

Senior Pharmacovigilance Associate

CONTACT ME

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EDUCATION

M Pharm

Kadi Sarva Vishva Vidhyalaya, Gandhinagar

2018 - 2019

B. Pharm

Gujarat Technological University 2012-2016

HSC

N.M. High School, Sabarmati, Ahmedabad.

2012

SKILLS

ICSR

Quality review

Team Leadership

Time line management

Interpersonal Skills

M S Office

Rutvi Joshi

Profile Summary

Enthusiastic, dedicated Pharmacovigilance expert with 3.5+ years of experience including case processing which involves triaging, bookin, data entry, MedDRA coding, quality review, narrative writing, reconciliation, and submission. To commit to work with full dedication for the achievement of the organization & enhancing my skill and knowledge and ready to learn new things. I am seeking a challenging and innovative pharmaceutical company where I can apply my expertise and contribute effectively.

WORK EXPERIENCE

Sr. Pharmacovigilance Associate

2019 - Present

APCER Life Sciences

Current Profile in Details

- Expertise in ICSR (Individual case safety report) Triaging, case processing, Quality check
 of ICSRs and submissions.
- Entry in case activity tracker, FUP ADR tracker (MQT)
- · Triaging of spontaneous cases.
- Book in of cases in ARGUS database.
- Full data entry including duplicate check, entering source data in the database, MedDRA Coding, narrative(s) writing, and labelling of events.
- Evaluation and review of literature articles for identification of valid/potential ICSRs for processing.
- Quality check of individual case safety reports in ARGUS.
- Quality review for spontaneous, literature, true spontaneous, post-marketing clinical study, regulatory and courtesy cases in ARGUS database.
- Review and evaluate AE case information to determine the validity of a case, seriousness, and expeditedness as per client and internal policies and procedures.
- Receipt and evaluation of safety data exchange agreements (as applicable) for sharing and other obligations.
- Generation and submission of reports to different regulatory authorities in the ARGUS safety database.
- Reconciliations for LRPs.
- Management of Compliance with the Company's Standard Operating Procedures and regulatory requirements.
- Liaise effectively and maintain excellent relationships with the internal/external contacts
- Maintain awareness of changes to/new regulations affecting pharmacovigilance activities. Communicate new or changed regulations to relevant members of the department to initiate any change in processes
- Builds and maintains good relationships across functional units and company affiliates
- Remain up-to-date with the latest information on the assigned product(s).
- Trains and mentors new employees in PVG (as required)

ACHIVEMENTS

 Appreciated and Recognised as top Performer of the Year for consecutive 2 years (2020, 2021-22)