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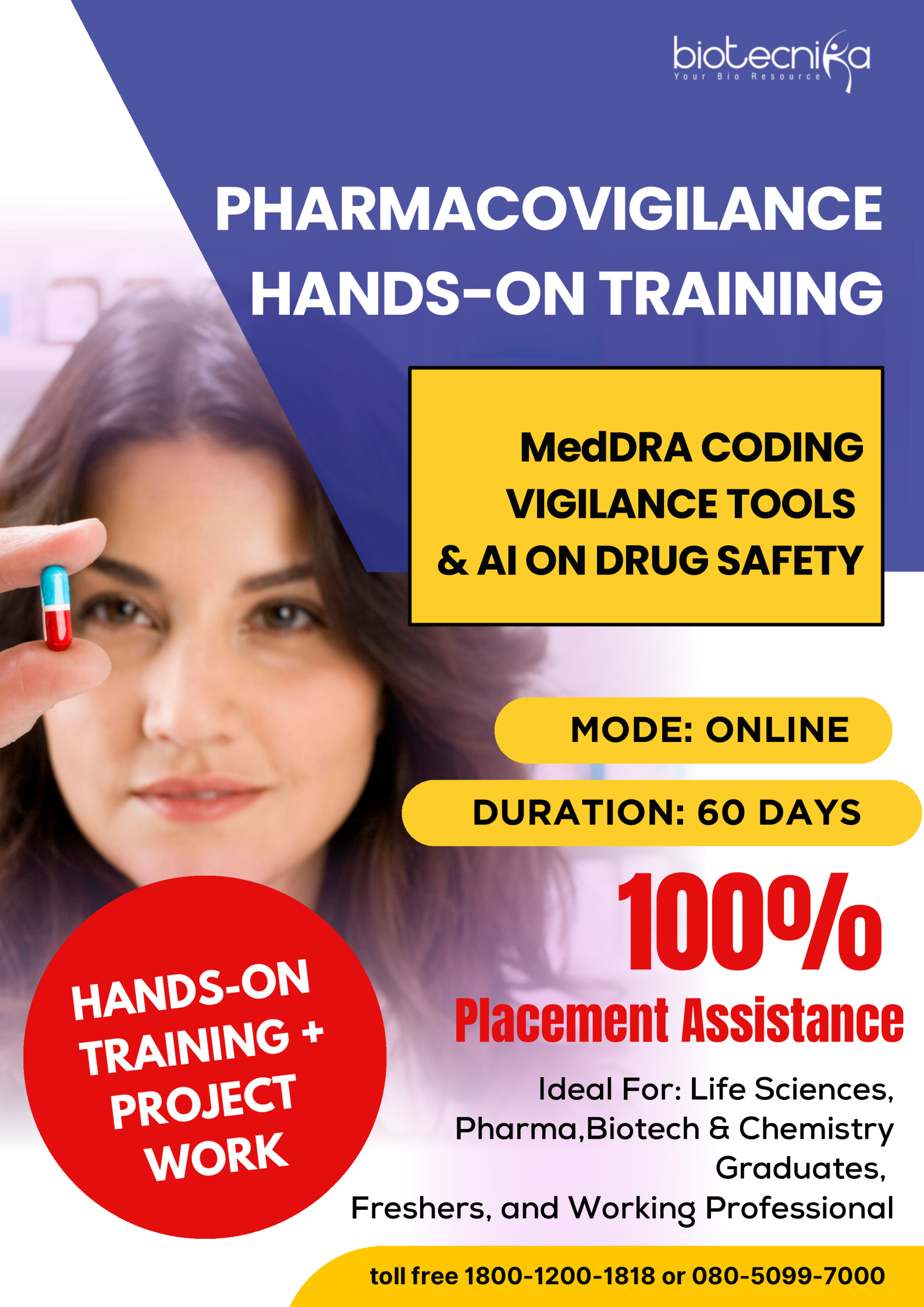
PHARMACOVIGILANCE HANDS-ON TRAINING



MedDRA CODING
VIGILANCE TOOLS
& AI ON DRUG SAFETY

MODE: ONLINE

DURATION: 60 DAYS

HANDS-ON TRAINING + PROJECT WORK

100%
Placement Assistance

Ideal For: Life Sciences, Pharma,Biotech & Chemistry Graduates, Freshers, and Working Professional

toll free 1800-1200-1818 or 080-5099-7000

WHY CHOOSE THIS TRAINING?

The Pharmacovigilance Hands-on Training Program offers a career-focused, skill-based curriculum that prepares you for success in one of the most in-demand fields of the life sciences industry.

