iLearn CRI

PUNE · EST. 2024

EVIDENCE, TAUGHT WELL.

iLearn Clinical Research Institute

ICH-GCP aligned training · Wakad campus, Pune · Classroom & live online

01

Four safety platforms

Argus, ARISg, Veeva Vault Safety and ABcube — extended hands-on time.

02

Regulatory affairs *in depth*

CTD/eCTD, dossier compilation, labelling and lifecycle maintenance.

03

Capstone *and* internship

An extended supervised project on real anonymised safety data.

PG DIPLOMA · 6 MONTHS

Pharmacovigilance & Regulatory Affairs

The extended programme for candidates targeting the stronger end of the entry market. Twenty-four modules across six months take you from pharmacology fundamentals through full ICSR operations, aggregate reporting, signal detection and risk management, into regulatory submissions, quality systems and inspection readiness — closing with a supervised capstone and internship.

DURATION	MODE	MODULES	FEES
6 months	Offline / online	24 + capstone	₹76,700 incl. GST

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What is in this *prospectus*.

DURATION

6 months

Twenty-four weeks across six structured months, closing with a capstone and internship block.

MODULES

24 + capstone

Including dedicated modules on AI in pharmacovigilance and in regulatory affairs.

MODE

Classroom or live online

Two batches per intake, same curriculum and same placement support.

FROM THE FACULTY COUNCIL

Why the longer programme looks the way it *does*.

Pharmacovigilance is the one function in pharmaceuticals that never switches off. A medicine's safety profile is not settled at approval — it is rebuilt continuously, case by case, for as long as the product is on the market. That obligation is written into regulation in every country that licenses medicines, which is why demand for trained safety and regulatory professionals holds steady through cycles that move every other part of the industry.

This six-month diploma exists because three months is enough to make someone employable, but not enough to make them fast. The additional time goes into the things that separate a competent associate from a valuable one: extended hands-on hours across four safety databases rather than an introduction to two, regulatory affairs taught as a discipline rather than a survey, and a supervised capstone with an internship block so you arrive at your first interview with work you can actually discuss.

We have also treated artificial intelligence as a working tool with regulatory limits, rather than either a threat or a slogan. Graduates should be able to use these systems and explain to an auditor why the output can be trusted.

Faculty Council
ILEARN CLINICAL RESEARCH INSTITUTE, WAKAD

50+	₹4.2L	100%	50+
ALUMNI ACROSS PHARMA & CRO	AVERAGE STARTING CTC	PLACEMENT ASSISTANCE SUPPORT	HIRING PARTNERS IN PUNE

Three-month certificate, or six-month diploma?

Both programmes start in the same place and are taught by the same faculty. The three-month certificate is built for speed to first job and covers seventeen modules. This six-month diploma adds seven further modules — biostatistics for safety, clinical trial safety and SUSAR reporting, literature surveillance, risk management planning, labelling and lifecycle maintenance, and quality systems with safety data exchange agreements — alongside two additional safety platforms, roughly double the supervised platform hours, and a capstone with an internship block. Candidates who want the fastest route into a case-processing role usually take the certificate; those targeting aggregate reporting, signal or regulatory tracks more often take the diploma.

THE OPPORTUNITY

Drug safety is the most *reliable* way into pharma.

Every medicine sold globally must be monitored for safety across its entire lifecycle, from first-in-human dosing to decades after launch. That obligation is written into regulation, which makes the demand structural rather than cyclical.

Why the demand is structural

- Safety reporting is a licensing condition, not a discretionary activity
- Indian pharmaceutical exports continue to expand into regulated markets
- Global regulators keep tightening expedited reporting timelines
- Large CROs are steadily expanding safety operations in Pune
- Work is process-driven, so skills compound quickly and transfer between employers

Why Pune concentrates it

The Hinjewadi–Wakad–Bhosari corridor hosts safety and regulatory operations for Cipla, Lupin, Mylan, Sun Pharma, Glenmark and Wockhardt, alongside CROs including Syngene, Veeda Clinical Research, Lambda Therapeutic Research and Reliance Life Sciences.

A trained professional in Pune is typically hired faster and has more lateral movement available than in almost any other entry-level pharmaceutical role.

HIRING LANDSCAPE

Employers across Pune's pharma corridor.

Cipla · Lupin · Mylan · Sun Pharma · Glenmark · Wockhardt · Syngene · Veeda · Lambda Therapeutic · Reliance Life Sciences · Serum Institute · IQVIA

A trained pharmacovigilance professional is hired faster, and moves laterally more easily, than almost any other entry-level role in the industry.

WHY WE BUILT THIS PROGRAMME

THE WORK ITSELF

Four activities make up the *job*.

Pharmacovigilance is widely misunderstood. It is not lab-based and it does not require a doctorate. The day-to-day work concentrates into four recurring activities, and this programme trains each of them to a working standard rather than an introductory one.

