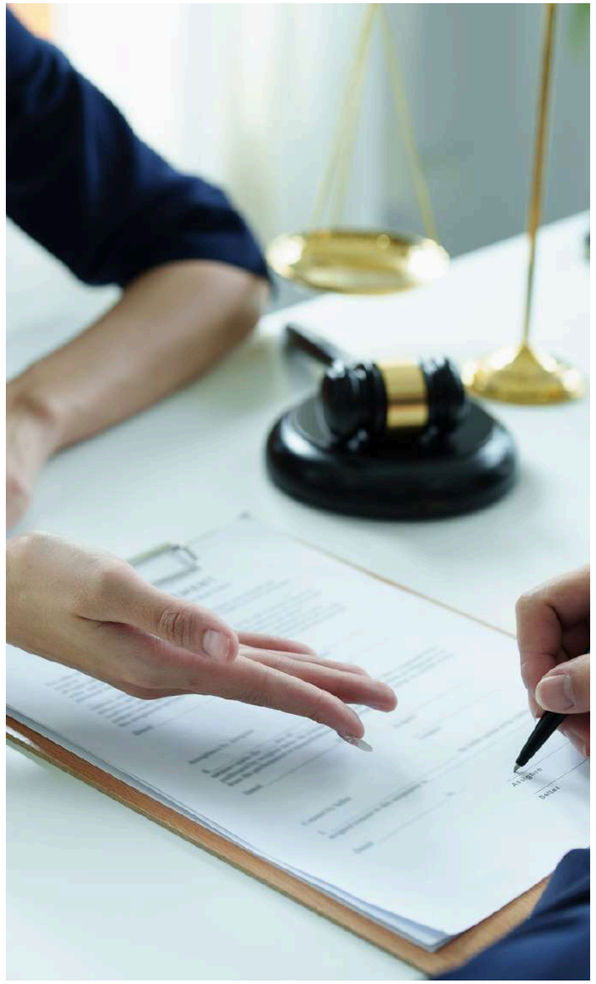
CareerInPharma™
Transformation, not Information!

# Diploma in
# Regulatory Affairs (RA)

3 MONTHS COURSE
ONLINE & FLEXIBLE



# Welcome to our Online RA Course

**Regulatory Affairs (RA)** is a key field in the pharmaceutical industries that ensures products like drugs, vaccines are **safe, effective, and meet legal standards**. RA professionals prepare and submit approval documents to agencies such as the **FDA, EMA, and CDSCO**, and manage product compliance throughout development and post-marketing. They also handle safety updates, labeling changes, and regulatory communication. In short, RA ensures healthcare products reach patients legally, safely, and efficiently.

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# BOOMING INDUSTRY

The Regulatory Affairs (RA) industry is set for significant growth, with the global market projected to reach USD 30 billion by 2030, driven by the increasing number of new drug approvals, complex global regulations, and rising demand for compliance across pharmaceuticals industry.

