RATHINAM

RATHINAM COLLEGE OF PHARMACY

3 – DAYS INDUSTRY ORIENTED

FOUNDATION PROGRAM

IN CLINICAL RESEARCH & PHARMACOVIGILANCE

Kickstart your career in one of the fastest-growing domains in healthcare.

- Industry Relevant Training
- Expert Led Sessions
- Practical Knowledge & Insights

Convenor

Principal

Prof. Dr. N. Balakrishnan

M.Pharm.,Ph.D.,

DATE

18.05.2026

TO

20.05.2026

WHAT YOU WILL GAIN

- In-depth Understanding of Clinical Research
- Knowledge in Pharmacovigilance & Drug Safety
- Hands-on Learning & Case Studies
- Career Guidance & Industry Exposure

"Build the Foundation. Shape the Future."

TRAINING & PLACEMENT CELL

EVENT REPORT

3–Days Industry Oriented Foundation Program in Clinical Research & Pharmacovigilance

Date: 18.05.2026 to 20.05.2026

Venue: Board Room

Organizer: Training & Placement Cell

Convenor: Prof. Dr. N. Balakrishnan, M.Pharm., Ph.D.,

Rathinam College of Pharmacy successfully organized a **3–Days Industry Oriented Foundation Program in Clinical Research & Pharmacovigilance** from **18th May 2026 to 20th May 2026** under the guidance of the Principal, Prof. Dr. N. Balakrishnan, M.Pharm., Ph.D. The program was conducted by the Training & Placement Cell with the objective of creating awareness and foundational knowledge among students regarding the rapidly growing domains of Clinical Research and Pharmacovigilance.

The program focused on providing students with practical exposure, industry-oriented concepts, and current trends followed in pharmaceutical industries. Sessions were designed to improve students' understanding of clinical trial processes, drug safety monitoring, regulatory requirements, adverse drug reaction reporting, pharmacovigilance workflow, and career opportunities available in the healthcare and pharmaceutical sectors.

DAY – 1 REPORT (18.05.2026)

The first day of the foundation program commenced with an inaugural session introducing the importance of Clinical Research and Pharmacovigilance in the pharmaceutical and healthcare industries. Students were provided with an overview of drug development processes, phases of clinical trials, ethical guidelines, and the significance of Good Clinical Practice (ICH-GCP). The resource person explained the fundamentals of clinical research with real-time industry examples and highlighted various career opportunities available in CROs and pharmaceutical industries.

An interactive session was conducted to improve students' understanding of clinical trial management and regulatory procedures. At the end of the session, a topic-based MCQ assessment related to Clinical Research and Clinical Trials was conducted to evaluate the participants' knowledge and learning outcomes.

DAY – 2 REPORT (19.05.2026)

On the second day, the session focused mainly on Pharmacovigilance and Drug Safety Monitoring systems followed in the pharmaceutical industry. The participants learned about Adverse Drug Reactions (ADR), Individual Case Safety Reports (ICSR), signal detection, post-marketing surveillance, and global pharmacovigilance practices. The speaker also explained the roles and responsibilities involved in pharmacovigilance departments and introduced regulatory authorities such as WHO, CDSCO, and US FDA.

Students actively participated in discussions related to patient safety and reporting procedures. Practical examples and workflow demonstrations helped participants understand real-world pharmacovigilance operations. A topic-wise MCQ assessment on Pharmacovigilance concepts was conducted at the end of the session to assess students' understanding and participation.

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DAY – 3 REPORT (20.05.2026)

The final day of the program concentrated on practical applications, case studies, and industry expectations in Clinical Research and Pharmacovigilance sectors. The session included discussions on data management, safety documentation, clinical trial monitoring, regulatory compliance, and future trends such as Artificial Intelligence and automation in pharmacovigilance. Participants were encouraged to enhance their technical and communication skills required for industry placements.

