CliMed™ Research Solutions | CURIO | CERTIFIED ISO 9001:2015 COMPANY | SKILL DEVELOPEMENT PROGRAM

NEW BATCH

Executive Diploma in Regulatory Affairs, Dossier Preparation & Global Regulatory Submissions

7-Month Industry-Oriented Skill Development Program

Particulars	Details
Course Name	*Executive Diploma in Regulatory Affairs, Dossier Preparation & Global Regulatory Submissions*
Total Duration	*7 Months*
Theory Training	*4 Months*
Online Industrial Internship	*3 Months*
Class Schedule	*Every Sunday*
Mode	*100% Live Online*
Course Start Date	**September 20, 2026**
Last Date to Register	**September 20, 2026**
Total Fee	*₹6,999/- (Actual Value ₹30,000/-) (Two instalment available)*
Instalment Structure	*1st Instalment: ₹4,000/- at Registration* *2nd Instalment: ₹2,999/- after Completion of 3 Months*
Certifications	*Executive Diploma Certificate + Industrial Internship Certificate + ICH-GCP E6 (R3) Guidelines Training Certificate*

Registration Link (First Instalment): https://rzp.io/rzp/medocj

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About Curio Training & Research Institute (CTRI)

Curio Training & Research Institute (CTRI), a constituent unit of CliMed Research Solutions, India, is dedicated to developing industry-ready healthcare professionals through specialized skill development programs. CTRI focuses on bridging the gap between academic learning and industry requirements by providing practical, application-based training delivered by experienced professionals from pharmaceutical, biotechnology, CRO, medical device, and healthcare industries.

About the Program

The Executive Diploma in Regulatory Affairs, Dossier Preparation & Global Regulatory Submissions is a comprehensive professional training program designed to prepare students and professionals for careers in pharmaceutical regulatory affairs, dossier preparation, lifecycle management, regulatory submissions, compliance management, and global market authorization processes.

The program provides practical exposure to regulatory pathways, Common Technical Document (CTD) preparation, electronic submissions, regulatory intelligence, post-approval maintenance, and global submission requirements across major regulatory agencies such as US FDA, EMA, MHRA, Health Canada, TGA, WHO, CDSCO, and GCC countries.

Participants will receive structured training, practical dossier-building exercises, submission projects, and a dedicated three-month internship focused on real-world regulatory documentation and submission workflows.

Why This Diploma?

Regulatory Affairs professionals play a critical role in bringing pharmaceutical products to global markets.

The increasing complexity of global regulations has created strong demand for professionals skilled in:

- *Dossier Preparation*
- *CTD & eCTD Submissions*
- *Regulatory Strategy*
- *Lifecycle Management*
- *Market Authorization*
- *Regulatory Intelligence*
- *Labeling & Compliance*
- *Global Product Registrations*

This diploma prepares participants for these high-demand industry functions.

Program Highlights

✅ *100% Online Learning & Internship*

✅ *7-Month Structured Diploma Program*

✅ *4 Months Theory + 3 Months Industrial Internship*

✅ *Hands-on CTD & eCTD Training*

✅ *Dossier Preparation Projects*

✅ *Global Regulatory Submission Exposure*

✅ *Regulatory Intelligence Training*

✅ *Lifecycle Management Projects*

✅ *Industry-Based Assignments*

✅ *Live Interactive Sessions*

✅ *Session Recordings Available*

✅ *Resume Building & Mock Interviews*

✅ *Personalized Mentorship*

✅ *Complimentary Regulatory Affairs Study Material Book Delivered to Doorstep*

✅ *Regulatory Templates & Submission Samples*

✅ *Additional ICH-GCP E6 (R3) Guidelines Training*

✅ *Separate ICH-GCP E6 (R3) Certification*

Who Can Attend?