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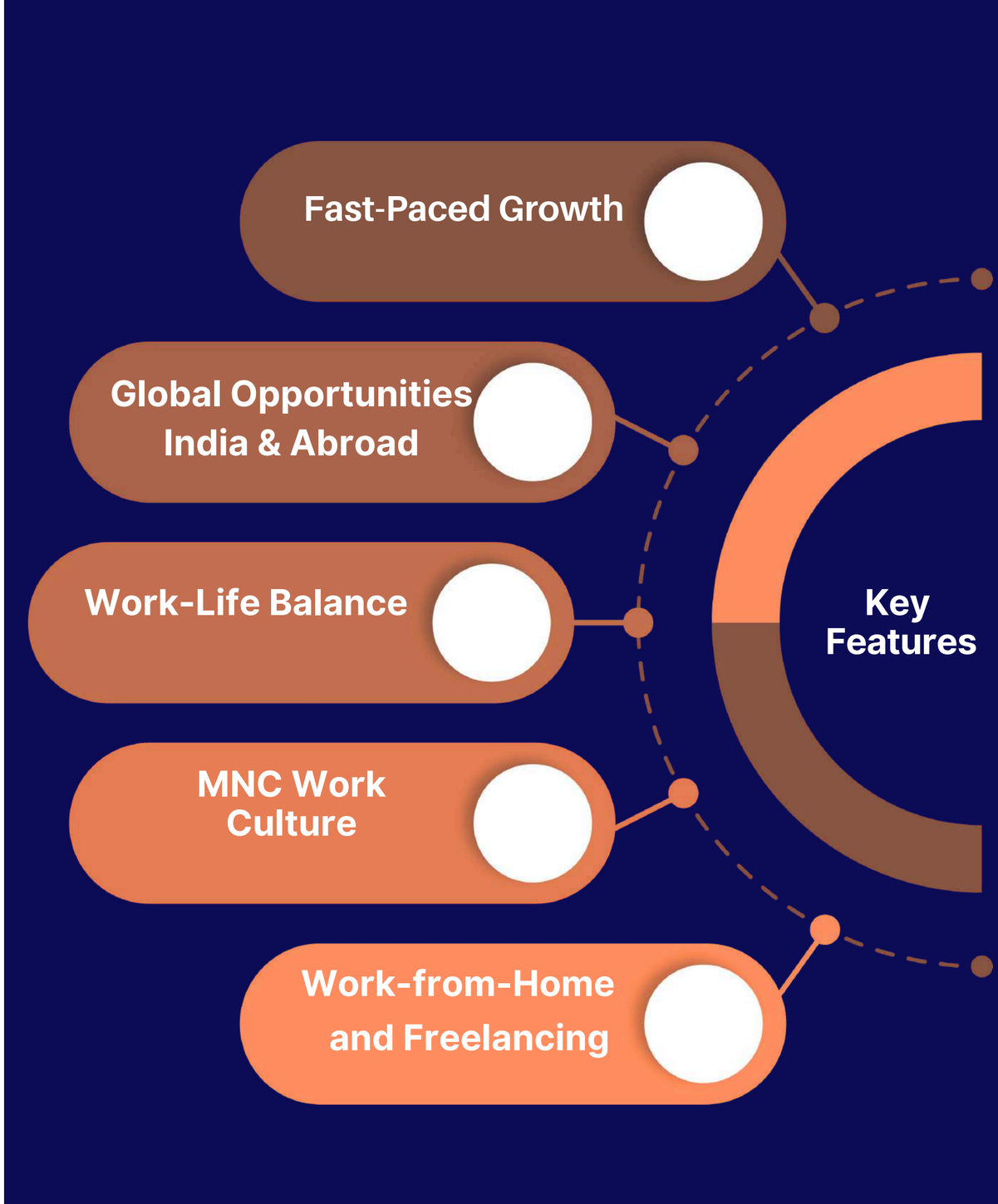
# What you will learn in this Course

In this RA course, you will learn how to navigate global regulatory systems, prepare CTD/eCTD submissions, communicate with agencies like FDA and EMA, and manage drug approvals and post-marketing updates. You'll gain hands-on knowledge in CMC, labeling, variation filings, and regulatory strategy—equipping you with the skills needed for a successful career in Regulatory Affairs.



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# The key takeaways for the course

- Clear understanding of global regulatory pathways (FDA, EMA, CDSCO)
- Overview- knowledge of CTD/eCTD structure and submissions
- Practical insights into CMC, labeling, and variation filing
- Skills to manage product lifecycle and post-marketing compliance
- Confidence to face regulatory interviews and build an RA-focused CV
- Readiness to work in pharma or CROs companies

# Course *Eligibility*

- Life Sciences/Biosciences B.Sc., M.Sc., (All Divisions)
- Pharmacy (B. Pharm, M. Pharm, Pharm.D)
- Doctors and healthcare medical professionals interested in learning and understanding the regulatory landscape of the pharmaceutical industry are highly encouraged to enroll.

Candidates should have a minimum of 55% in his/her graduation.