A concluding interactive session was conducted where students clarified their queries regarding higher studies, certifications, internships, and career pathways in Clinical Research and Pharmacovigilance. The program concluded with a final topic-based MCQ assessment, feedback collection, and certificate distribution. The overall program provided valuable industry exposure and foundational knowledge to all the participants.

Program Co-Ordinators
Training & Placement Cell
Rathinam College of Pharmacy
Coimbatore - 641 021.

Principal
Principal
Rathinam College of Pharmacy
Rathinam Techzone,
Pollachi Main Road, Eachanari,
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Rathinam College Of Pharmacy
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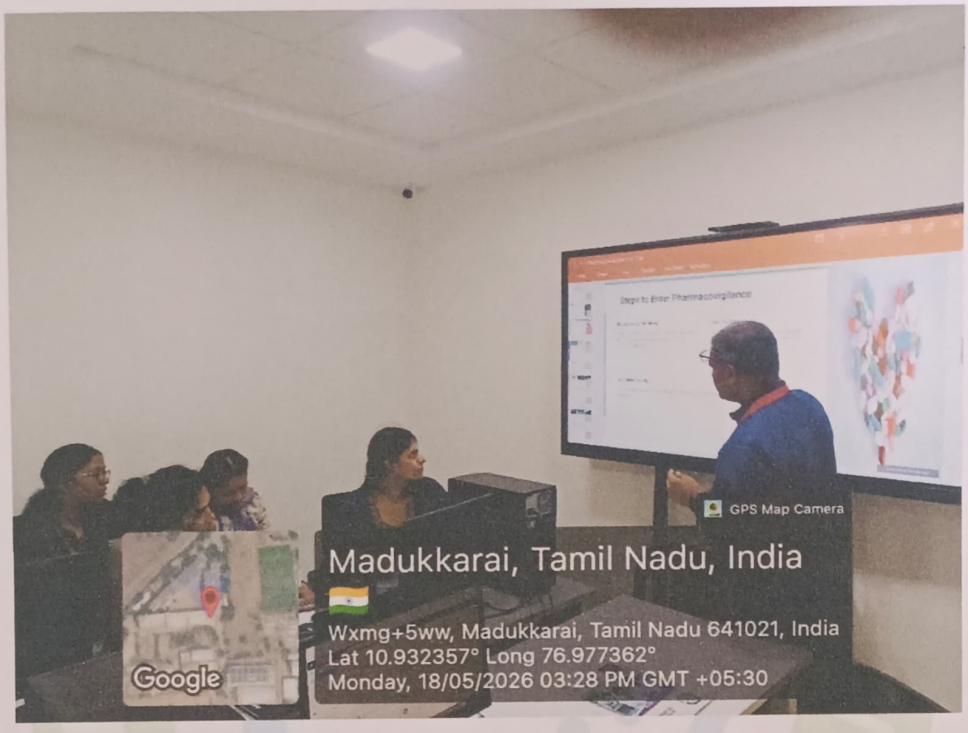
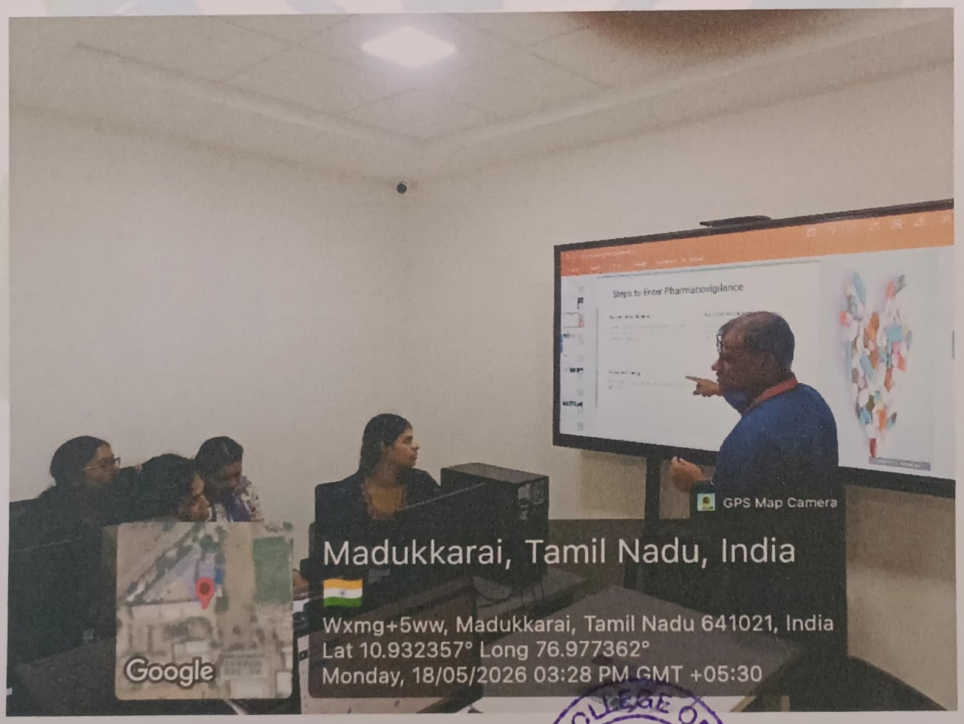
EVENT PHOTOS DAY 1