- *PharmD Students & Graduates*
- *BPharm & MPharm Students*
- *MBBS, BDS & Medical Graduates*
- *Nursing Students & Professionals*
- *Life Science Graduates*
- *Biotechnology Professionals*
- *Clinical Research Professionals*
- *Regulatory Affairs Professionals*
- *Pharmacovigilance Professionals*
- *Quality Assurance Professionals*
- *Medical Writers*
- *Freshers aspiring for regulatory careers*

Course Curriculum

4 Months Theory Training

Module 1

Introduction to Regulatory Affairs

Module 2

Drug Development & Regulatory Pathways

Module 3

Global Regulatory Authorities

Module 4

Pharmaceutical Legislation & Guidelines

Module 5

Regulatory Documentation Fundamentals

Module 6

CTD Dossier Preparation

Module 7

eCTD Submissions

Module 8

Regulatory Submissions

Module 9

Generic Drug Regulatory Affairs

Module 10

Regulatory Affairs for Biologics & Biosimilars

Module 11

CMC Documentation & Quality Modules

Module 12

Post-Approval Regulatory Affairs

Module 13

Regulatory Intelligence

Module 14

Medical Device & Combination Product Regulations

Module 15

Audits, Inspections & Compliance

Module 16

Professional Development & Capstone Project

Special Certification Program

ICH-GCP E6 (R3) Guidelines Training

All participants will undergo exclusive training on the latest ICH-GCP E6 (R3) Guidelines.

Coverage

- *Fundamentals of Good Clinical Practice*
- *Key Updates in E6 (R3)*
- *Investigator Responsibilities*
- *Sponsor Responsibilities*
- *Risk-Based Quality Management*
- *Patient Safety & Ethics*
- *Data Integrity*
- *Inspection Readiness*

Certification

Separate Certificate in ICH-GCP E6 (R3) Guidelines Training

Industrial Internship

3 Months Project-Based Industry Internship

Internship Domains

Dossier Preparation

- *CTD Module Development*
- *Regulatory Documentation Exercises*
- *Dossier Compilation*

Regulatory Submissions

- *IND Components*
- *NDA Components*
- *ANDA Documentation*
- *Submission Readiness Review*

Regulatory Intelligence

- *Regulatory Landscape Analysis*
- *Product Registration Tracking*
- *Regulatory Updates Monitoring*

Lifecycle Management

- *Variation Exercises*
- *Renewal Documentation*
- *Compliance Review Activities*

Internship Features

- *100% Online Internship*
- *Assignment-Based Learning*
- *Project-Based Training*
- *Weekly Mentor Reviews*
- *Industry Case Discussions*
- *Portfolio Development*
- *Individual Performance Evaluation*
- *Internship Completion Certificate*

Assessment & Evaluation

Participants will be evaluated through:

- ➥ *Assignments*
- ➥ *Dossier Preparation Exercises*
- ➥ *CTD Projects*
- ➥ *Regulatory Case Studies*
- ➥ *Submission Simulations*
- ➥ *Internship Assessments*
- ➥ *Final Evaluation*

