1. Good Regulatory practices
2. Documentation & Regulatory Writing.
3. Clinical Research Regulations.
4. Indian Regulations and Intellectual property Rights.
5. Practical -I
6. Seminar and Assignment

SECOND SEMESTER:

1. Regulatory Aspects of Drugs & Cosmetics.
2. Regulatory Aspects of Herbals & Biologics.
3. Regulatory Aspects of Medical Devices.
4. Regulatory Aspects of Food & Nutraceuticals.
5. Practical -II
6. Seminar and Assignment

THIRD SEMESTER:

1. Research Methodology & Biostatistics.
2. Journal Club.
3. Research Proposal.
4. Project.

FOURTH SEMESTER

1. Journal Club.
2. Research presentation.
3. Project submission.

Learning Resources

Books, thesis, journals, are available for the students for the use of students and scholars. New e-CTD software were purchased in the last few years. Smart class room facility also available for students. Journal club, invited lectures, seminar, workshop, industrial visit, webinar, ICT enabled teaching, etc are regularly organized for updating knowledge. Industrial training for a period of 8 months as a part of academics for practical knowledge in Department of Pharmaceutical Regulatory Affairs in leading pharmaceutical industries in the country with stipend.

Students assessment

The Ph.D, P.G and U.G students are continuously assessed through the lab works, internal tests, and they are asked to submit assignments which are discussed in student seminar to improve their presentation skills. Project works are also made mandatory. Research audits are conducted regularly in front of expert panel comprising Heads of department and other teaching staff to monitor the progress in research.

Job opportunities

RA professional can get employment as

- Regulatory Affairs Consultants
- Regulatory Affairs Associates
- Regulatory Affairs Assistants/ specialist
- Regulatory Affairs head/ Director
- Regulatory administrator
- Regulatory Compliance Manager
- Medical Information Associates
- Drug Inspector/Drug Controller
- Drug Safety Specialist/ Regulatory Food Safety Scientist.



Placement and internship

In general 90 percent of the students are placed in the industry, 5 percent are in academia and 5 percent are going for higher studies.



JSS College of Pharmacy, Ooty

(ISO 9001 : 2015 Certified Institution)

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