

KALYANI SHARMA

CLINICAL RESEARCH COORDINATOR - Clinical Documentation & Research Support

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PROFILE SUMMARY

Clinical research & pharmacy oriented professional transitioning into a Clinical Research Coordinator role, with experience in supporting pharmacovigilance, and inspection readiness within Canadian and global frameworks. Expertise in safety case review, regulatory submissions, TMF reconciliation, and protocol compliance. Maintained patient documentation, informed consent review, and audit support activities. Initiated data integrity across CTMS, eTMF, and EMR platforms while upholding ICH-GCP R3, TCPS2, and Health Canada Division 5 documentation. Committed to ethical research conduct, participant safety, and quality-driven clinical site operations.

SKILLS

- **Clinical Data & Research Support:** Source data verification, document reconciliation, protocol compliance.
- **Participant & Study Coordination:** Informed consent, subject screening, visit coordination, CRF review.
- **Clinical Systems & Tools:** CTMS, eTMF, EMR, Excel documentation, MS Office Suite, IATA-compliant.
- **Regulatory & Ethics Submissions:** REB/IRB submission, ISF maintenance, regulatory binder organization.
- **Quality & Compliance Support:** ICH-GCP R3 adherence, TCPS2, PIPEDA standards, audit readiness.
- **Clinical Safety Documentation:** AE/SAE intake reporting support, CAPA documentation logs assistance.

WORK EXPERIENCE

Pharmacy Assistant

Shifa Pharmacy

June 2024 - January 2025

Toronto, Canada

- Processed and documented 150+ prescriptions weekly within EMR systems, maintaining 99% documentation accuracy and full compliance with provincial regulatory standards.
- Resolved 40+ insurance claim rejections per month, improving billing turnaround time by 25% and reducing patient wait times by 20%.
- Conducted monthly inventory audits of 2,000+ medication units, decreasing expired stock losses by 18% through monitoring and documentation controls.
- Guided 60+ patients weekly on dosage schedules, contraindications, and refill coordination, increasing medication adherence rates by 22%.
- Identified and escalated 15+ potential adverse drug reactions (ADRs) to supervising pharmacists, reinforcing pharmacovigilance compliance and patient safety oversight.

Drug Safety Associate

PharmaLex India Pvt. Ltd. (Cencora)

March 2021 - April 2023

India

- Processed 10,000+ ICSRs involving MedDRA coding, seriousness assessment, and narrative writing, achieving 95% regulatory compliance across FDA, EMA, and Health Canada submissions.
- Executed full ICSR lifecycle management, including triage, duplicate checks, follow-ups, and data validation, reducing average case processing time by 15%.
- Conducted quarterly literature surveillance and reconciled 2,000+ safety records to support signal detection and aggregate reporting activities.
- Led TMF reconciliation and supported site activation documentation, ensuring 96% audit readiness during sponsor and internal inspections.

Pharmacovigilance Trainee

Academy of Clinical Intelligence (ACI)

June 2020 - February 2021

India

- Performed initial triage and structured data entry of 500+ adverse event cases under team supervision.
- Coordinated in monitoring safety timelines and regulatory follow-ups, improving tracking efficiency by 20%.
- Analyzed audit reviews of informed consent forms and safety documentation, identifying 25+ compliance gaps.
- Collaborated in preparation of AE listings and reconciliation 20+ reports used in signal detection & evaluation.

Pharmacy Associate

Sujay Life Sciences

August 2014 - August 2017

India

- Refined GMP-compliant dispensing and handling of 300+ pharmaceutical units daily, maintaining compliance.
- Managed labeling, storage, and documentation for 1,500+ SKUs, ensuring adherence to regulatory standards.
- Assessed QA documentation logs and material records supporting 5+ internal quality inspections annually.
- Ensured adherence to safety protocols and documentation accuracy, contributing to zero major audit findings.

Quality Analyst
Ranbaxy Labs Ltd.

August 2013 - August 2014
India

- Improved quality control testing of 200+ raw product samples monthly, ensuring 100% GMP compliance.
- Reviewed 150+ batch manufacturing records quarterly, identifying and resolving 10+ documentation deviations.
- Coordinated in deviation investigations and CAPA documentation, reducing repeat quality issues by 22%.
- Maintained laboratory QC logs with 99% data integrity accuracy, ensuring traceability and regulatory readiness.

PROJECT EXPERIENCE

Review Paper - Pulsatile Drug Delivery Systems (JETIR)

Role: Author & Research Analyst

- Authored and published a peer-reviewed review paper analyzing 25+ pulsatile drug delivery technologies, evaluating formulation strategies, and release kinetics.
- Implemented critical review of 40+ scientific studies and synthesized regulatory and quality considerations influencing modified-release drug approvals.

Formulation & Evaluation of Pulsatile Drug Delivery System for Nocturnal Asthma

Role: Research Lead & Formulation Developer

- Developed and evaluated 10+ prototype formulations targeting delayed drug release, optimizing lag time through dissolution and kinetic analysis.
- Performed 10+ stability and compatibility testing under controlled laboratory conditions and documented results in compliance with GMP-oriented research standards.

EDUCATION

Post-Graduate Diploma in Clinical Research, Pharmacovigilance & Regulatory Affairs

Academy of Applied Pharmaceutical Sciences, Canada

January 2025 - December 2025

Postgraduate Degree in Health Care Administration & Management

Northern College of Applied Arts and Technology, Canada

May 2023 - January 2024

Master of Pharmacy (M.Pharma) in Pharmaceutical Sciences

Uttarakhand Technical University, Dehradun, India

August 2018 - October 2020

Bachelor of Pharmacy (B.Pharma)

Maharshi Dayanand University, India

July 2009 - June 2013

LICENSES & CERTIFICATIONS

- **IATA - Shipping of Category A & B Infectious Substances**, Myo Clinic Laboratories Ongoing
- **Verified International Academic Qualifications**, World Education Services (WES) March 2025
- **Health Canada Division 5 Certification**, Academy of Applied Pharmaceutical Sciences
- **TCPS2- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans**
- **CTMS Platform Training**, Academy of Applied Pharmaceutical Sciences
- **ICH GCP R3 Training**, Syneos Health
- **WHMIS - Workplace Hazardous Materials Information System**, Aix Health Safety and Environmental
- **PIPEDA Training**, Academy of Applied Pharmaceutical Sciences