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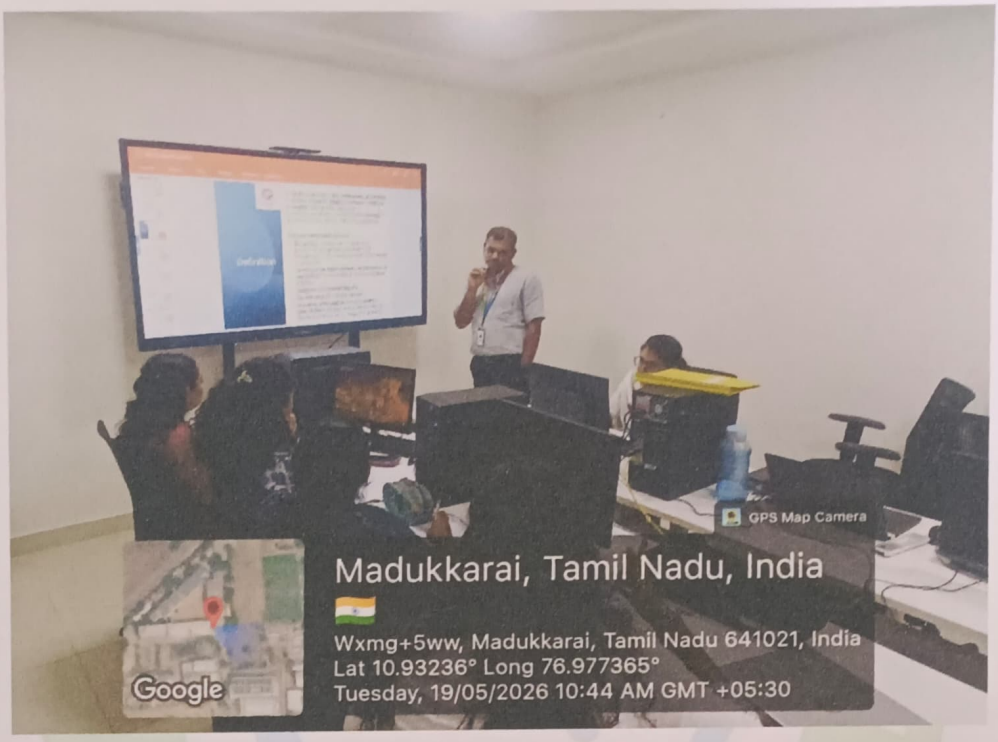
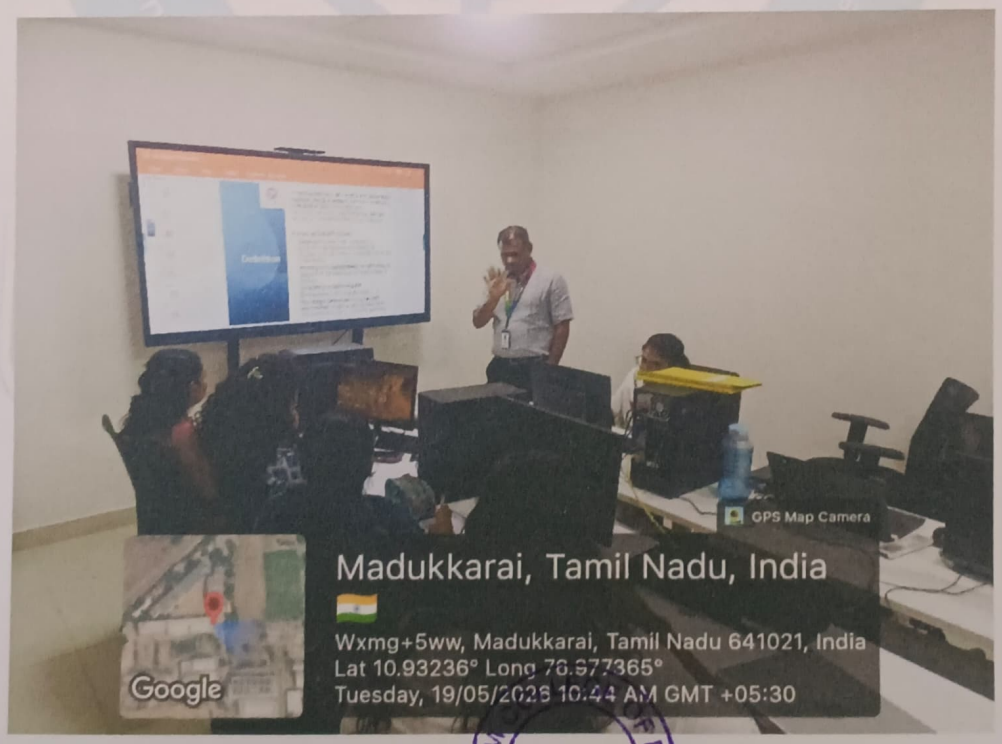
EVENT PHOTOS DAY 2





