

CENTRE FOR ADVANCEMENT IN HEALTH SCIENCES

M.S. in Regulatory Affairs

This degree program will provide a comprehensive background in regulatory science with the additional training and experience required of regulatory affairs professionals. Main focus is on laws and regulations of regulated markets USFDA, EU, ICH, Indian MOH and non-regulated markets, related to drug discovery, development, testing, and manufacture of products for commercial distribution. Also included are requirements for ongoing post-marketing surveillance. The degree program will provide students with detailed knowledge and understanding of current regulations and their practical application to the development and commercialization of drug, biologics, and medical device products. Also incorporated into the degree program are business administration courses that will provide students with communication and management skills essential for the successful regulatory affairs professional in an industry work environment.

Program Outline:

The 38-credit program includes 28 credits in required courses, and 10 thesis credits. The student is required to submit a final written scientific report to the faculty committee. In a final oral examination, the thesis project is presented and defended. The thesis committee consists of at least three graduate faculty members.

- RA 01 Pharmaceutical, Biotechnology & Medical Device Industries (3 credits)
- RA 02 Food & Drug Law of Regulated and non-regulated market (6 credits)
- RA 03 Current Good Manufacturing Practice (3 credits)
- RA 04 Medical Device Regulations (3 credits)
- RA 05 Clinical Trials: Issues In Design, Conduct and Evaluation (3 credits)
- RA 06 Validation Of Pharmaceuticals, Biologics and Medical Devices (3 credits)
- RA 07 Quality Control And Quality Assurance: Pharmaceuticals, Biologics, and Medical Devices (3 credits)
- RA 08 Indian Food and Drug laws (4 credits)
- RA 09 - Thesis or Project (10 credits)

COMMENCEMENT OF PROGRAM: January

APPLICATION DEADLINE: November

CONTACT: Dr. Vaidehi: +919820345616, Ms. Rajashree: +919860697268

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Please fill in all the details.

All entries should be made in CAPITALS.

For Office Use Only :

Application Number: _____

Application received on: _____

Enrolment number: _____

Paste your self
Attested
Photograph here

- Full name of the Candidate: _____
- Date of Birth: _____ Email: _____
- Address: _____

- Telephone Residence: _____ Mobile _____
- Academic Qualifications (After 10 + 2)

Examination Passed	University / College	Year	Class / Percentage

Payment Details: Demand Draft No.: _____ **Date:** _____

Drawn on (Bank) _____ for
Rs. _____ (Bank draft must be drawn in favour of “**Centre
For Advancement In Health Sciences**” payable at Mumbai. Candidate should write his/her
name and address on the back of the demand draft)

Signature of the candidate: _____ Date: _____

**Enclosures: Demand Draft, 2 Photographs, Photocopy of last examination
passed / degrees obtained.**

Photocopy of this form can be used.