

Pharmacovigilance Internship

Advanced Focussed Areas for Interns in Pharmacovigilance Internships

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• Fundamentals of Pharmacovigilance

- Introduction to Pharmacovigilance
- History and Evolution of Drug Safety Monitoring
- Role of Pharmacovigilance in Public Health
- Key Terminology: ADRs, AE, Signal Detection
- Applications of Pharmacovigilance in Research
- Ethics and Safety in Pharmacovigilance
- Future Directions in Pharmacovigilance

Adverse Drug Reactions (ADRs) and Safety Reporting

- Types and Classifications of ADRs
- Spontaneous Reporting Systems and Databases
- Case Studies in ADR Reporting
- Signal Detection and Risk Assessment
- Future Directions in ADR Monitoring
- Challenges in Identifying and Reporting ADRs
- Regulatory Aspects of ADR Reporting
- o Impact of ADRs on Drug Safety
- Public Engagement and Education in Drug Safety
- Ethical Considerations in ADR Reporting

• Risk Management and Regulatory Compliance

- Risk Management Plans (RMPs) and Strategies
- Post-Marketing Surveillance and Periodic Safety Update Reports (PSURs)
- Case Studies in Risk Management
- o Future Trends in Risk Management
- Challenges in Implementing Risk Mitigation Strategies
- Regulatory Aspects of Risk Management
- Impact of Risk Management on Patient Safety
- Public Engagement and Education in Risk Management
- Integration of Risk Management with Pharmacovigilance

• Pharmacovigilance in Clinical Trials and Regulatory Affairs

- Safety Monitoring in Clinical Trials
- Regulatory Requirements and Guidelines

- o Case Studies in Clinical Trial Safety
- Future Directions in Clinical Pharmacovigilance
- Challenges in Clinical Safety Assessment
- Regulatory Aspects of Clinical Trials
- Impact of Pharmacovigilance on Regulatory Decisions
- Public Engagement and Education in Clinical Safety
- Ethical Considerations in Clinical Pharmacovigilance
- Integration of Pharmacovigilance with Clinical Research

• Future Directions and Emerging Trends

- Innovations in Pharmacovigilance and Drug Safety
- Role of Pharmacovigilance in Personalized Medicine
- Emerging Applications in Biomedical Research
- o Global Trends in Pharmacovigilance Research
- o Future of Pharmacovigilance in Healthcare and Industry
- Ethics and Regulation in Pharmacovigilance
- Future Research Priorities in Pharmacovigilance
- o Impact of Pharmacovigilance on Society
- Public Engagement and Education in Drug Safety Sciences
- Integration of Pharmacovigilance with AI and Data Science

Contact Via Whatsapp on +91-7993084748 for Fee Details