

NIVEDITHA DK

Pharmacovigilance

📞 7899317235 @nivedithadk9@gmail.com 🌐 niveditha-dk-100991267 📍 Bengaluru, KA.

SUMMARY

Detail-oriented professional with nearly 2 years of hands-on experience in Quality Control, poised to transition into Pharmacovigilance. Proven ability to ensure adherence to regulatory standards and quality assurance protocols within the pharmaceutical industry. Demonstrates a strong understanding of drug safety principles and keen interest in PV processes. Possesses solid technical skills including adverse event case processing, and risk management strategies.

EXPERIENCE

Quality Control officer

Adcock Ingram 📅 10/2021 - 08/2023 📍 Bengaluru, KA.

- In-depth knowledge of pharmaceutical quality control processes and procedures.
- Skilled in utilizing laboratory equipment and analytical tools like, Calibration of PH and Analytical balance.
- Proficient in performing Spectroscopic analysis using FTIR and UV spectrometers, along with titration methods using Karl Fischer auto titrator to determine moisture content.
- Software Handled: Caliber lims, Caliber E-log, Tiamo, Lab solutions. Preparation and analysis of samples for chromatographic studies.
- Assisted senior chemists in interpreting chromatographic data from HPLC/UPLC analyses.
- Maintained accurate and detailed laboratory records.

Assistant Professor

SET's College of Pharmacy 📅 11/2020 - 09/2021 📍 Dharwad, KA.

- Supervised and mentored students in academic research and professional development.

EDUCATION

Master of Pharmacy

Rajiv Gandhi University of Health Sciences,

📅 08/2019 - 08/2021 📍 Dharwad, KA

Bachelor of Pharmacy

Rajiv Gandhi University of Health Sciences,

📅 07/2015 - 07/2019 📍 Davanagere, KA.

TECHNICAL SKILLS

Protocol, Clinical trials, Investigator Brochure

Casualty assessment, Signal Management process, ICSR, PSUR, MedDRA

CRF, eCRF, CFR INDA, NDA, ANDA,

ICH guidelines, GMP, GLP, GCP,

Proficient in Microsoft Excel, power point and word.

Excellent attention to detail and accuracy.

Strong analytical and problem-solving skills.

Ability to work effectively in a team.

TRAINING AND CERTIFICATION

ADVANCED DIPLOMA IN CLINICAL RESEARCH

Covered 5 modules Clinical Research, Pharmacovigilance, Clinical Data Management, Regulatory affairs, and Medical writing. LEARNING LAB RESEARCH INSTITUTE, BENGALURU.

INTERPRETATION AND APPLICATION OF ICH E6(R2)

THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD.

DRUG REGULATORY AFFAIRS

SG PHARMA TRAININGS

NIDA CERTIFIED

NIDA CLINICAL TRIALS NETWORK.