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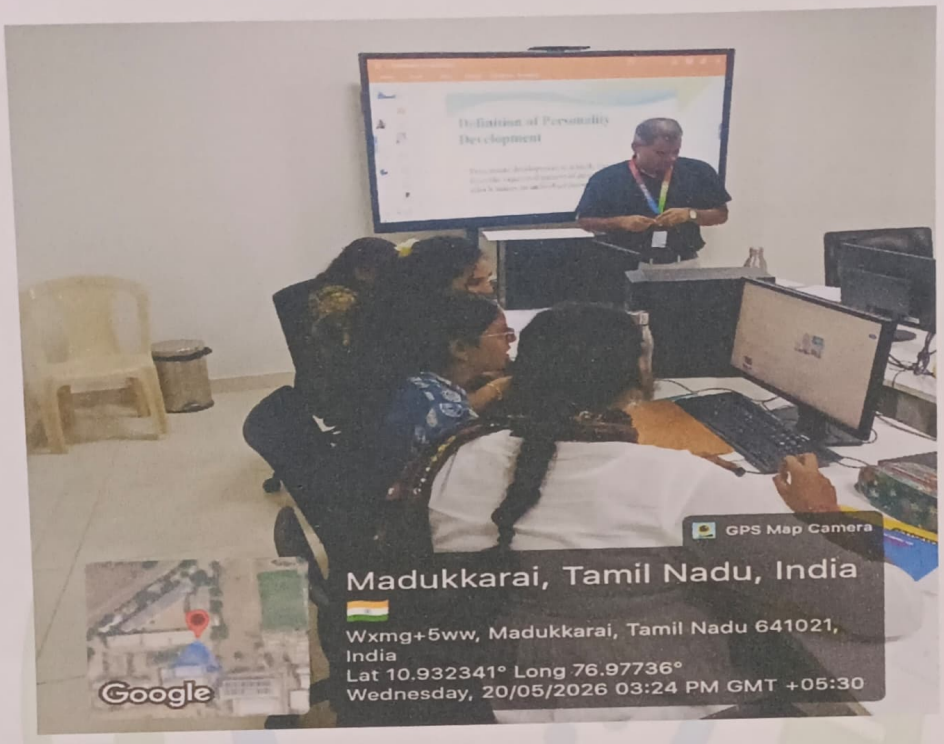
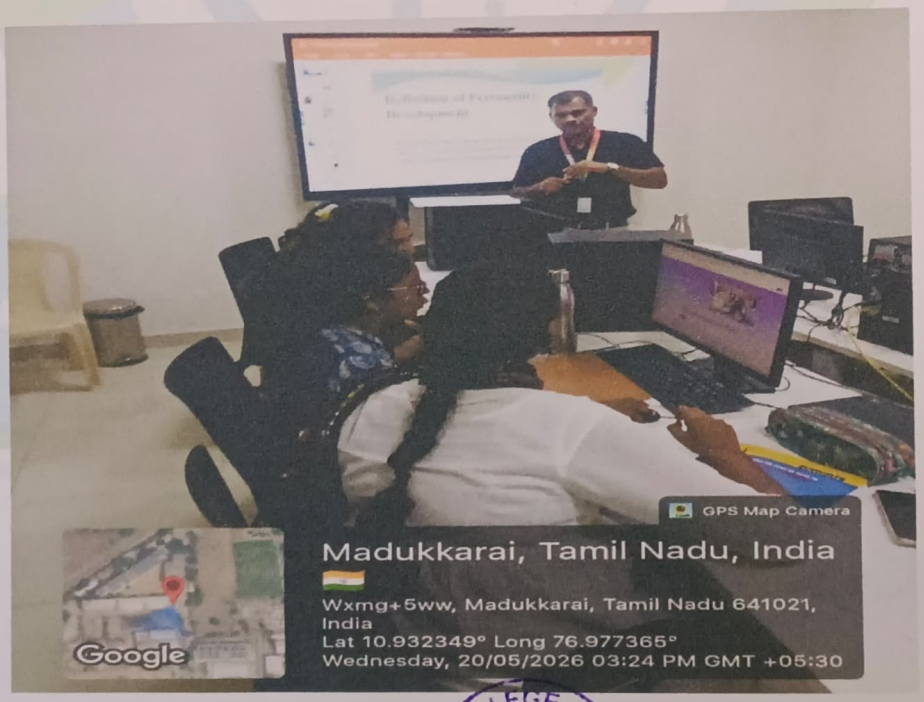
EVENT PHOTOS DAY 3