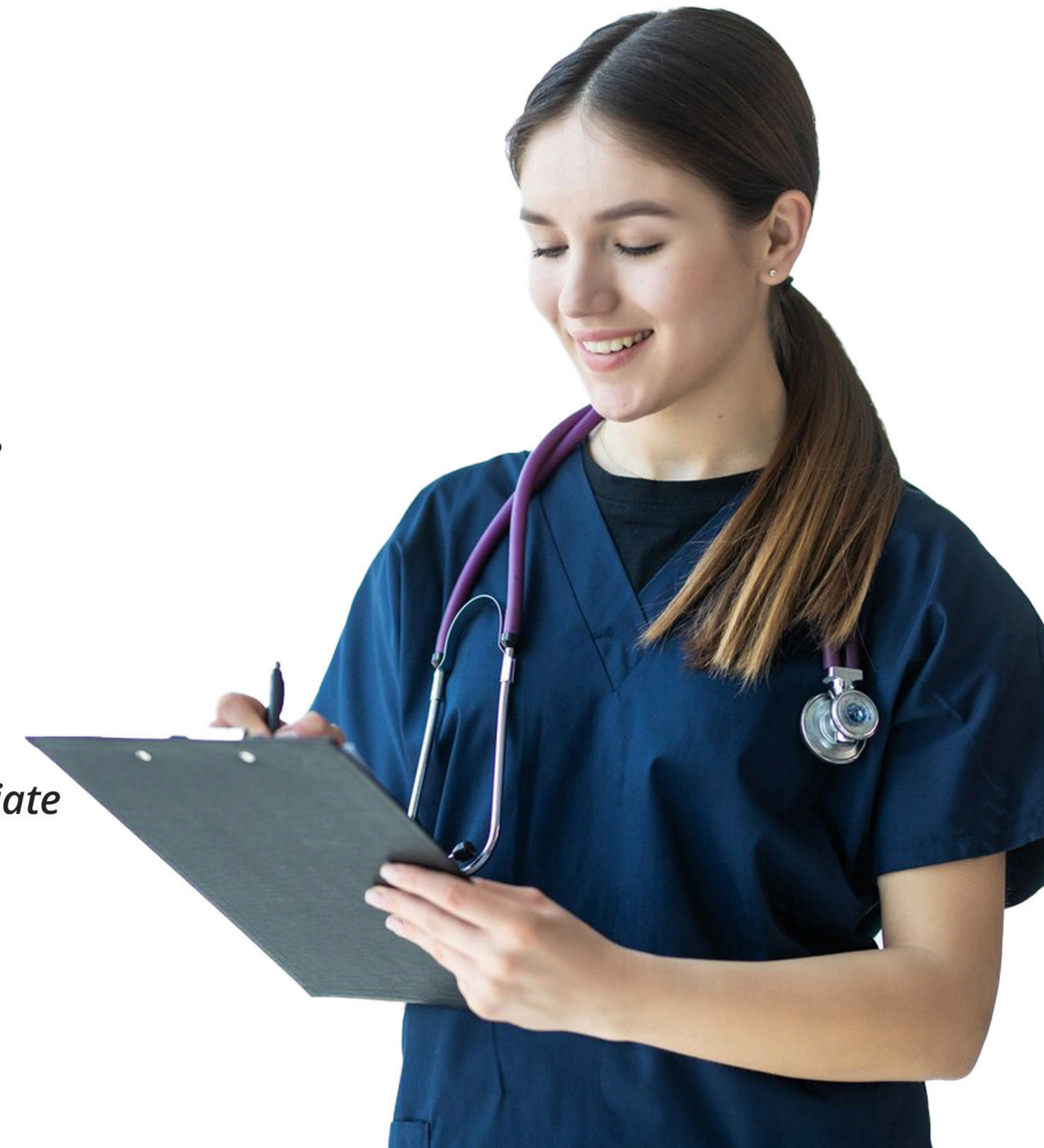
Certifications Awarded

- *Executive Diploma in Regulatory Affairs, Dossier Preparation & Global Regulatory Submissions*
- *Industrial Internship Completion Certificate*
- *Certificate in ICH-GCP E6 (R3) Guidelines Training*

Career Opportunities

Graduates can pursue careers as:

- *Regulatory Affairs Associate*
- *Regulatory Affairs Executive*
- *Dossier Preparation Associate*
- *Submission Specialist*
- *Regulatory Publishing Associate*
- *Regulatory Intelligence Associate*
- *Regulatory Compliance Associate*
- *Product Registration Executive*
- *CMC Documentation Associate*
- *Lifecycle Management Associate*
- *Medical Device Regulatory Associate*
- *Regulatory Consultant*



Registration Details:

Course Starts:

September 20, 2026

Last date to register:

September 20, 2026

Full Course Fee:

₹6,999/- *~~₹30,000/-~~*

Instalment Structure

- **1st Instalment:** ₹4,000/- *at the time of registration*
- **2nd Instalment:** ₹2,999/- *after completion of 3 months of theory training*

This introductory fee structure is provided under a limited-period professional skill development initiative to make industry-oriented healthcare documentation training accessible to students and healthcare professionals.

Program Convener

Dr. Ajit Singh

Founder & CEO,
CliMed & Curio,
India

Registration Link (First Instalment)

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