01

Individual Case Safety Reports

Every adverse event reported about a drug — from a trial, a hospital, a healthcare professional or a patient — is processed into a standardised report and submitted to regulators inside tight statutory timelines. You receive the case, code the medical terms, write the clinical narrative, assess causality and submit electronically. This is where almost every PV career begins.

INTAKE & TRIAGE · MEDDRA · NARRATIVE · E2B(R3)

02

Aggregate safety reporting

Periodically, all cases for a product are consolidated into detailed benefit-risk reviews submitted to regulators. As you gain seniority you move from contributing data to authoring and reviewing these documents — a step that materially changes what you are paid.

PSUR · PBRER · DSUR · PADER

03

Signal detection

When a new adverse event pattern emerges, safety scientists investigate whether it represents a real risk requiring a label change or, occasionally, withdrawal. This is the most analytical part of the discipline and the most highly compensated.

DISPROPORTIONALITY · DATA MINING · RMP

04

Regulatory submissions

Safety data has to reach regulators in the right structure, through the right pathway, on the right clock. Regulatory affairs professionals compile and maintain the dossier, manage the submission lifecycle and track changing requirements across markets.

CTD / ECTD · CDSCO · USFDA · EMA

WHO IT IS FOR

Entry routes, and what you leave *able to do*.

Who this programme is for

- B.Pharm and M.Pharm graduates seeking a structured first role in pharma
- B.Sc / M.Sc in life sciences, biotechnology, microbiology or biochemistry
- BDS, BHMS, BAMS and BPT graduates
- Working professionals in medical writing, clinical research or QA adding PV and RA
- Candidates returning to work who want a process-driven, remote-friendly domain

Who it is not for

This is a vocational programme aimed at employment in drug safety and regulatory operations. It is not the right choice if you are looking for a wet-lab or bench research career, or if you cannot commit to the full three-month schedule including the capstone.

What you will be able to do

- Process an ICSR end to end and defend every judgement in it
- Code accurately in MedDRA and WHO-DD across the full hierarchy
- Work confidently inside Argus, ArisGlobal and ABcube
- Draft and review PSUR, PBRER, DSUR and PADER reports
- Compile a CTD/eCTD dossier and map submission routes

LEARNING OUTCOMES

On completion you will understand:

01 The importance of drug safety monitoring and how the discipline developed

02 The national and international pharmacovigilance landscape

03 Dictionaries, coding conventions and terminologies used in PV

04 Detection of new adverse drug reactions and their assessment

05 International standards for the classification of diseases and drugs

06 ADR reporting systems and risk communication

07 Generating safety data across pre-clinical, clinical and post-approval phases

08 Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation

09 Good Pharmacovigilance Practices and regulatory requirements

10 Pharmacovigilance project management

11 Case narratives of adverse events and their quality assessment

12 Preparing for pharmacovigilance audits and regulatory inspections

CURRICULUM · MONTHS ONE AND TWO

Foundations and core *case processing*.

The first two months establish the science, vocabulary and assessment logic the rest of the programme depends on, then move directly into processing supervised cases end to end.

MONTH 01 Scientific & regulatory foundation

01 Pharmacology & Drug Development

Basics of pharmacology, pharmacodynamics and pharmacokinetics, routes of administration, dosage forms, and the drug development pipeline.

02 The Clinical Research Industry & Trial Phases

Structure of the industry, sponsor and CRO roles, phases of clinical trials, and where safety obligations attach at each stage.

03 Introduction to Pharmacovigilance & Drug Safety

History and evolution of drug safety surveillance, the WHO-UMC framework, key terminology, and stakeholders across the safety ecosystem.

04 Pharmacoepidemiology & Biostatistics for Drug Safety

Epidemiological and statistical principles used in PV practice and research, study designs, measures of association and their interpretation.

MONTH 02 ADR science & ICSR operations

05 Adverse Drug Reactions & Safety Reports

AE versus ADR, classification of ADRs, SAE reporting, side effects and medication errors.

06 Seriousness, Expectedness & Causality Assessment

Expectedness assessment, causality methods, the Naranjo algorithm and Hill's criteria applied to worked cases.

07 ICSR Processing & Case Management

Full ICSR lifecycle — intake, triage and prioritisation, data entry, narrative writing, quality review, reconciliation and E2B(R3) submission.

08 Drug Dictionaries & Coding

MedDRA hierarchy and coding conventions, WHO Drug Dictionary, MedWatch, and version migration scenarios with practical exercises.

