Sneha Kulkarni

Pharmacovigilance Associate (Drug Safety)

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Personal statement

Pharmacovigilance associate with 2 years of experience in end-to-end ICSR case processing for spontaneous, literature and clinical trial cases. Skilled in Oracle Argus Safety, MedDRA coding, causality and seriousness assessment and narrative writing, with 98% quality scores and zero late submissions.

Certifications

Certificate course in pharmacovigilance and drug safety · Professional training institute — Oct 2023

Work experience

Drug Safety Associate · Vigilex Drug Safety Services Pvt Ltd, Mysuru — Sep 2024 – Present

- Process 7–9 ICSRs a day end to end in Argus Safety, covering triage, data entry, MedDRA and WHO-DD coding, and narrative writing.
- Assess seriousness, expectedness against the reference safety information and reporter causality for spontaneous and post-marketing cases.
- Maintain a 98.2% first-pass quality score over 12 months and met every 15-day and 7-day expedited reporting timeline.
- Draft follow-up queries to reporters, increasing complete-case rate for a key product by 20%.

Pharmacovigilance Trainee · Kaveri Pharmaceutical Research Pvt Ltd, Bengaluru — Jan 2024 – Aug 2024

- Screened 250+ literature articles a month for adverse event reports on 6 marketed molecules.
- Performed duplicate checks and case booking for incoming email and call-centre reports.
- Supported reconciliation between the safety database and the medical information log.

Education

Pharm.D in Doctor of Pharmacy · College of Pharmacy, Mysuru — 2017 – 2023
Grade: 8.4 CGPA

Skills

- ✓ ICSR case processing
- ✓ Oracle Argus Safety
- ✓ MedDRA coding
- ✓ WHO Drug Dictionary
- ✓ Narrative writing
- ✓ Seriousness and causality assessment
- ✓ Literature screening
- ✓ E2B (R3) basics

Languages

English · Fluent | Kannada · Native | Marathi · Fluent | Hindi · Conversational

Core skills

- Medical writing
- Attention to detail
- Regulatory timelines
- Quality focus
- Teamwork

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