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DAY - 01

PRASHANTHINI M
9361096967

Pharmacovigilance & Materiovigilance

1. Pharmacovigilance is mainly concerned with:
A. Drug marketing
B. Drug safety monitoring
C. Drug manufacturing
D. Drug pricing

2. Which of the following is an example of an ADR?
A. Wrong storage condition
B. Tablet discoloration
C. Rash after taking medicine
D. Missing doses

3. An Adverse Event (AE) is:
A. Always caused by a drug
B. Never related to medicine
C. Any undesirable event after medicine use
D. Only serious reactions

4. Which phase of clinical trial mainly focuses on safety and tolerability?
A. Phase I
B. Phase II
C. Phase III
D. Phase IV

5. Post-Marketing Surveillance is also called:
A. Phase I study
B. Phase II study
C. Phase III study
D. Phase IV study

6. Which organization coordinates Pharmacovigilance in India?
A. WHO
B. IPC
C. EMA
D. NIH

7. CDSCO stands for:
A. Central Drug Safety Control Organization
B. Central Drugs Standard Control Organization
C. Clinical Drug Safety Control Office
D. Central Drug Surveillance Coordination Office

8. Which of the following is considered a serious adverse event?
A. Mild headache
B. Temporary itching
C. Hospitalization
D. Bad taste