What makes this program unique

- Learn essential pharmacovigilance concepts with hands-on training in ICSR processing, MedDRA coding, and narrative writing
- Gain exposure to drug safety workflows, regulatory guidelines, and case management systems
- Work on real-world projects designed using freely available datasets, open-source tools, and simulated environments
- Receive 100% placement assistance, including resume building, LinkedIn optimization, and mock interviews
- Get mentored by industry experts and be certified at the end of the program
- Access recorded sessions, assignments, quizzes, and feedback support

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www.Biotecnika.org

Eligibility

This program is suitable for:

- Students and graduates in Life Sciences, Biotechnology, Pharmacy, and related fields
- Freshers interested in a career in pharmacovigilance or clinical research
- Professionals in the healthcare domain looking to transition into drug safety roles
- Individuals preparing for roles in CROs, pharma companies, and regulatory departments

Career Path After This Program

- Pharmacovigilance is a growing industry that offers multiple career opportunities across different sectors:

Industry Sectors:

- Pharmaceutical & Biotech Companies
- Contract Research Organizations (CROs)
- Hospitals & Clinical Trial Units
- Health IT & Drug Monitoring Systems
- Regulatory Affairs Departments

Career Roles You Can Target:

- Drug Safety Associate
- Pharmacovigilance Officer
- ICSR Processor
- MedDRA Coder
- Safety Data Analyst

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What You'll Learn – Detailed Curriculum

Weeks 1: Foundations of Pharmacovigilance

- Day 1: Introduction to Pharmacovigilance & its Importance
- Day 2: Drug Development Lifecycle & PV's Role
- Day 3: Types of Adverse Events (AE) and ADRs
- Day 4: Classification: Serious vs Non-serious Events
- Day 5: AE Reporting Timelines & Workflow
- Day 6: Glossary Exercise + Assignment
- Day 7: Weekly Quiz + Live Q&A

Weeks 2 : Regulatory Guidelines & Case Processing

- Day 8: ICH Guidelines: E2A to E2F Overview
- Day 9: Global Regulatory Authorities: USFDA, EMA, CDSCO, WHO-UMC
- Day 10: PV Case Processing Lifecycle
- Day 11: CIOMS & MedWatch Forms
- Day 12: Narrative Writing: Structure + Sample
- Day 13: SOP Drafting for AE Reporting
- Day 14: Weekly Quiz + LIVE Review

Weeks 3: MedDRA & Causality Assessment

- Day 15: MedDRA Terminology: SOC, PT, LLT
- Day 16: Hands-on MedDRA Browser Practice
- Day 17: WHO Drug Dictionary Overview
- Day 18: Causality Assessment: Naranjo Scale
- Day 19: Coding Practice with Fictional Cases
- Day 20: Writing Integrated Narratives
- Day 21: Weekly Quiz + LIVE Discussion

Weeks 4 : ICSR Compilation & Risk Management

- Day 22: ICSR Components and Structure
- Day 23: Data Entry Simulation (ICSR Fields)
- Day 24: Compilation of ICSRs
- Day 25: Introduction to Risk Management Plans (RMPs)
- Day 26: Spontaneous vs Solicited Reporting
- Day 27: Case Processing Workflow Simulation
- Day 28: Vaccine Pharmacovigilance
- Day 29: Weekly Quiz + Peer Feedback

Weeks 5: Software Tools in PV

- Day 30: WHO VigiFlow Walkthrough
- Day 31: OpenClinica Data Management Basics + Demo
- Day 32: Argus Safety: Interface Overview + Demo
- Day 33: ArisG Concepts & User Flow + Demo
- Day 34: Introduction to SAS in Pharmacovigilance
- Day 35: Mock Case Entry + SOP Integration
- Day 36: Weekly Quiz + LIVE Tools Recap

Weeks 6 : Signal Detection & Workflow Design

- Day 37: Introduction to Signal Detection: PRR, ROR
- Day 38: Dummy Data Analysis using Excel
- Day 39: Case to Report Workflow Design
- Day 40: SOP Development: Safety Unit Protocols
- Day 41: LIVE Weekly Review + Readiness Assessment

Weeks 7: Vigilance Tools & AI In Pharmacovigilance

- Day 42: FDA FAERS – Identifying and Analyzing Real-World Adverse Drug Event Patterns(Live DEMO)
- Day 43: EMA EudraVigilance – Monitoring Drug Safety Trends(Live DEMO)
- Dy 44: VigiAccess – Global Safety Signal Exploration Through WHO Safety Reports(Live DEMO)
- Day 45: Future of Pharmacovigilance: AI in Drug Safety Systems
- Day 46: Innovative Pharmacovigilance Practices Using AI-Based Tools
- Final Assessment