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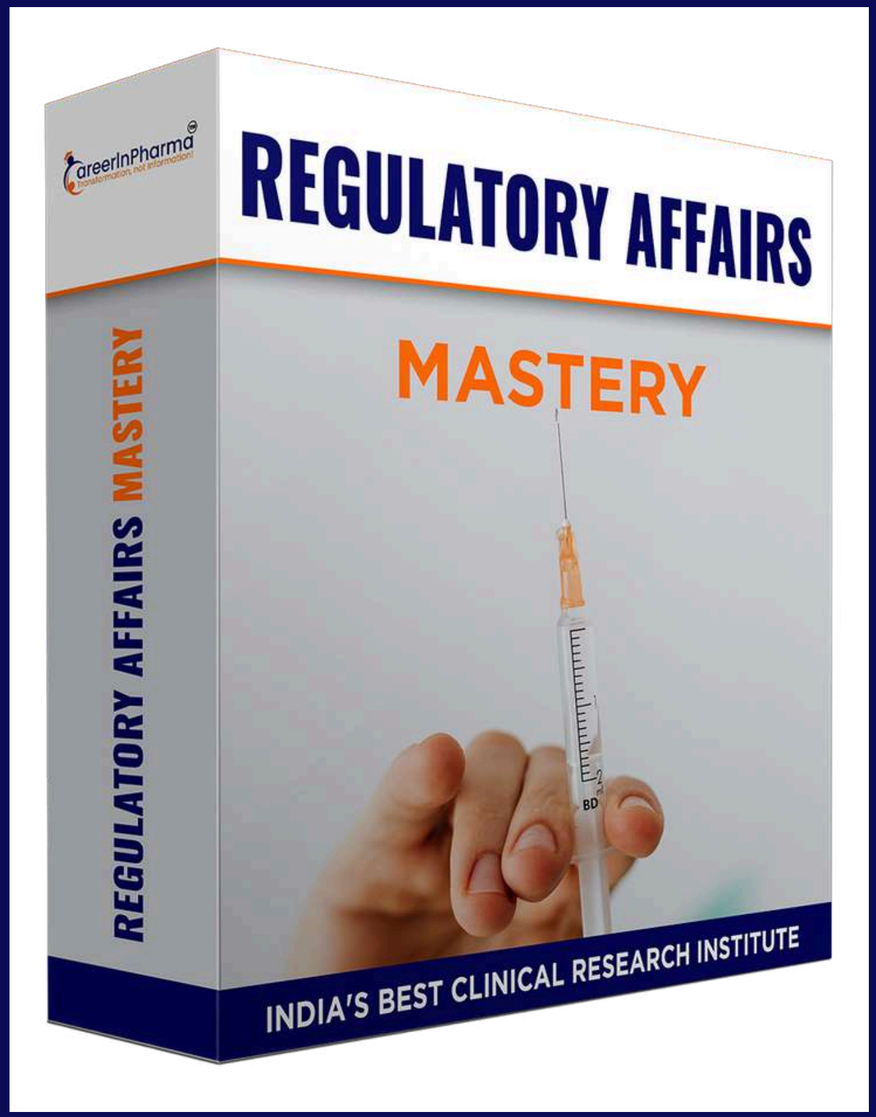
# 3 Months Course Benefits

- Get Training from India’s first online ISO certified leading training Institute.
- Industry-Aligned Course Content.
- Lifetime Access to Course Materials.
- E-Certification Upon Completion.
- Flexible Online Learning – Anytime, Anywhere
- Recorded session for future review.
- Interactive Sessions with Instant Doubt Resolution.
- Convenient Timings for Students & Working Professionals.
- Job & Research-Oriented Courses at Affordable Prices.
- Job updates for Career Growth (6 months)



# 25 Modules

Training by Expert Industry Professionals-All our faculty members are working in the industry from a long time and teach practical insights which they get in daily professional life.

We also help in transformation through our never ending constant 24x7 support. Always available over email, phone call or Whatsapp for a discussion.

We also provide emotional counselling on regular basis by bringing experts to address our student's stress or any other emotional disturbance so that they get success in getting job.

24X7 SUPPORT

TRAINERS EXPERT INDUSTRY PROFESSIONALS

EMOTIONAL COUNSELLING

JOB ASSISTANCE




# Modules Outline

01

## Orientation & Introduction to Regulatory Affairs

Get introduced to the Regulatory Affairs field, course structure, and what you will learn.

02

## The Road to Approval

Understand the entire drug approval journey from discovery to post-marketing.

03

## CTD & eCTD – Your Digital Filing Cabinet

Learn how to structure and submit regulatory documents using the CTD/eCTD format.

04

## US Playbook – IND, NDA & Exclusivity

Explore U.S. drug submission routes and exclusivity benefits like ANDA, 505(b)(2), and NCE.

05

## Talking to the FDA

Understand the types of meetings with the FDA and how to prepare and follow up effectively.