MONTH	FOCUS AND MILESTONE
01	Scientific foundation — pharmacology, trial phases, PV principles, biostatistics
02	ADR science and full ICSR processing; first assessed case assignment
03	Extended platform training across four safety databases; aggregate reporting
04	Literature surveillance, signal detection, risk management and AI in safety
05	Regulatory affairs — submissions, dossiers, labelling and regulatory intelligence
06	Quality, audits and inspections; capstone, internship and placement preparation

CURRICULUM · MONTHS THREE AND FOUR

Platforms, surveillance and *signal*.

The middle of the programme is deliberately hands-on. Extended supervised hours across four safety databases sit alongside aggregate reporting, literature surveillance, signal detection and risk management.

MONTH 03 Safety platforms & aggregate reporting

09 Argus Safety — Extended Hands-on

Interface walkthrough, case entry, workflow management and case assignment, querying, user roles and access management.

10 ARISg, Veeva Vault Safety & ABcube

Case processing across mid-market and modern platforms, comparative analysis of the four systems, and database migration projects.

11 Clinical Trial Safety, SAE & SUSAR Reporting

Safety reporting inside clinical trials, SAE and SUSAR management, blinding and unblinding, and expedited reporting timelines.

12 Aggregate Safety Reports

DSUR, PADER, PBRER and PSUR — data sources, structure, authoring conventions, review cycles and submission obligations.

MONTH 04 Surveillance, signal & risk management

13 Literature Surveillance & Case Retrieval

Systematic literature search strategies, screening and duplicate detection, local literature obligations and documentation standards.

14 Signal Detection & Data Mining

Data sources and tools, disproportionality analysis (PRR, ROR, EBGM), data-mining methodologies and signal validation workflows.

15 Risk Management Plans & Risk Minimisation

RMP structure, safety specifications, pharmacovigilance plans, additional risk minimisation measures and effectiveness evaluation.

16 AI & Automation in Pharmacovigilance

Machine learning for intake and triage, NLP literature screening and duplicate detection, AI-assisted coding and narrative drafting, and the validation and GxP expectations governing AI in a regulated safety system.

Why the extra platform hours matter

Most candidates arriving at interview have seen a safety database in a demonstration. Far fewer have processed cases through one under supervision until the workflow is second nature. This programme allocates roughly double the supervised platform time of the three-month certificate and spreads it across four systems, so that the question "which database have you worked in?" has a substantive answer whichever stack the employer runs.

CURRICULUM · MONTHS FIVE AND SIX

Regulatory affairs, quality and *capstone*.

The final third converts safety knowledge into regulatory capability, then into audit-ready practice, closing with an assessed capstone, an internship block and interview preparation.

MONTH 05 Regulatory affairs & submissions

17 Global Regulatory Framework & Agencies

CDSCO India, USFDA, EMA Europe, MHRA UK and TGA Australia — obligations, timelines and medicines risk communication.

18 Regulatory Submissions — CTD, eCTD & Dossiers

CTD and eCTD architecture, module-by-module dossier compilation, submission pathways and publishing conventions.

19 Labelling, Safety Communication & Lifecycle Maintenance

Company core data sheets, SmPC, USPI and patient information, safety label changes, variations and post-approval commitments.

20 AI in Regulatory Affairs & Regulatory Intelligence

AI-assisted dossier authoring and document management, automated regulatory intelligence and change monitoring, structured product data and IDMP, and evolving agency positions on AI.

MONTH 06 Quality, compliance & capstone

21 PvPI, Materiovigilance & Herbal Pharmacovigilance

Indian Pharmacopoeia Commission services and ADR reporting in India, the Materiovigilance Programme, device vigilance abroad, and PV of herbal medicines.

22 GVP, Audits & Regulatory Inspections

Good Pharmacovigilance Practices, PV System Master File, inspection coordination and readiness, and common audit findings.

23 Quality Management, SDEA & PV Project Management

Deviations and CAPA, safety data exchange agreements and vendor oversight, metrics and compliance tracking, and PV project management.

24 Industry Case Studies, Capstone & Internship

Real anonymised scenarios from partner CROs, an assessed capstone project, and a supervised internship block.

+ Bonus: Resume Building & Interview Preparation

PV and RA specific resume, LinkedIn optimisation and mock interviews simulating hiring rounds at pharma and CRO employers.

PLATFORMS & STANDARDS YOU WILL WORK WITH

Oracle Argus Safety · ArisGlobal ARISg · Veeva Vault Safety · ABcube · MedDRA · WHO-DD · MedWatch · E2B(R3) · CTD / eCTD · IDMP · GVP · ICH E2A–E2F · Schedule Y · RMP · AI/ML signal detection · NLP case intake

LEARNING EXPERIENCE

Taught by practitioners, assessed like the *job*.

Faculty

Modules are taught by practising pharmacovigilance leads, senior ICSR processors, regulatory affairs specialists and CRO project managers drawn from Pune's pharma corridor — professionals who close cases and file submissions every working day, not academic instructors.