9. Signal detection in Pharmacovigilance means:
A. Drug advertisement
B. Identifying possible new safety risks
C. Manufacturing medicines
D. Packaging medicines

10. Which database is maintained by the US FDA for device adverse events?
A. PvPI
B. EUDAMED
C. MAUDE
D. Vigibase

11. Materiovigilance deals with:
A. Vaccine safety
B. Medical device safety
C. Herbal medicine safety
D. Cosmetic safety

12. MvPI was launched in India in:
A. 2010
B. 2012
C. 2015
D. 2018

13. Which of the following is an implantable medical device?
A. Thermometer
B. Pacemaker
C. Glucometer
D. Nebulizer

14. Software as Medical Device is abbreviated as:
A. SMD
B. SaMD
C. SMAD
D. SDM

15. Which healthcare professional can report device adverse events?
A. Doctors only
B. Pharmacists only
C. Biomedical engineers only
D. All of the above

16. Class D medical devices are considered:
A. Low risk
B. Moderate risk
C. Moderate-high risk
D. High risk

17. A device malfunction is an example of:
A. Medication adherence
B. Device-related adverse event
C. Clinical trial phase
D. Drug interaction

18. Which of the following is a challenge in Materiovigilance?
A. Excess reporting
B. Lack of awareness
C. Low number of devices
D. Over-regulation

19. Real-world evidence is mainly collected during:
A. Preclinical studies
B. Phase I trials
C. Post-marketing surveillance
D. Drug discovery

20. Which of the following is NOT a seriousness criterion?
A. Death
B. Hospitalization
C. Congenital anomaly
D. Bitter taste

21. Risk management in Pharmacovigilance aims to:
A. Increase drug cost
B. Reduce patient safety
C. Minimize drug-related risks
D. Stop clinical trials

22. Which organization operates EudraVigilance?
A. WHO
B. EMA
C. IPC
D. CDSCO

23. Which of the following is a therapeutic device?
A. Ventilator
B. Pacemaker
C. Test kit
D. Software

24. Under-reporting is a major challenge in:
A. Pharmacovigilance and Materiovigilance
B. Drug manufacturing
C. Pharmacy marketing
D. Clinical coding

25. The primary goal of Materiovigilance is to:
A. Increase device sales
B. Promote advertisements
C. Ensure patient safety
D. Reduce manufacturing cost

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DAY - 02. 22/25

MCQ- Clinical Trails

1.Which phase of clinical trial mainly focuses on safety and dosage?
A) Phase II
B) Phase III
C) Phase I
D) Phase IV

2. Phase III clinical trials are mainly conducted to:
A) Test toxicity in animals
B) Confirm safety and efficacy
C) Study drug metabolism only
D) Monitor post-marketing safety

3. Pharmacokinetics mainly includes:
A) Drug mechanism only
B) ADME process
C) Drug toxicity only
D) Drug formulation

4. EC50 refers to:
A) Maximum toxic dose
B) Half maximal effective concentration
C) Therapeutic index
D) Drug elimination rate

5. Therapeutic Index indicates:
A) Drug color
B) Drug cost
C) Safety margin of drug
D) Drug half-life

6. Which stage comes before clinical trials?
A) Pharmacovigilance
B) Regulatory approval
C) Preclinical testing
D) Phase IV study

7. NDA stands for:
A) National Drug Approval
B) New Drug Application
C) New Development Analysis
D) National Development Authority

8. Pharmacovigilance mainly deals with:
A) Drug marketing
B) Drug pricing
C) Drug safety monitoring
D) Drug manufacturing

9. Which ethical code introduced voluntary consent?
A) Belmont Report
B) ICH-GCP
C) Nuremberg Code
D) Schedule Y

10. ICH-GCP mainly ensures:
A) Drug advertisement
B) Ethical and quality standards
C) Sales monitoring
D) Manufacturing profit

