



RACC



Regulatory Affairs Crash Course

About the Course

Regulatory Affairs is the area with a broad overview and the responsibility for collecting all data from the development processes and sending it to the regulatory authorities where the trained people in regulatory affairs is required. The development of new drugs and medicinal products is a long and complicated process that starts with the glimmer of a new idea and ends with the effective marketing of a finished product i.e. the success is dependent on the approval by the authorities. With an in-depth industrial insight, we offer our students the practical world of Drug Regulatory Affairs. **The course is ideal for ones who are aspiring to choose a career path in RA** and be a part of an esteemed network.

Career Opportunities in RA

A career in RA is both a highly rewarding and challenging career. It opens up a lot of opportunities as it covers a variety of disciplines. To maintain safety & efficacy in pharma, regulatory agencies like US FDA, UK MHRA, EDQM, DCGI, etc all over the world are imposing a number of regulations. This has resulted in creation of distinct departments with highly qualified professionals who will help companies meet these requirements with ease.

Benefits of the Course

1. E-Learning Materials
2. Experienced & Quality Faculty
3. Knowledge Sharing on the Practical Industry Experience
4. Online Interaction facility with the Faculty
5. Soft Skills, Resume & Interview Session
6. Completion Certificate
7. 100% Job Assistance
8. Life-Time Network & Assistance

Course Contents

1. Introduction to Global Drug Regulatory Affairs
2. ICH Quality Guidelines
3. ICH M4 Q CTD and ACTD Guidelines
4. API Regulatory
 - DMF preparation module 2 and module 3
 - DMF Submission to USFDA
 - Regulatory submission to Europe (ASMF, CEP)
5. Formulation Regulatory
 - Dossier preparation in CTD format: Module 2,3,4,& 5
 - ANDA approval process
 - Regulatory submission to Europe
 - Regulatory submission to emerging market
 - Regulatory submission to India
6. eCTD Submissions & Response to Queries
7. Soft Skills, Resume Building & Interview Preparation

Fee Structure

INR 6000/-* Only

*Fees increases for every upcoming batch

Contact us for further details at:

Email Id: info2racc@gmail.com | Phone: +919156759404 / +918425899903

Certificate of Completion

is presented to

Pallavi Suryawanshi

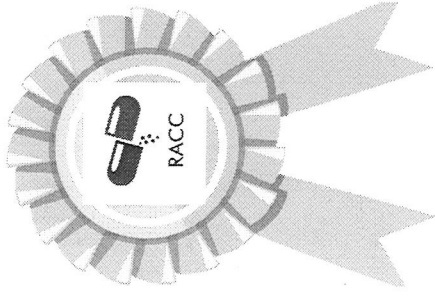
for successfully completing the crash course in
Drug Regulatory Affairs

20- Jun-2021

Date

A. Jeyaraj

Director, RACC



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is presented to

Pradnya Sagar

for successfully completing the crash course in
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Date

A. S. Jeyaraj

Director, RACC