Placement assistance

Structured preparation in the final month: resume review against PV and RA hiring criteria, mock interview rounds with hiring managers, and direct introductions to our 50+ pharma and CRO partners across Pune. Every participant receives 100% placement assistance support.

Programme deliverables

- Comprehensive study material in hard copy for every module
- Module-wise assignments for continuous evaluation and guidance
- Interactive live sessions across all key areas of the programme
- Weekend live online classes for part-time participants
- A doubt-clearing session scheduled before the examination
- All learning and training delivered in English

Assessment & certification

Participants submit a completed assignment after each module and sit an online examination at the end of the programme, with structured feedback collected at the close of every module.

On successful completion, the **Certificate in Pharmacovigilance & Regulatory Affairs** is awarded by iLearn Clinical Research Institute.

Eligibility

- B.Pharm or M.Pharm graduates
- B.Sc / M.Sc in life sciences, biotechnology, microbiology or biochemistry
- BDS, BHMS, BAMS and BPT graduates
- Working professionals seeking a transition into pharma

Batch modes

Two batches run per intake — classroom at the Wakad campus, and live instructor-led online from anywhere in India. Both cover the same curriculum and placement support.

Discipline & conduct

Participants are expected to maintain professional conduct through classes, assessments and examinations, and to follow faculty instruction. Drug safety is a regulated discipline in which documentation habits and accountability matter from day one, and the programme is run accordingly.

Capstone project

The programme closes with an assessed capstone drawn from real anonymised scenarios, giving you a piece of defensible work to discuss in interviews.

CAREER OUTCOMES

Roles our graduates step *into*.

Salary bands below reflect entry and early-career positions across Pune pharma companies and CROs. The additional platform hours, capstone and internship in this programme are aimed at the upper end of these bands and at the aggregate reporting, signal and regulatory tracks rather than case processing alone.

ROLE	AVG. CTC
Pharmacovigilance Associate	₹3.6-4.2 LPA
Drug Safety Associate	₹3.8-4.5 LPA
ICSR Case Processor	₹3.5-4.0 LPA
PV Quality Reviewer	₹4.0-5.5 LPA
Aggregate Report Writer	₹4.5-6.0 LPA
Signal Detection Analyst	₹5.0-7.5 LPA

50+
ALUMNI ACROSS PHARMA & CRO

₹4.2L
AVERAGE STARTING CTC

100%
PLACEMENT ASSISTANCE SUPPORT

50+
HIRING PARTNERS IN PUNE

1
Talk to admissions
A short conversation about your degree, experience and the right intake batch.

2
Submit your application
Application form with academic documents and identification.

3
Confirm your seat
Fee payment in full or on EMI, and choice of classroom or live online batch.

4
Begin
Study material and batch schedule are issued ahead of day one.

FEES & ADMISSIONS

How to *join* the next batch.

PROGRAMME FEES

₹76,700 inclusive of GST

Course fee ₹65,000 · GST @ 18% ₹11,700

EMI options available

Early-batch discounts apply

Seats limited per batch for platform access

Why choose the six-month diploma over the three-month certificate?

The diploma adds seven modules, two further safety platforms, substantially more supervised platform time, and a capstone with an internship block. It suits candidates targeting aggregate reporting, signal detection or regulatory tracks rather than the fastest possible entry into case processing.

What is the difference between Argus and ARISg?

Both are drug safety databases. Argus, from Oracle, holds the largest global share and dominates Indian pharma; ARISg from ArisGlobal is widely used by mid-sized companies. The course covers both, plus ABcube, so you are not tied to one employer's technology stack.

Is MedDRA coding covered?

Yes. MedDRA is central to ICSR processing. The course covers the full hierarchy, coding conventions and version migration scenarios with practical exercises, alongside WHO-DD.

Can I do this while working?

Yes. The live online batch runs on weekends, and a doubt-clearing session is scheduled before the examination. Both batches follow the same curriculum and placement support.

How is pharmacovigilance different from a CRA role?

Pharmacovigilance covers drug safety across a product's lifecycle and is largely office-based with structured workflows. A CRA monitors clinical trial sites and travels regularly. Both are valid entry routes; the choice depends on the working pattern you want.

Will AI reduce the number of entry-level PV jobs?

AI is changing how cases are triaged and drafted rather than removing the regulated accountability for the judgement in them. The programme teaches these tools alongside the validation and GxP expectations that govern their use, which is what employers are currently hiring for.

Apply for the next batch.

Batches start every quarter at our Wakad campus, with direct access from Wakad, Hinjewadi, Baner, PCMC and Kothrud. Early applications receive priority for placement preparation and corporate partner introductions.

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Fees are inclusive of 18% GST and are current at the time of print. Batch schedules, fees and certification details may be revised. Placement assistance does not constitute a guarantee of employment. Please confirm current intake details with the admissions team.