CURIO

CliMed Research Solutions

Azadi Ka Amrit Mahotsav

SKILL DEVELOPEMENT PROGRAM

NEW BATCH STARTING
FROM JANUARY 18, 2026

# Executive Diploma in
# Drug Regulatory Affairs

## Six-Months Specialized Skill Development Program to Excel in the Pharmaceutical Industry

# About the Curio

Curio Training and Research Institute (CTRI) is the Constituent Unit of CliMed Research Solutions India, dedicated to providing Pharma and Healthcare Industry Training. Curio is established to transform the pharma & healthcare landscape by nurturing talent, fostering innovation, and driving excellence in these critical sectors.

Curio commits to producing professionals well-versed in theory and equipped with practical skills to lead, innovate, and create positive change. Curio provides industryoriented value-added, skill development courses, corporate training, and career consultation to individuals and institutions/ universities.

# About the Course

The Curio Diploma in Drug Regulatory Affairs is designed to equip participants with the essential knowledge and skills required to navigate the complex regulatory landscape of the pharmaceutical industry. The course will cover essential regulatory concepts, frameworks, and processes, equipping participants with the skills needed to navigate complex regulatory environments.

# Course Objectives

- *Understand the fundamentals of pharmaceutical regulations and their importance in the drug development process.*
- *Familiarize students with submission requirements and regulatory guidelines for major regulatory authorities (FDA, EMA, ICH, WHO, etc.).*
- *Develop expertise in regulatory submissions, including INDs, NDAs, BLAs, and supplements.*
- *Equip learners with practical skills for preparing regulatory submissions and ensuring compliance.*
- *Gain knowledge of regulatory inspections and compliance requirements.*
- *Learn about post-market surveillance and pharmacovigilance activities.*

# Course Highlights:

1. 100% Live classes, recordings on demand
2. Expert-led training and end-to-end engagement
3. Faculty members & resource persons from top-notch industry
4. 100% Placement Assistance
5. Leadership Dialogues & Interactions
6. Personalized Assignments & Interview Preparations

# Who can Attend

- *Pharmacy/Medical & Other Life Science Students & Professionals*
- *Professionals working in the pharmaceutical industry, such as regulatory affairs specialists, quality assurance professionals, and clinical research associates*
- *Students pursuing careers in pharmaceutical sciences or regulatory affairs.*
- *Individuals interested in understanding the regulatory landscape of the pharmaceutical industry.*

# Course Coverage

## Introduction to Regulatory Affairs

- *Definition and Scope of Regulatory Affairs*
- *Role of Regulatory Affairs in the Pharmaceutical Industry*
- *Overview of Regulatory Bodies: FDA, EMA, WHO, ICH, etc.*
- *Lifecycle of Pharmaceutical Products: R&D to Market*

## Pharmaceutical Legislation and Ethics

- *Key Regulations Governing Pharmaceuticals*
- *Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), Good Clinical Practice (GCP)*
- *Code of Ethics in Regulatory Affairs*
- *Case Studies on Regulatory Non-compliance*
- *U.S. FDA Regulatory System*
- *European Medicines Agency (EMA) Regulatory System*
- *Regulatory Affairs in Emerging Markets*
- *WHO Prequalification and Global Harmonization*

## Regulatory Affairs in Drug Development

- *Phases of Drug Development: Preclinical to Post-marketing*
- *Role of Regulatory Affairs in Each Phase*
- *Clinical Trials Regulations and Submission Requirements*
- *Investigational New Drug (IND) Application Process*

## Regulatory Affairs Documentation

- *Types of Regulatory Submissions (NDA, ANDA, BLA)*
- *Key Regulatory Documents (CTD, eCTD, Dossier Preparation)*
- *Importance of Dossier in Regulatory Submissions*
- *Case Study: Regulatory Documentation in Drug Approval*

## Common Technical Document (CTD) Format

- *Structure and Content of CTD*
- *Overview of eCTD (Electronic Common Technical Document)*
- *Module-wise Analysis of CTD (Quality, Non-clinical, Clinical)*
- *eCTD Submission Process and Software Tools*

## Regulatory Submissions for Generic Drugs

- *Overview of Abbreviated New Drug Application (ANDA)*
- *Requirements for Bioequivalence Studies*
- *Patent and Exclusivity Considerations in ANDA*
- *Case Study: Generic Drug Approval Process*

## Post-Approval Changes and Regulatory Maintenance

- *Post-marketing Surveillance and Pharmacovigilance*
- *Variations and Changes in Regulatory Submissions*
- *Risk Management Plans (RMP) and REMS*
- *Annual Reports and Regulatory Compliance Updates*

## Good Regulatory Practices and Quality Assurance

- ➥ *Good Regulatory Practice (GRP) and its Importance*
- ➥ *Regulatory Audits and Inspections*
- ➥ *Role of Quality Assurance in Regulatory Compliance*
- ➥ *Handling Regulatory Non-conformance*

