ROMA AJIT PANDIT

☏+91-9427010542; +91-8655063101

✉ romanayak22@gmail.com

CAREER OBJECTIVE

To be a part of a progressive organization where my skills and experience can be utilized to improve quality and operational efficiency to achieve personal, team and organizational success.

SUMMARY

- Around 8.5 years of experience in the Pharmacovigilance.
- Experienced in case processing, literature management, aggregate reports (PADERs and PSURs/PBRERs), Medical information and SDEA management, compliance metrics management.
- Well-versed with various safety databases - ARISg, SCEPTRE, Sapphire, Global AERS and PV247.
- Subject Matter Expert for developing in-house database,
- Skilled in SOP development, Technical Agreement / Safety Data Exchange Agreement, Team and Project management.

CORE COMPETENCIES

- Process Improvements
- Team Management
- Relationship Building
- Scientific knowledge
- Good Communication Skills
- Resource Allocation
- Computer Skills
- Project Management

WORK EXPERIENCE

❖ **APCER Lifesciences** — **Senior Pharmacovigilance Associate (Acting Team Lead)** — ***May-2018 to Jan-2021***

- Compliance management – Preparing metrics for SOP and regulatory compliance
- Participate in audits and regulatory inspections in cooperation with QA, and perform RCA, impact assessment and CAPA management
- Ensuring timely delivery, investigation and query resolution including escalating critical calls to concerned manager and clients
- Updating Project progress and daily status to the stakeholders including client and QPPV
- Generation of line listings for aggregate reports (PSURs/PBRERs, PADERs). Support during preparation of reports
- Monitoring the work progress for all workflows from Literature screening to Submission of ICSR
- Monitoring SDEAs and managing sharing obligations as per SLA
- Monitoring, Tracking of Deletion/Nullification cases, Product Quality Complaints, and Translations with relevant departments, vendors, and client.

ROMA AJIT PANDIT

☏+91-9427010542; +91-8655063101

✉ romanayak22@gmail.com

Achievement

- Certificate of Recognition for Quarter 2 (Oct 2018)

❖ **Cliantha Research Limited** **Pharmacovigilance Officer - 2** ***Jun-2016 to May-2018***

- Preparation of Periodic Benefit Risk Evaluation Reports (PBRERs) and Periodic Adverse Drug Experience Reports (PADER)
- Generate periodic reports from safety database as well as review safety line listings as required
- Review initial and follow up information, case narratives, medical coding in global safety database
- Perform expedited reporting / submissions to Regulatory authorities
- Participate in audits and regulatory inspections in cooperation with QA, and perform RCA, impact assessment and CAPA management
- Review and preparation of SOPs, training materials, providing inputs to SOPs
- Monitor workload and allocates resources appropriately
- Ensure that incoming Adverse Events are processed by the team within timelines
- Monitor the quality of work produced by the team and support quality improvement initiatives
- Provide feedback to team members on quality and train team members as appropriate to improve quality.
- Establish and maintain effective project communications by representing department at interdepartmental project team meetings to understand and adhere to specific safety reporting requirement.

Other Activities

- Handling of Safety Mailbox and Client specific mailbox
- Possess general working knowledge of local and international PV regulatory framework and remain up-to-date on regulation changes
- Serve as Subject Matter Expert for development of E2B complaint Global Safety Database

Achievement

- Successfully completed **XEVMPD knowledge evaluation examination** of European Medicines Agency and hold certificate for same.
- Completed online training course on **'Signal Detection and Causality Assessment'** arranged by Uppsala Monitoring Center (UMC)
- Awarded as Quarter of the Employee as well as Month of the Employee

❖ **Lupin Limited** **Drug Safety Officer** ***Oct-2015 to Feb-2016***

- Case processing in ARISg - MedDRA + WHODD coding, narrative writing, peer review, case follow-up, check label approvals, causality assessment of AEs and SAEs from sources like literature, regulatory (MHRA and BfArM) and spontaneous
- Co-ordinate with the Cross functional department for resolving product complaint or product queries like quality control and quality assurance department
- Handling Medical Information queries, recording adverse drug reactions and product complaints
- Data entry of medical information in Lupin's application for Medical and relevant Knowledge (LaMarK)