Weeks 8 : Project Work & Career Preparation

- Day 47: Project Topic Orientation + Mentor Q&A
- Day 48:LinkedIn Optimization & Career RoadMap: Scope, Qualifications, Job roles,
- Salary Trends & Skills required"
- Day 49-50: Project Briefing + Literature Review (Dataset Work / ICSR Compilation / SOP Draft)+ Report Writing
- Day 51: Resume Building + Career Counseling Session
- Day 52-55: Mid-Project Review by Mentor
- Day 56: Final Compilation + Submission
- Day 57-60: Project Presentation (Live) + Mock Interview + Interview Skills guidance

Tools You'll Learn

Tool	Purpose	Access Type
MedDRA Browser	ADR Coding	Free
WHO VigiFlow	Case Reporting (for demo use)	Public Demo
OpenClinica	Clinical Data Entry	Open Source
Argus Safety	Case Management System	Video Walkthroughs / Simulations
ArisG	Adverse Event Reporting	Public Demos / Conceptual Overview
Excel / R	Signal Detection & Data Analysis	Free/Open Source

Important Note:

Due to licensing restrictions, access to commercial tools like Argus and ArisG may not be available. However, we ensure all learning and projects are fully executable using:

- Open-source alternatives
- Public demo versions
- Simulations and video-based walkthroughs

Project Topics

These projects are designed to provide real-world exposure using free tools:

Project Work: 1 Month Duration

Topics

1. Systematic Review of Case Reports on Rare ADRs from PubMed/Case Reports Journals
2. Pick few rare MedDRA PT – Find which drugs most report it in VigiAccess
3. Overview of Clinical Trial Terminations Due to Safety Issues
4. ICSR Compilation with Dummy Data for Pharmacovigilance Training
5. Off-Label Drug Safety Monitoring Using MedDRA

Project Topics

These projects are designed to provide real-world exposure using free tools:

Project Work: 2 Month Duration

Topics

1. Analysis of Drug Withdrawals in the Last Decade Using WHO/FDA Alerts / Recent Drug Withdrawals
2. Pharmacovigilance (PV) Analysis of Adverse Events in a Clinical Trial
3. Polypharmacy Adverse Event (AE) Risk Stratification Using MedDRA
4. Disproportionality Analysis of ADRs Using FAERS
5. Signal and Trend Analysis of Adverse Drug Reactions Using VigiAccess
6. Safety Monitoring of Drugs Used in Special Populations (Pregnancy / Elderly / Pediatrics)
7. Comparative Safety Analysis of Drugs Within the Same Class
8. Serious vs Non-Serious ADR Patterns and Outcomes Analysis

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What You Receive

- 60 Days of Full Training with Project Work
- One-on-One Mentoring and Peer Feedback
- Resume and LinkedIn Optimization
- Mock Interviews with Expert Feedback
- Experience Letter
- 100% Placement Assistance
- Certification Ceremony & Career Counseling

Enroll Now & Jumpstart Your PV Career

Whether you're starting out or planning a career switch, this program is your stepping stone to success in pharmacovigilance.

Seats are limited. Enroll today and unlock your career potential in drug safety and regulatory affairs.

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Course Instructors

Bhanu Melvin

Scientist & Trainer | Clinical Data Management, Pharmacovigilance & Regulatory Affairs | Biotecnika

With a solid academic foundation in Pharmacy and over a decade of versatile experience spanning academia, healthcare, regulatory affairs, and corporate training, Mrs. Melvin brings a holistic and agile approach to professional development and organizational excellence.

She has successfully trained 1,500+ learners — from academic aspirants to seasoned professionals — across critical domains, including:

- Clinical Research
- Pharmacovigilance (PV)
- Clinical Data Management (CDM)
- Regulatory Affairs (RA)
- Clinical SAS Programming

She also holds globally recognized certifications in:

- Pharmacovigilance
- Lean Six Sigma Black Belt
- Clinical Research
- Clinical SAS Programming
- ISO 9001:2015 Lead Auditor

Her multidisciplinary expertise enables her to seamlessly connect scientific knowledge, regulatory frameworks, and operational excellence. Whether it's designing skill-oriented curricula, enhancing compliance standards, or streamlining clinical workflows, Mrs. Melvin is deeply passionate about delivering transformative training and strategic solutions tailored to the evolving needs of the life sciences industry.