06

## Europe Unlocked

Learn submission pathways in Europe including Centralised, DCP, MRP, and National procedures.

# Modules Outline

07

## Label Mastery – US, EU, India

Explore how to manage and align product labels across regulatory regions.

08

## India Gateway – Form-44 & SUGAM

Understand the Indian drug approval process, including forms, timelines, and regulatory bodies.

09

## Variation Command – The Change Game

Learn how to handle post-approval changes through variation classifications and processes.

10

## IDMP & xEVMPD – What and Why

Discover global product information systems and why data consistency is critical.

11

## IDMP Hands-On & Easy Q-and-A

Practice filling IDMP data fields correctly and learn to fix common data errors.

12

## Introduction to CMC

Understand what Chemistry, Manufacturing & Controls (CMC) involves across product lifecycle.

# Modules Outline

13

## Validation Basics – Lab & Factory

Learn how to prove that lab methods and manufacturing processes work reliably.

14

## Stability & Expiry Dates in Plain Words

Understand how drug shelf-life is tested, set, and supported by regulatory data.

15

## Specifications Made Simple

Learn how to set and maintain product quality standards (specs) and handle OOS results.

16

## CPPs & Simple Control Strategy

Identify Critical Process Parameters and develop basic control strategies for manufacturing.

17

## Choosing the Right Container

Explore packaging options, testing requirements, and how they affect drug stability and delivery.

18

## CMC Interview Drill (All Topics)

Review and practice key CMC concepts and questions for regulatory job interviews.

# Modules Outline

19

## Life-Cycle Basics

Understand regulatory responsibilities after product launch, including safety updates and reports.

20

## Building a Variation File

Learn how to prepare documentation for changes, including red-line pages and eCTD sequences.

21

## Global Label Maintenance

Manage label updates across countries and maintain alignment with global safety changes.

22

## Interview Prep Fundamentals

Prepare for interviews with resume matching, STAR answers, and body language tips.

23

## Choosing Route & Incentive

Compare approval strategies and regulatory incentives like Orphan Drug and Priority Review.

24

## Writing an RA-Friendly CV

Build a resume that highlights regulatory experience and passes ATS scans.

# Modules Outline

25

## Networking

Learn how to build professional relationships, connect with industry experts, and grow your career through strategic networking—online and offline.

# Certification

All participants are required to submit completed assessment or assignments on time, typically after relevant module, throughout the program.

Upon successful completion, participants will be awarded a Diploma in Regulatory Affairs (RA) course certificate.

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(registered as Ishita EduVentures)

Certificate Of Completion

THIS CERTIFICATE IS PRESENTED TO

DR. HARSHIT M

for successfully completing

Diploma Program in Regulatory Affairs

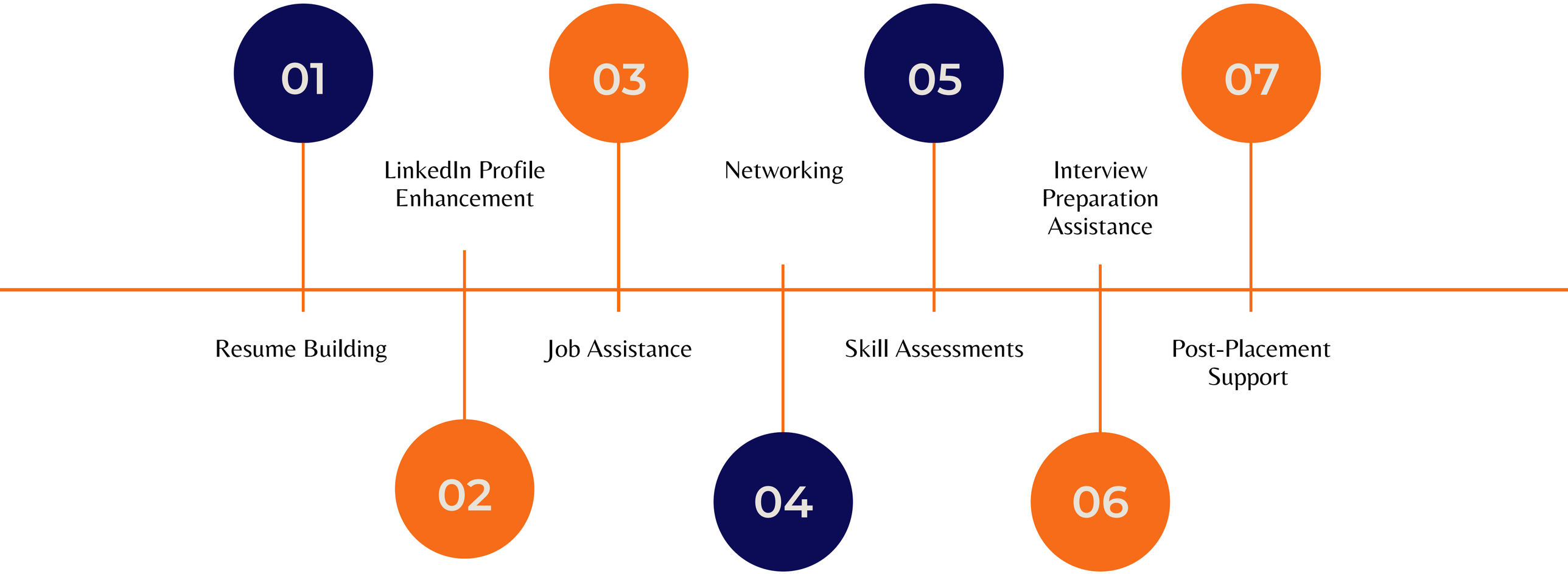
by CareerInPharma Clinical Research Training Institute with Grade A