11. Informed consent must be:
A) Forced
B) Hidden
C) Voluntary and documented
D) Oral only

12. ALCOA+ principle relates to:
A) Drug pricing
B) Data integrity
C) Patient recruitment
D) Packaging system

13. Schedule Y is associated with:
A) USA regulations
B) Animal ethics
C) Indian clinical trial regulations
D) Manufacturing license only

14. CRO stands for:
A) Clinical Research Organization
B) Clinical Regulatory Office
C) Central Research Organization
D) Clinical Review Office

15. One major advantage of outsourcing clinical trials is:
A) Reduced documentation
B) Cost efficiency
C) No regulations
D) Elimination of monitoring

16. Randomization in clinical trials helps to:
A) Increase bias
B) Reduce bias
C) Delay studies
D) Avoid data analysis

17. Which study design is considered the gold standard?
A) Case report
B) Cross-sectional study
C) Randomized Controlled Trial
D) Observational study

18. Primary endpoint means:
A) Additional outcome
B) Main study outcome
C) Adverse event
D) Statistical error

19. TMF stands for:
A) Trial Monitoring Form
B) Trial Master File
C) Testing Management File
D) Trial Medical Folder

20. Which tool improves real-time data access in trials?
A) ECG
B) EDC
C) HPLC
D) ELISA

21. SUSAR reporting for fatal cases should be done within:
A) 30 days
B) 21 days
C) 7 days
D) 60 days

22. Dechallenge means
A) Restarting the drug
B) Increasing dose
C) Stopping the drug to observe event resolution
D) Changing trial site

23. QC in clinical trials mainly focuses on:
A) Marketing strategy
B) Error prevention
C) Drug advertisement
D) Sales performance

24. SDV stands for
A) Source Data Verification
B) Safety Data Validation
C) Statistical Data Verification
D) Standard Drug Verification

25. 21 CFR Part 11 mainly deals with:
A) Animal studies
B) Electronic records and signatures
C) Drug packaging
D) Sales audit

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DAY - 03 25/25

Rithishree. K
8148522261

MCQs – Pharmacovigilance

1. Pharmacovigilance is mainly concerned with:

A) Drug marketing
B) Drug safety monitoring
C) Drug manufacturing
D) Drug pricing

2. The primary aim of pharmacovigilance is to:

A) Increase drug sales
B) Improve patient safety
C) Reduce packaging cost
D) Promote advertisements

3. ADR stands for:

A) Adverse Drug Reaction
B) Adverse Drug Report
C) Additional Drug Reaction
D) Active Drug Response

4. An Adverse Event (AE) is:

A) Always caused by drug
B) Any unwanted event after drug use
C) A manufacturing defect
D) A medication error only

5. Pharmacovigilance helps in:

A) Detecting rare ADRs
B) Increasing drug cost
C) Reducing clinical trials
D) Avoiding prescriptions

6. Which phase mainly evaluates safety and tolerability?

A) Phase IV
B) Phase III
C) Phase II
D) Phase I

7. Post-marketing surveillance is performed:

A) Before animal studies
B) Before approval
C) After drug approval
D) During manufacturing only

8. ICSR stands for:

A) International Clinical Safety Report
B) Individual Case Safety Report
C) Integrated Case Study Report
D) Individual Clinical Study Review

9. Which is NOT part of minimum four criteria of ICSR?

A) Identifiable patient
B) Identifiable reporter
C) Drug price
D) Adverse event

10. The first step in ICSR workflow is:

A) Data entry
B) Validation
C) Case intake
D) Submission

11. Medical coding is performed during:

A) Drug discovery
B) ICSR workflow
C) Manufacturing
D) Marketing

12. PSUR is a type of:

A) Clinical trial
B) Aggregate reporting
C) Manufacturing process
D) Drug approval system

13. DSUR stands for:

A) Development Safety Update Report
B) Drug Safety Unified Report
C) Data Safety Update Review
D) Drug Submission Update Report

14. Signal management includes:

A) Drug promotion
B) Packaging design
C) Signal detection and assessment
D) Sales forecasting