## Case Studies in Regulatory Affairs

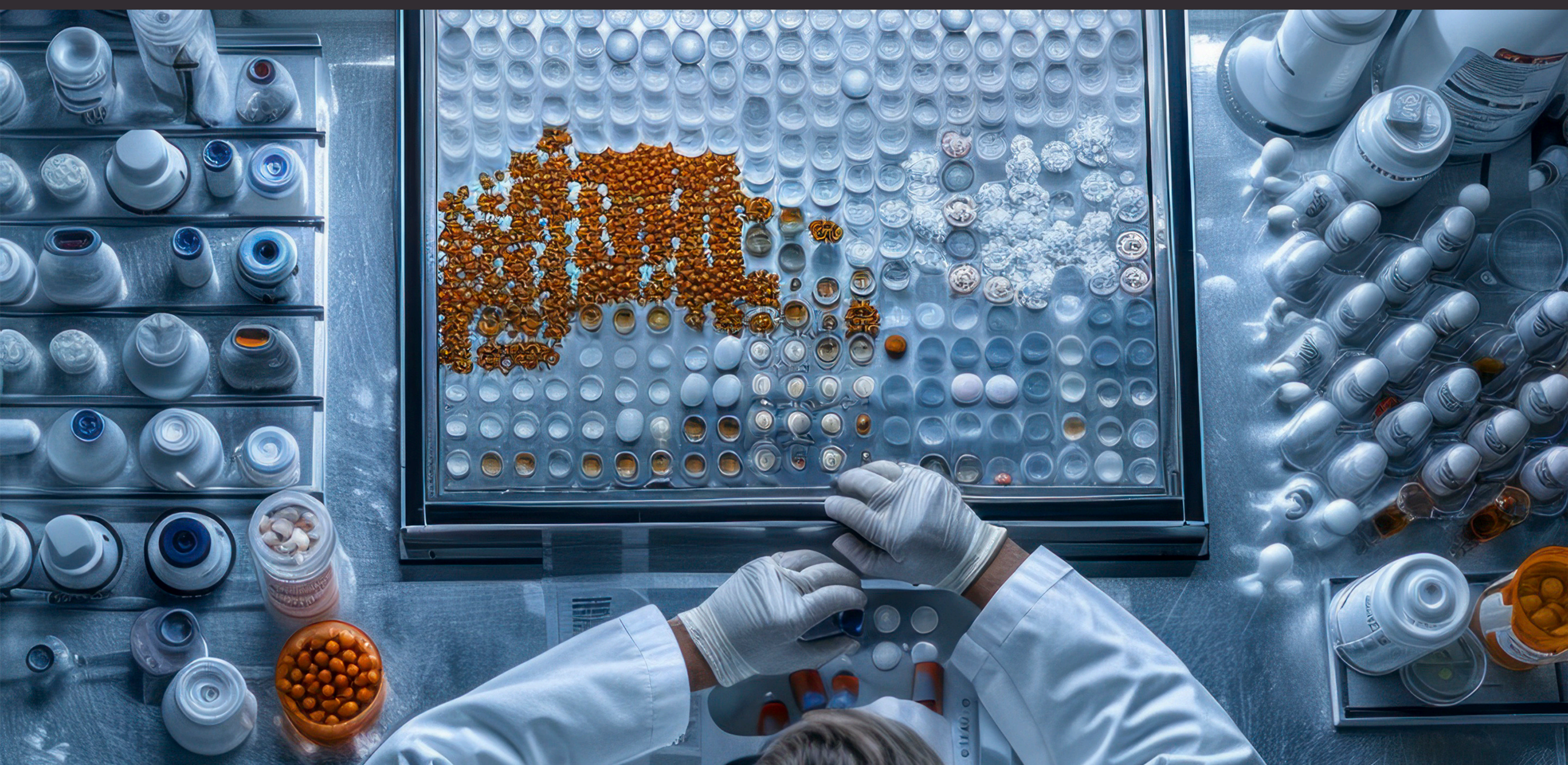
- ➥ *In-depth Case Studies on Successful and Failed Regulatory Submissions*
- ➥ *Lessons from Regulatory Failures (e.g., product recalls, compliance breaches)*
- ➥ *Impact of Globalization on Regulatory Practices*

## Career Paths in Regulatory Affairs

- ➥ *Overview of Career Opportunities in Regulatory Affairs*
- ➥ *Skills Required for a Career in Regulatory Affairs*

## Certification:

- *Certificate: A certificate will be given to all participants based on their performance in in-course assignments & quizzes*



**Date of Commencement:**
**JANUARY 18, 2026**

**Last Date of Registration:**
**JANUARY 4, 2026**

**Course Fees:**
**INR 4999 (after 75% CSR discount on 19999/- INR)**

**Classes:**
Saturday & Sunday Evening Classes

**Register Here**
https://rzp.io/rzp/regjan26

# Course Convener

## Dr. Ajit Singh

CEO and Founder, CliMed Research Solutions & Curio
Research Scientist for ICMR, Department of Medicine,
Kasturba Medical College & Hospital, MAHE

Dr. Ajit Singh, Founder, and chief Executive Officer at CliMed Research Solutions & Curio - India, a young entrepreneur & scientist, has completed his Ph.D. in Cardiology from the eminent Manipal Academy of Higher Education (MAHE), a leading organization in research and education in India. Recently, he was appointed as Research Scientist & RAIII for ICMR'' at the Department of Medicine, Kasturba Medical College, Manipal. He also serves as 'National Director for Research' at 'World Youth Heart Federation' (WYHF-India) & 'Principal Investigator for 'Manipal Heart Failure Registry (MHFR).' In July 2021, he was appointed as Vice president of the Medical Artificial Intelligence Wing at Indika AI, Mumbai.

He has published more than 40 papers in different streams of medicine, including Cardiology, Cardio-oncology, and Infectious Diseases. He is the investigator and site coordinator for many international clinical trials. Dr. Singh is an honorary reviewer in many reputed journals, including Oxford Group, BMJ Group, and The Springer Group of Journals. Dr. Singh has been appointed as Editor-in-chief for the Journal of Basic and Clinical Cardiovascular Research and an editorial board member for several medical journals. He has received several international research and travel grants from esteemed organizations, including the European Society of Cardiology, the Indian Council for Medical Research, DST-SERB, and the American College of Cardiology. He received the 'Young Achievers Award 2019' and 'The Young Scientist Award 2020' in Cardiology Research from reputed international organiztions. Dr. Singh has traveled to more than ten countries regarding his research presentations and invited lectures.