Certificate Serial No: 15112024179
Issued On: 25/12/2022
Batch No: 11
Course Duration: September 2022 to November 2022

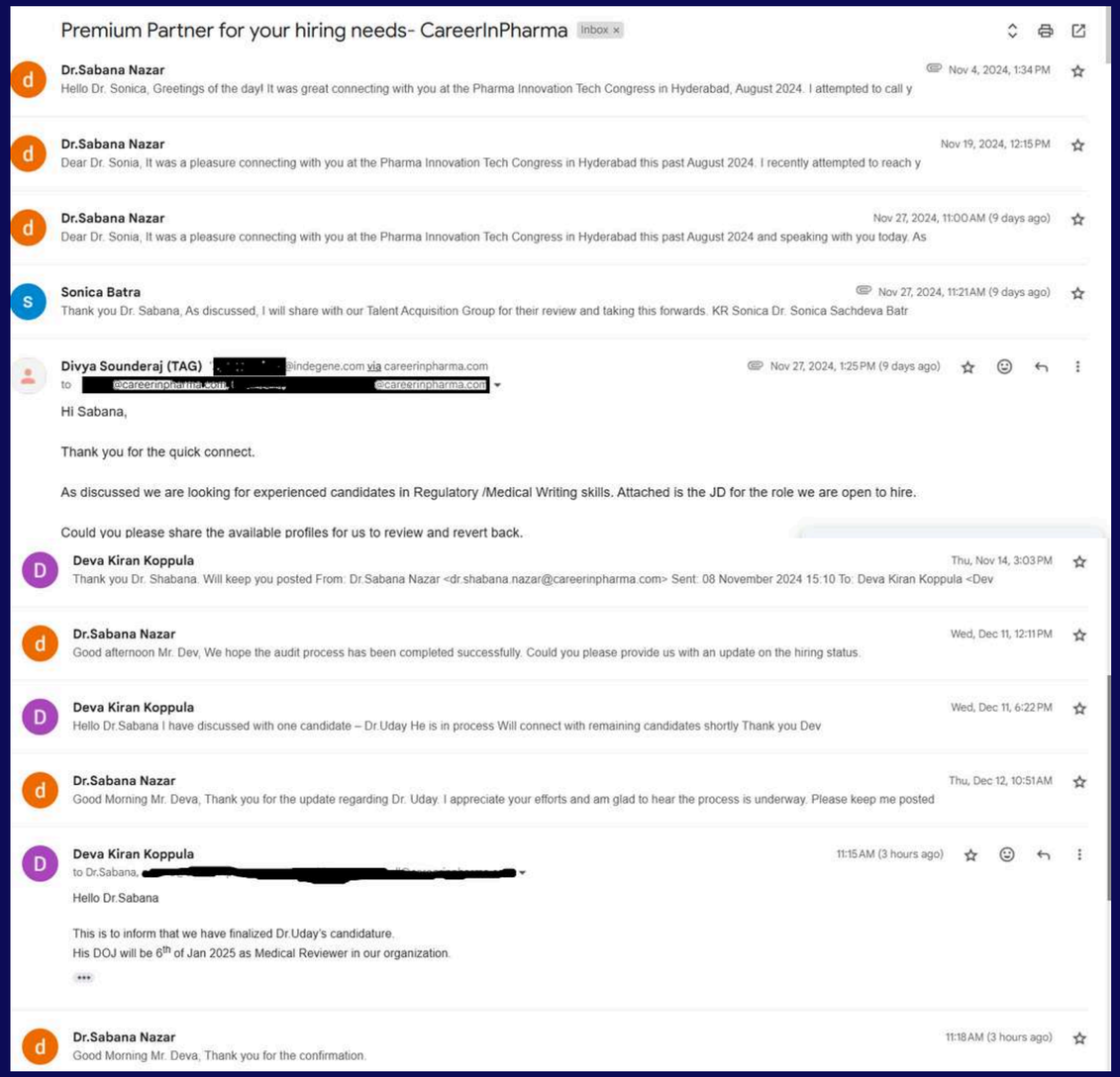
Dr. Neema Bisht
Program Director

www.careerinpharma.com

# Our Placement Process



# Placement Support



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**Dr.Sabana Nazar** Nov 4, 2024, 1:34 PM
Hello Dr. Sonica, Greetings of the day! It was great connecting with you at the Pharma Innovation Tech Congress in Hyderabad, August 2024. I attempted to call y

**Dr.Sabana Nazar** Nov 19, 2024, 12:15 PM
Dear Dr. Sonia, It was a pleasure connecting with you at the Pharma Innovation Tech Congress in Hyderabad this past August 2024. I recently attempted to reach y

**Dr.Sabana Nazar** Nov 27, 2024, 11:00 AM (9 days ago)
Dear Dr. Sonia, It was a pleasure connecting with you at the Pharma Innovation Tech Congress in Hyderabad this past August 2024 and speaking with you today. As

**Sonica Batra** Nov 27, 2024, 11:21 AM (9 days ago)
Thank you Dr. Sabana, As discussed, I will share with our Talent Acquisition Group for their review and taking this forwards. KR Sonica Dr. Sonica Sachdeva Batr

**Divya Sounderaj (TAG)** [redacted]@indegene.com via careerinpharma.com Nov 27, 2024, 1:25 PM (9 days ago)
to [redacted]@careerinpharma.com

Hi Sabana,

Thank you for the quick connect.

