iLearn CRI

PUNE · EST. 2024

EVIDENCE, TAUGHT WELL.

iLearn Clinical Research Institute

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

01

Hands-on safety databases

Argus, ArisGlobal and ABcube — the platforms your first employer runs.

02

PV *and* regulatory, together

CTD/eCTD and dossier compilation across CDSCO, USFDA and EMA pathways.

03

AI-ready curriculum

Machine learning and NLP in safety and submissions, within GxP limits.

CERTIFICATE PROGRAM · 3 MONTHS

Pharmacovigilance & Regulatory Affairs

A practitioner-built certificate covering the full drug-safety lifecycle — ICSR processing, MedDRA coding, signal detection and aggregate reporting — paired with the regulatory competencies that pharma actually hires for: CDSCO, USFDA and EMA pathways, CTD/eCTD and dossier compilation.

DURATION	MODE	MODULES	FEES
3 months	Offline / online	17 + capstone	₹47,200 incl. GST

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CONTENTS

What is in this *prospectus*.

DURATION

3 months

Twelve weeks across three structured months, closing with an assessed capstone.

MODULES

17 + capstone

Including dedicated modules on AI in pharmacovigilance and regulatory affairs.

MODE

Classroom or live online

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

FROM THE FACULTY COUNCIL

Why this 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.

We built this certificate around what that work actually looks like on a Tuesday morning: a case that arrived overnight, a coding decision that has to be defensible, a submission clock that started without asking. The modules follow the sequence a new associate is trained in on the job, and the platforms are the ones already running in Pune's pharma corridor.

We have also done something most syllabi in this field have not yet caught up with — 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

Graduates should be able to use these systems and explain to an auditor why the output can be trusted.

ON TEACHING AI INSIDE A REGULATED DISCIPLINE

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

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.

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 · MONTH ONE

Foundations of *drug safety*.

The first month establishes the science, vocabulary and assessment logic the rest of the programme depends on. Nothing here is optional background — every judgement made in a live case traces back to it.

MONTH 01

Foundations of drug safety

01 Pharmacology, Clinical Trials & Pharmacoepidemiology

Basics of pharmacology, the clinical research industry, phases of clinical trials, PV methods, clinical application of pharmacoepidemiology.

02 Adverse Drug Reactions & Safety Reports

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

03 Methodologies & Benefit Assessment

Passive reporting and case series, active surveillance, targeted clinical investigations, descriptive studies.

04 Seriousness, Expectedness & Causality

Expectedness assessment, causality assessment, the Naranjo algorithm and Hill's criteria.

WEEKS	FOCUS
1-2	Pharmacology, drug development and the clinical research industry
2-3	Adverse events, adverse drug reactions and classification
3-4	Surveillance methodologies and benefit assessment
4	Seriousness, expectedness and causality — first assessed assignment

Why the foundation month is not optional

It is tempting to treat month one as background reading and rush to the software. In practice, every contested judgement in a live case — whether an event is serious, whether it was expected, whether the drug plausibly caused it — resolves back to the material taught here. Associates who skip it can operate a database but cannot defend their decisions in a quality review, which is precisely what limits how far they progress.

CURRICULUM · MONTH TWO

Core operations, platforms and *AI*.

The second month is deliberately hands-on. You process supervised cases on the same safety databases used across Pune's pharma corridor, and learn where automation genuinely helps.

MONTH 02 Core PV operations & platforms

05 ICSR Processing & Case Management

Case intake, triage and prioritisation, data entry, narrative writing, quality review, reconciliation and submission.

06 Drug Dictionaries & Coding

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

07 Safety Database Training

Hands-on Argus, ArisGlobal and ABcube — case entry, workflow management, querying and periodic report generation.

08 Aggregate Safety Reports

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

09 Signal Detection & Data Mining

Data sources and tools for signal detection, statistical techniques, data-mining methodologies, risk identification.

10 AI & Automation in Pharmacovigilance

Machine learning for case intake and triage, NLP-based literature screening and duplicate detection, AI-assisted MedDRA coding and narrative drafting, ML approaches to signal detection, and the validation and GxP expectations that govern AI in a regulated safety system.

11 Materiovigilance Across the Globe

Materiovigilance Programme of India, US FDA device vigilance, MHRA manufacturer guidance, EU and non-EU practice.

WEEKS	FOCUS
5	ICSR lifecycle, intake and triage on supervised cases
6	MedDRA and WHO-DD coding practice
6–7	Argus, ArisGlobal and ABcube hands-on case processing
7	Aggregate report structure and authoring conventions
8	Signal detection, data mining and AI-assisted workflows

CURRICULUM · MONTH THREE

Regulatory affairs, compliance and *capstone*.

The final month converts safety knowledge into regulatory capability — submission pathways, dossier work and inspection readiness — closing with an assessed capstone and interview preparation.

MONTH 03

Regulatory affairs, compliance & capstone

12 Global Regulatory Framework & Risk Communication

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

13 Regulatory Affairs Essentials

CTD and eCTD architecture, dossier compilation, submission pathways across CDSCO, USFDA and EMA, lifecycle maintenance.

14 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 CDSCO, USFDA and EMA positions on AI across the product lifecycle.

15 Pharmacovigilance Programme of India (PvPI)

IPC services, ADR reporting in India, PV System Master File and capacity building, recent developments.

16 Compliance, Audits & Inspections

Good Pharmacovigilance Practices, NMRA inspection guidelines, audit readiness and common findings. Includes PV of herbal medicines.

17 Industry Case Studies & Capstone Project

Real-world scenarios drawn from partner CROs, followed by an assessed capstone project.

+ Bonus: Resume Building & Interview Preparation

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

WEEKS	FOCUS
9	Global regulatory framework and risk communication
10	CTD/eCTD, dossier compilation and regulatory intelligence
11	PvPI, compliance, audits and inspection readiness
12	Capstone project, examination and placement preparation

PLATFORMS & STANDARDS YOU WILL WORK WITH

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

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. Progression in this field is unusually structured — process-driven work makes competence visible quickly.

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

₹47,200 inclusive of GST

Course fee ₹40,000 · GST @ 18% ₹7,200

EMI options available

Early-batch discounts apply

Seats limited per batch for platform access

Is this worth doing after B.Pharm?

Pharmacovigilance is among the highest-demand entry routes into pharma for B.Pharm graduates in India, and Pune concentrates the hiring. Adding regulatory affairs widens the range of roles you can apply for from the same certificate.

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.