

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	Sunday, 12 July 2026
Last Date to Register	30 June 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

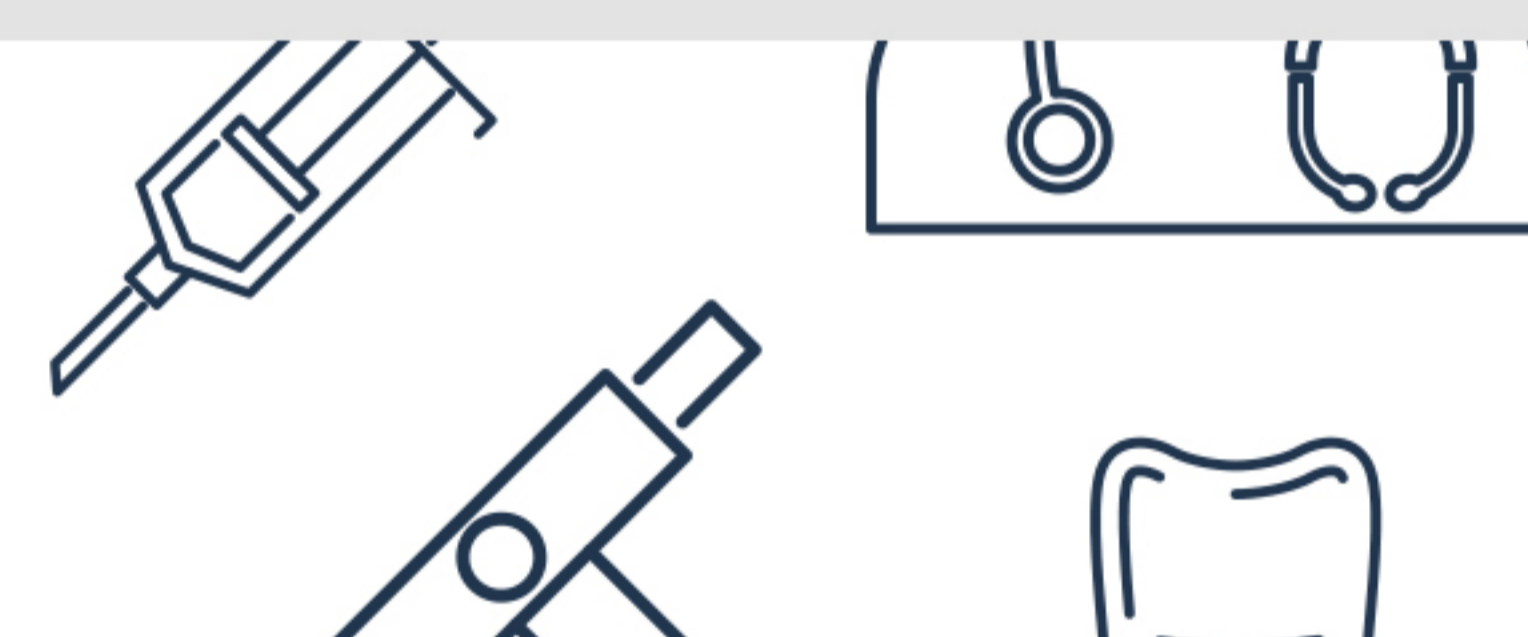


Module 6

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

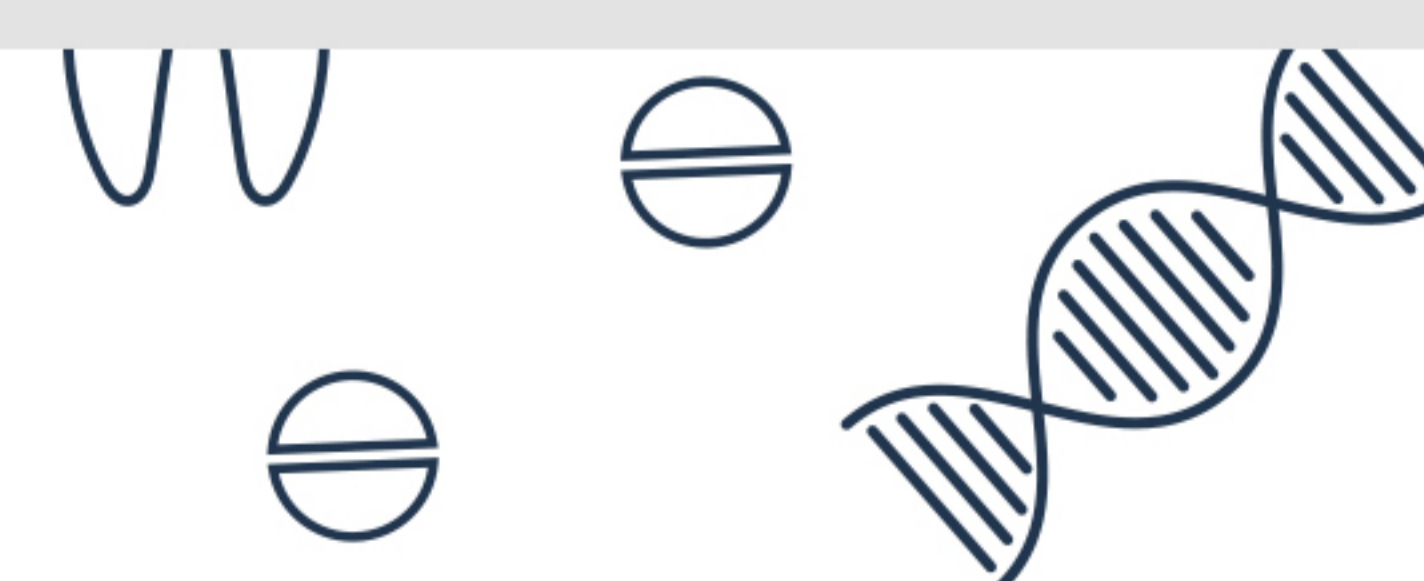


Module 12

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*

Lifecycle Management

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

Regulatory Submissions

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

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*

Regulatory Intelligence




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

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:

Sunday, 12 July 2026



Full Course Fee:

₹6,999/-

~~₹30,000/-~~



Last date to register:

30 June 2026

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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