As discussed we are looking for experienced candidates in Regulatory /Medical Writing skills. Attached is the JD for the role we are open to hire.

Could you please share the available profiles for us to review and revert back.

**Deva Kiran Koppula** Thu, Nov 14, 3:03 PM
Thank you Dr. Shabana. Will keep you posted From: Dr.Sabana Nazar <dr.shabana.nazar@careerinpharma.com> Sent: 08 November 2024 15:10 To: Deva Kiran Koppula <Dev

**Dr.Sabana Nazar** Wed, Dec 11, 12:11 PM
Good afternoon Mr. Dev, We hope the audit process has been completed successfully. Could you please provide us with an update on the hiring status.

**Deva Kiran Koppula** Wed, Dec 11, 6:22 PM
Hello Dr.Sabana I have discussed with one candidate – Dr.Uday He is in process Will connect with remaining candidates shortly Thank you Dev

**Dr.Sabana Nazar** Thu, Dec 12, 10:51 AM
Good Morning Mr. Deva, Thank you for the update regarding Dr. Uday. I appreciate your efforts and am glad to hear the process is underway. Please keep me posted

**Deva Kiran Koppula** 11:15 AM (3 hours ago)
to Dr.Sabana, [redacted]

Hello Dr.Sabana

This is to inform that we have finalized Dr.Uday's candidature.
His DOJ will be 6th of Jan 2025 as Medical Reviewer in our organization.

**Dr.Sabana Nazar** 11:18 AM (3 hours ago)
Good Morning Mr. Deva, Thank you for the confirmation.

CIP Alumni_MBBS Group
only admins can send messages

4 December 2024

Your security code with ~ Shirisha changed. Tap to learn more.

