Akansh Goel

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SUMMARY

Experienced Senior Pharmacovigilance Associate with expertise in preparing DSURs, triaging clinical trial cases, and managing ICSRs in Argus Safety. Skilled in data entry, MedDRA coding, narrative writing, and follow-up query management. Proficient in signal management, regulatory reporting, and maintaining compliance with SOPs. Strong ability to train teams, perform database reconciliation, and ensure accurate documentation and archiving.

TECHNICAL SKILLS

- DSUR
- Signal Management
- Regulatory Submissions
- Aggregate reports
- Reconciliation activities
- Literature Monitoring
- ICSR case processing
- Argus safety database

WORK EXPERIENCE

Senior Pharmacovigilance Associate, AWINSA Life Sciences, June-2023-Current

As a Senior Pharmacovigilance Associate, I prepare and review Developmental Safety Update Reports (DSURs) in compliance with regulatory requirements. I conduct literature monitoring, triage clinical trial cases, and provide team training on triage procedures. My responsibilities include data entry and quality review of ICSRs in Argus Safety, MedDRA coding, and narrative writing. I manage follow-up queries, resolve issues with clients, and ensure proper archiving of documents. I validate case data, generate queries for missing information, and contribute to signal management activities. I also review Change Control Forms (CCFs) and User Access Management Forms (UAM), maintain trackers, and train the team on SOPs. Additionally, I perform database reconciliation, draft discrepancy logs, and submit safety reports to regulatory bodies and investigational sites.

Pharmacovigilance Associate, AWINSA Life Sciences, March 2021-May 2023

As a Pharmacovigilance associate, I conduct literature monitoring, triage clinical trial cases, and provide team training on triage procedures. I manage data entry and quality review of ICSRs in Argus Safety and client databases, including MedDRA coding and narrative writing. I handle follow-up queries, resolve issues with clients, and ensure proper document archiving. I validate case data, generate queries for missing information, and review Change Control Forms (CCFs) and User Access Management Forms (UAM). I train the team on SOPs and guidelines, perform database reconciliations, and draft discrepancy logs.

QUALIFICATIONS

M. Pharmacy ISF College of Pharmacy	2018-2020
B.Pharmacy, Kurukshetra University, Kurukshetra	2015-2018
D. Pharmacy, R.K.S.D College of Pharmacy	2013-2015

WEBSITES, PORTFOLIOS, PROFILES

https://www.linkedin.com/in/akansh-goel-280818152/