15. Which organization is a global health authority?

A) IPC
B) WHO
C) CDSCO
D) FDA

16. FDA is the regulatory authority of:

A) India
B) Japan
C) USA
D) China

17. CDSCO is associated with:

A) Europe
B) India
C) Australia
D) Canada

18. One major challenge in pharmacovigilance is:

A) Over-reporting
B) Under-reporting
C) Excess manufacturing
D) High packaging quality

19. Incomplete safety data may affect:

A) Drug color
B) Drug packaging
C) Accurate safety evaluation
D) Tablet size

20. Artificial Intelligence in PV is mainly used for:

A) Drug taste improvement
B) Automation and analytics
C) Tablet coating
D) Packaging only

21. Real-world evidence is mainly collected during:

A) Drug discovery
B) Preclinical studies
C) Post-marketing surveillance
D) Animal testing

22. Which report supports continuous safety evaluation?

A) PBRER
B) IB
C) CRF
D) SOP

23. Pharmacovigilance mainly supports:

A) Unsafe drug use
B) Rational use of medicines
C) Drug advertisement
D) Manufacturing only

24. Which is an important future trend in pharmacovigilance?

A) Handwritten reports
B) Big data analytics
C) Reduced monitoring
D) Avoiding automation

25. Pharmacovigilance ultimately helps to:

A) Increase drug price
B) Save lives through early risk detection
C) Reduce patient care
D) Stop clinical trials completely

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3 – Days Industry Oriented Foundation Program in Clinical Research & Pharmacovigilance

Date : 18.05.2026- 20.05.2026

ATTENDANCE SHEET

S.No	Students Name	Signature		
		18.05.2026	19.05.2026	20.05.2026
1.	M. PRASHANTHINI	Prashanthini.	Prashanthini.	Prashanthini.
2.	K. RITHISHREE	Rithishree	Rithishree	Rithishree
3.	JITCY .K.J.	Jitcy	Jitcy	Jitcy
4.	MIRUDHU BARSHINI .B.	B.Mirudhu	B.Mirudhu	B.Mirudhu

20/05/2026

Program Co – Ordinator

For
(M.AJMALKHAN)
Training & Placement Cell
Rathinam College of Pharmacy
Coimbatore - 641 021.

TRAINING & PLACEMENT CELL

Principal

Principal
Rathinam College of Pharmacy
Rathinam Techzone,
Pollachi Main Road, Eachanari,
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3 – Days Industry Oriented Foundation Program in Clinical Research & Pharmacovigilance

FEEDBACK FORM

Date : 18.05.2026- 20.05.2026

S.No	Students Name	Feedback
1.	M. PRASHANTHINI.	knowledgable and Informative
2.	RITHISHREE . K	Educational and useful
3.	JITLY K . J.	Immensely valuable & Incredibly clarifying.
4.	MIRUDHU BARSHINI . B.	This program help me to boost the confident level in the pharmacovigilance oriented side.

For
Program Co-Ordinator

Training & Placement Cell
Rathinam College of Pharmacy
Coimbatore - 641 021.

Principal

Principal
Rathinam College of Pharmacy
Rathinam Techzone,
Pollachi Main Road, Eachanari,
Coimbatore - 641 021.

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FOUNDATION CERTIFICATE

IN CLINICAL RESEARCH & PHARMACOVIGILANCE

THIS IS TO CERTIFY THAT

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has successfully completed the **3 Days Industry-Oriented Foundation Program** in **Clinical Research & Pharmacovigilance** conducted from **18-May-2026** to **20-May-2026**. Organised by, Training & Placement Cell, Rathinam College of Pharmacy.

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Throughout the program, he/she demonstrated enthusiasm, active participation, and a keen interest in enhancing knowledge and skills for a successful professional journey. We appreciate his/her sincere efforts and wish him/her all the best for a bright and promising future.

20.05.2026
DATE

Organised by,
Training & Placement Cell

PRINCIPAL

INSTITUTION'S INNOVATION COUNCIL
(Ministry of Education Initiative)

NPTEL