5 December 2024

**Exclusive Opportunity for CareerInPharma Students - Indegene company / Bangalore / Office based**

**Job Title:** Regulatory Medical Writer
**Company** : Indegene
**Job Description:** Please refer to the attached JD file for detailed information.
**Qualification:** MBBS / PhD / MDS / BDS / MPharm / PharmD
**Experience:** Freshers (writing clinical and regulatory documents supporting global filings (CTD Module 2 and Module 5)).
**Location:** Bangalore
**Work Arrangement:** Full-time employment
**Working Days:** Monday to Friday
**Working Hours:** General work timings (9:00 AM – 6:00 PM)
**Salary:** As per company standards
**Additional Requirements:**
Excellent communication skills.
Relevant expertise in regulatory medical writing.

**How to Apply:**
If you meet the qualificat... Read more

Edited 11:02 am

Message

Exclusive Hiring for CareerInPharma Students by Leading Pharma Companies!

# Industry Partners- Hiring Collaboration

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Arcolab | Cipla | VIZEN LIFE SCIENCES | Oviya Med Safe | IQVIA | MEDILENZ AI-Powered Medical Legal Solutions

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Fortrea | Norwich CLINICAL SERVICES | Syneos Health | ConcertAI

APCER LIFE SCIENCES | BIOGENICO | NAVITAS LIFE SCIENCES | loop | 20+ & so on

SCITUS | Soterius™ ACCELERATING OUTCOMES | ESS EMM | iVRS


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EXCELLENT

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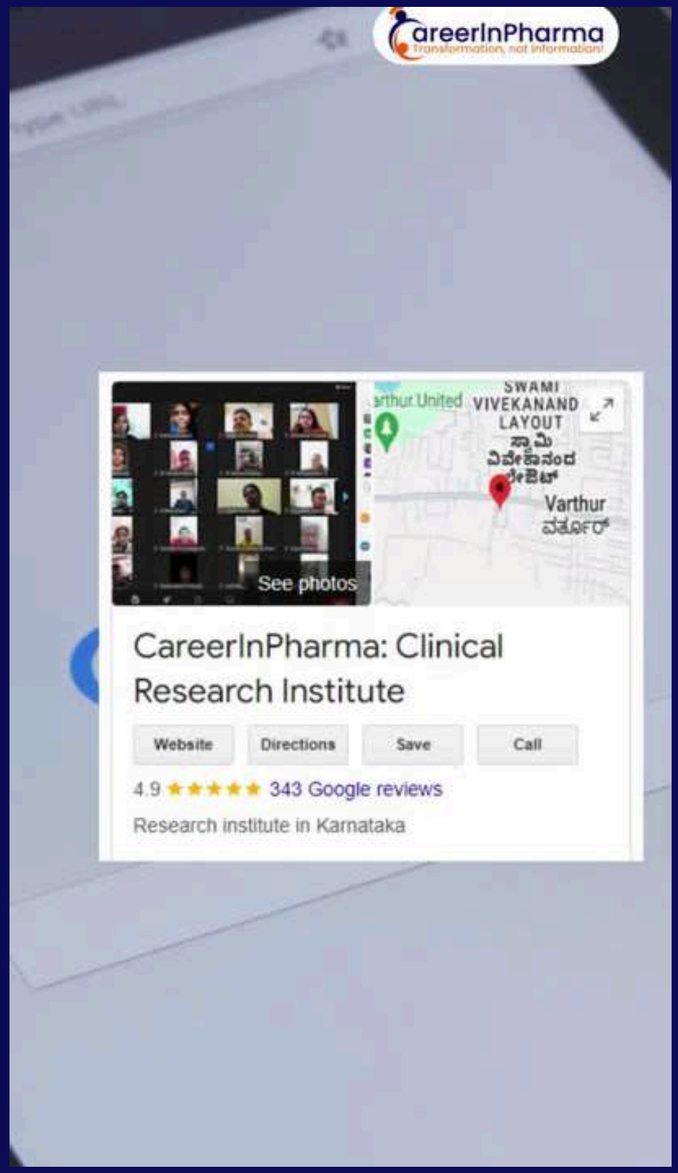
# 4.9 Ratings

Click to view



# Connect with us

| | | |
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| 27000+ connections | 18000+ followers | 4000+ subscribers |

# Thank You

*for watching*

**Get in touch:**

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