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Course Instructors

Ms. K. Geethanjali

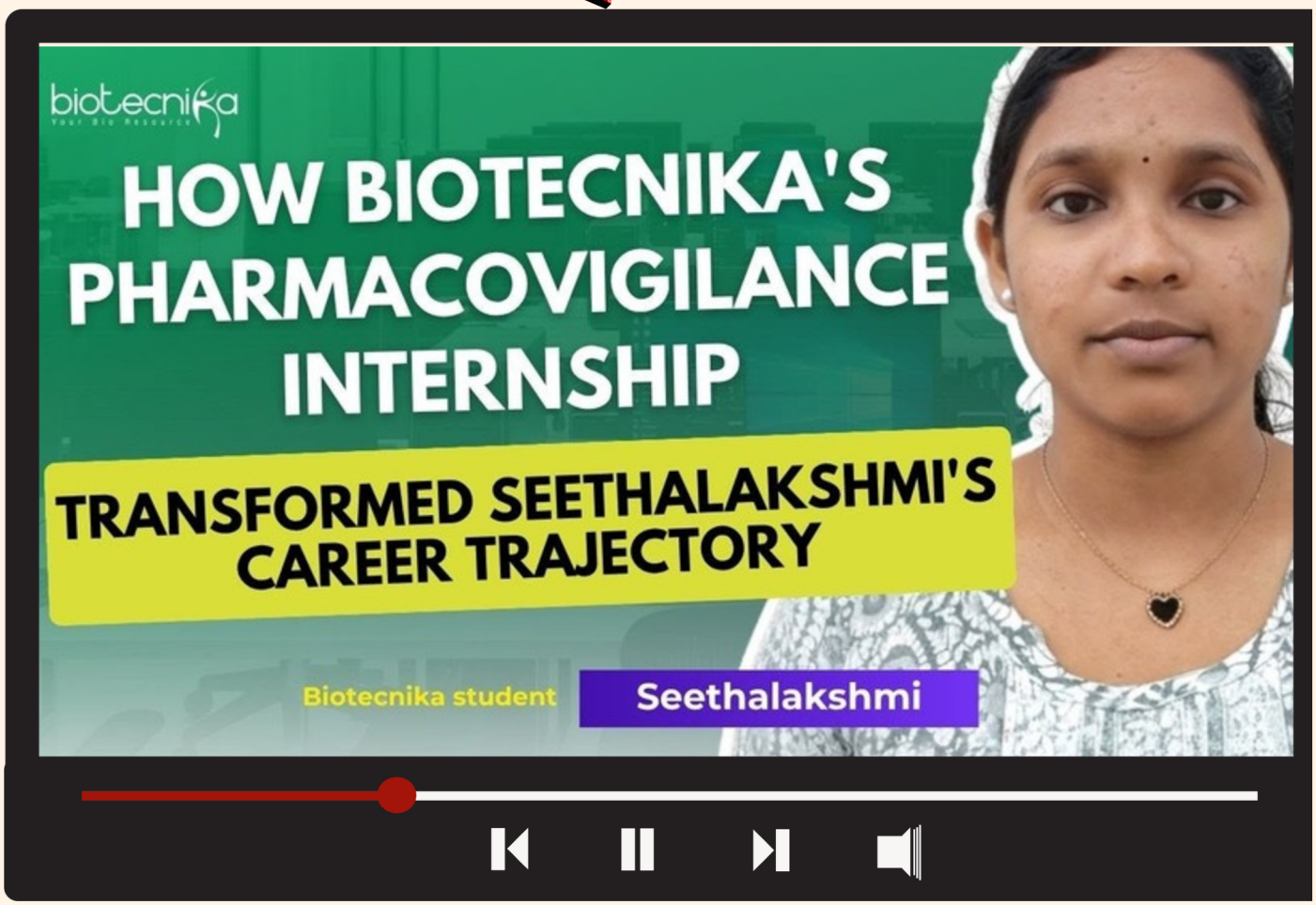
Pharmacovigilance &
Drug Safety Trainer

Ms. K. Geethanjali is a dedicated pharmaceutical professional with a strong academic foundation and practical experience in pharmacovigilance, drug safety, and patient counseling. She holds an M.Pharm in Pharmaceutics from PSG College of Pharmacy, Coimbatore, and has completed projects focused on drug delivery systems and clinical studies on metabolic disorders like PCOS.

Her hands-on industry experience includes working as a Junior Drug Safety Associate at Bioclinica Ltd., where she was responsible for case entry, adverse event evaluation, and accurate MedDRA coding using ARGUS safety database. She has also worked as a community pharmacist, demonstrating a deep understanding of prescription verification, medication compliance, and patient counseling.
Geethanjali has attended multiple national and international pharmaceutical conferences, contributing to her continuous learning and passion for teaching. Her knowledge, combined with her multilingual communication skills and real-world industry exposure, makes her an inspiring mentor for students aspiring to build a career in pharmacovigilance and regulatory affairs.

As a part of Biotecnika's Pharmacovigilance Training Program, she will guide students through industry-relevant projects, ensuring they gain both conceptual clarity and practical skills for a successful career in drug safety.

Hear how a Biotecnika student's Pharmacovigilance Internship reshaped her career path



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