CURIO

CliMed™ Research Solutions

CERTIFIED ISO 9001:2015 COMPANY

SKILL DEVELOPEMENT PROGRAM

Executive Certificate Program in Medical Reviewing (EPMR)

a three-month value-added program for PharmDs and healthcare professionals with Job-ready Medical Reviewer skillset

Course Fee Waived upto 80% by CSR funds

₹ Fee: Only 1999 INR | **Mode: Online**

Limited Seats with Placement Assistance and Reading Materials

Faculty Members and experts from top-notch Pharma industry

About the Course

The **Medical Reviewer Certification Course** is a structured, industry-oriented program designed to train healthcare and life-science professionals in the critical evaluation of clinical, regulatory, safety, and scientific documents. The course focuses on developing **medical judgment, regulatory compliance thinking, and patient-safety–driven decision-making**, which are core competencies expected from medical reviewers globally. Through real-world examples, document review exercises, and AI-enabled workflows, participants gain hands-on exposure to reviewing clinical trials, pharmacovigilance reports, manuscripts, and promotional materials. This program bridges the gap between academic knowledge and industry expectations, preparing participants for roles in pharmaceutical companies, CROs, regulatory bodies, and medical publishing.

Course Objectives

Participants will be able to:

- *Understand the role and responsibilities of a Medical Reviewer*
- *Apply regulatory and ethical guidelines in document review*
- *Critically evaluate clinical efficacy and safety data*
- *Perform pharmacovigilance and risk–benefit assessments*
- *Review manuscripts and medical communications for accuracy and compliance*
- *Use AI tools responsibly to improve review efficiency & quality*

Who Should Attend

- **PharmD, BPharm & MPharm Graduates** – to enter or transition into medical affairs, pharmacovigilance, regulatory medical review, and clinical research roles.
- **MBBS / MD / Dental / Nursing & Other Healthcare Professionals / AYUSH Graduates** – to explore non-clinical, industry-facing careers while applying medical knowledge beyond bedside practice.
- **Life Sciences & Biomedical Graduates (MSc / PhD)** – to gain applied clinical and regulatory exposurerequired for pharma, CRO, and research organizations.
- **Clinical Research Professionals & Study Coordinators** – to upgrade from execution roles to decision-making and reviewer positions.
- **Pharmacovigilance & Drug Safety Professionals** – to strengthen causality assessment, signal review, and risk–benefit evaluation skills.
- **Medical Writers & Scientific Editors** – to move into medical reviewer, journal reviewer, and editorial board roles.
- **Clinical Pharmacists & Hospital Professionals** – to develop medication safety, clinical evaluation, and compliance-focused expertise.
- **Regulatory Affairs & Medical Affairs Executives** – to enhance medical judgment and regulatory interpretation skills.
- **Faculty Members & Researchers** – to improve peer-review capability, research evaluation, and publication ethics understanding

COURSE MODULES & FULL SYLLABUS

MODULE 1: Foundations of Medical Reviewing (3 Hours)

Introduction to Medical Reviewer Role

- *What is Medical Reviewing?*
- *Difference between:*
  - *Medical Reviewer vs Medical Writer*
  - *Medical Reviewer vs Safety Physician*
  - *Medical Reviewer vs Clinical Scientist*
- *Where Medical Reviewers work:*
  - *Pharma, CROs, Regulatory Agencies, Journals*
- *Ethical responsibility & patient safety perspective*

Regulatory & Ethical Framework

- *Overview of:*
  - *ICH guidelines*
  - *US FDA medical review role*
  - *EMA assessor process*
  - *CDSCO clinical oversight*
- *GCP, GVP, Declaration of Helsinki*
- *Ethics Committee & IRB expectations*

MODULE 2: Clinical Research & Data Understanding (3 Hours)

Clinical Trials for Medical Reviewers

- *Phases I–IV (reviewer lens)*
- *Endpoints, outcomes & clinical relevance*
- *Inclusion–exclusion criteria review*
- *Risk–benefit evaluation*

Statistics & Data Interpretation (Non-Statistician Friendly)

- *Basics of:*
  - *P-values, confidence intervals*
  - *Relative risk, odds ratio*
- *Tables, listings & figures (TLFs)*
- *Detecting data inconsistency & red flags*

MODULE 3: Document-Specific Medical Reviewing (3 Hours)

Reviewing Clinical Documents

- *Protocol review checklist*
- *Clinical Study Report (CSR) structure*
- *Investigator Brochure (IB) review*
- *Informed Consent Form (ICF) medical accuracy*

Pharmacovigilance & Safety Review

- *Individual Case Safety Reports (ICSRs)*
- *Causality assessment*
- *Signal detection basics*
- *Aggregate safety reports:*
  - *PSUR / PBRER*
- *Labeling & risk minimization*

MODULE 4: Medical Writing Review & Publication Ethics (3 Hours)

Manuscript & Evidence Review

- *Reviewing:*
  - *Original research*
  - *Systematic reviews*
  - *Meta-analyses*
- *Detecting:*
  - *Bias*
  - *Data manipulation*
  - *Over-interpretation*
- *Reviewer comments writing*

Promotional & Medical Communication Review

- *Medical–Legal–Regulatory (MLR) review*
- *Claims substantiation*
- *Off-label risk*
- *Fair balance & compliance*

MODULE 5: Applied Medical Reviewing & Industry Practice (3 Hours)

Medical Judgment & Decision-Making

- *What is "medical judgment"?*
- *Handling conflicting data*
- *Safety vs efficacy trade-offs*
- *Risk communication*

AI & Digital Tools for Medical Reviewers

- ***AI tools for:***
  - *Literature validation*
  - *Consistency checks*
  - *Signal identification*
- ***Responsible use of AI***
- ***Limitations & ethical boundaries***

MODULE 6: Career Readiness & Capstone (3 Hours)

Career Pathways & Industry Expectations

- *Entry-level & senior roles*
- *Medical reviewer job descriptions*
- *Skills recruiters look for*
- *Portfolio building (review samples)*

Capstone Project & Assessment

- *Live medical review of:*
  - *Literature validation*
  - *Consistency checks*
  - *Signal identification*

Who Should Attend

*Medical Reviewers are in high demand across **pharmaceutical companies, CROs, regulatory agencies, and medical publishing platforms** due to increasing regulatory scrutiny and complex clinical data. Global regulators such as the US FDA, EMA, and WHO employ medical reviewers for regulatory assessment and safety oversight.*

Leading pharmaceutical and biotech companies including Pfizer, Novartis, Roche, and AstraZeneca offer roles in medical affairs and safety review. In India, opportunities exist with CDSCO, multinational pharma companies, and CROs such as IQVIA, Parexel, and Syneos Health.

Roles include Medical Reviewer, Safety Reviewer, Clinical Scientist, and Regulatory Medical Assessor.

Assessment and Certification:

- Continuous assessment through assignments and practical reviews
- Final capstone medical review project
- **Certificate in Medical Reviewing (3 Months)** issued on successful completion

Course Details:

Course Fee:
₹1999 INR
(Including GST and other taxes)

CSR-Supported Benefit:
80% CSR Funding Discount
Actual Value of Course: ₹10,000 INR

Date of Commencement:
February 8, 2026

Last Date of Registration:
January 25, 2026

Registration Link:
https://rzp.io/rzp/medrev

Course Director

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.