ROHIT CHOWRI

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CAREER OBJECTIVE:

Highly motivated recent Pharmacy graduate with a strong foundation in pharmacology, drug development, and regulatory processes. Eager to leverage my academic knowledge and research skills to contribute to a dynamic clinical research or regulatory affairs team. Seeking an entry-level position to gain experience in the development and approval of safe and effective medications.

EDUCATION DETAILS:

Qualification	Institution	Board/University	Year of passing
B pharmacy -CGPA-7.84	HKE's MTRIPS college of Pharmacy	Rajiv Gandhi University of Health sciences	2023
PUC (science) – 81%	Chandrakant Patil memorial pre university college	KSEEB	2019
SSLC – 84%	Government high school Chandanakera	KSEEB	2017

CERTIFICATES:

- Certificate in overview of Indian Pharma industry and Generic product development process.
- Quality Cosmetics: Role of evolving technologies and regulations.
- GCP certification by NIDA Clinical Trials network.
- Certified in Microsoft Office.

PROJECT DETAILS:

- Exploring routes of administration, anaesthetic techniques, blood collection and euthanasia in rodents.
- Formulation and evaluation of Cream.

TECHNICAL SKILLS:

- MSOffice (MS Word, PowerPoint, and Basic Excel)
- SAS
- Minitab
- Computer Applications
- Pharmacy Laws and Regulations

PROFESSIONAL SKILLS:

- Clinical Research – Drug discovery and development process, Animal research, Clinical research phases 0, 1, 2, 3, & 4; ICH, GCP, & Ethics, Dossiers (INDA, NDA, ANDA, & BLA), CTD modules, Clinical study designs – experimental & observations (RCT, n-RCT, prospective, retrospective, cross-sections, case study, case-series & case controls), Placebo, Biasness, Centralized & De-centralized trials, Responsibilities of CRA, CRC, Investigator & Sponsor.
- Clinical Data Management – CDM overview, Aims & objectives, Study start-up phase (CRF & Database designing), Study conduct phase (data collection, CRF tracking, data entry, data validation, discrepancy management, medical coding, & SAE reconciliation), Study close-out phase (declaring clean file & database lock), 21 CFR 11 & CDM databases (Rave, Macro & Oracle clinical).
- Pharmacovigilance – PV overview, Responsibilities, definitions (AE, ADR, SAE, SUSAR, abuse, misuse, off-label use, medication error), Sulfanilamide tragedy, Thalidomide tragedy, 21 CFR 312 & 314, GVP, ICH E2A-F, CIOMS, ICSR processing, Causality assessment scales – WHO UMC, Naranjo, De-challenge & Re-challenge, Reporting systems, PVPI, Aggregate reports (DSUR, PSUR, PADER & PBRER, MedDRA, WHO COSTAT, & ART
- Regulatory Affairs – RA, overview, responsibilities, Dossiers (INDA, NDA, MAA, ANDA, & BLA), CTD modules 1, 2, 3, 4, and 5 & Regulatory bodies.
- Pharmacology – Basic knowledge of medical conditions including Diabetes, Cancer, Asthma, COPD, Hypertension, COVID-19, Malaria etc.,
- Standard Operating Procedure
- ICH-GCP Guidelines

AREA OF INTEREST:

- Pharmacovigilance
- Regulatory affairs
- Clinical data management
- Clinical trials
- Data safety associate

PERSONAL DETAILS:

Date of birth –20 /02/2001

Gender – Male

Nationality – Indian

Marital status – unmarried

DECLARATION: I hereby declare that the above written particulars are true to the best of my knowledge and belief**.**

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- Rohit chowri