ROMA AJIT PANDIT

☏+91-9427010542; +91-8655063101

✉ romanayak22@gmail.com

❖ **Sciformix Corporation** **Junior Safety Data Analyst** ***May-2014 to Oct-2015***

- Responsible for In-Line Quality Review (ILQR) of case processing in SCEPTRE database, MedDRA and WHODD coding, narrative writing, peer review, case follow-up, check label approvals, causality assessment and reporting to submissions team
- Address queries raised by Local Safety Officers (country specific)
- Cases processed from various sources - spontaneous, solicited, literature and clinical trial cases
- Also, pro-actively perform ad-hoc activities of assigning cases to QR team and collating status at EOD
- Additionally, handle client mailbox (back-up activity)

Achievement:

- Received many appreciation mails and SMART cards for productivity and quality of the cases processed

❖ **Tata Consultancy Services Ltd.** **Patient Safety Specialist** ***Aug-2012 to Feb-2014***

- Perform initial triage of the received safety notifications from Spontaneous and Clinical Trial source
- Responsible for drug safety data management process in Sapphire database - case review, safety and medical assessment, case validation (medical coding, causality assessment, seriousness assessment, safety narrative writing)
- Full narrative writing and Development Safety Update Report (DSUR) writing
- Co-ordinate with sponsor and sites for any discrepancy and incompleteness in source documents

Achievement:

- Received 'Star Performer' certificate for the month of September'13.

❖ **GeBBs Healthcare Solutions** **Process Associate** ***Sep-2011 to Jul-2012***

- Underwent ICD-9 CM Training and as a Coder had responsibility to read appropriate diagnosis and code them as per ICD-9 CM guidelines and link codes to their respective CPT codes
- PharMerica - Data Entry of Patient Administration info and Physician's prescription
- Experience of Epost Rx software in the process of Enclara which deals with Clinical Services

CONFERENCES ATTENDED

- Attended 14th Pharmacovigilance 2017 held on 09 Nov 2017 at Mumbai, India
- Attended 2nd Annual Pharmacovigilance Summit held on 26 Oct 2017 at Mumbai, India
- Participated as Delegate in the education activity 'DRUG DILIGENCE 2017' organized and conducted by VHEO Ventures in knowledge participation with OviyaMedSafe Pvt. Ltd. at IMA Hall, Coimbatore on March 17 & 18, 2017
- Presented a Paper on Topic 'Need for development of Centralized e-Reporting system in India' in the education activity 'DRUG DILIGENCE 2017' March 18, 2017

ROMA AJIT PANDIT

☏+91-9427010542; +91-8655063101

✉ romanayak22@gmail.com

EDUCATION

- Completed **Bachelor of Pharmacy** from University of Mumbai in 2011 with 69.3 %
- Registered Pharmacist under Pharmacy Council of India

PROFESSIONALACTIVITIS

- Participated as Delegate in the education activity 'DRUG DILIGENCE 2017' organized and conducted by VHEO Ventures in knowledge participation with OviyaMedSafe Pvt. Ltd. at IMA Hall, Coimbatore on March 17 & 18, 2017
- Presented a Paper on Topic 'Need for development of Centralized e-Reporting system in India' in the education activity 'DRUG DILIGENCE 2017' March 18, 2017
- In-plant training in Galentic Pharma [India] Pvt. Ltd. From 01.06.2010 to 30.06.2010
- Participated in ICMR sponsored "One Day Workshop on ICH-GCP Training" jointly organized by Shivrath Centre of Excellence in clinical research (a joint venture with GSBTM, Govt. of Gujarat) and Clinical Research Programs, Gujarat University, Ahmedabad on 6th August 2011
- A review article on IMPURITY PROFILING OF PHARMACEUTICALS has been published in Advance research in Pharmaceuticals and Biologicals in VOL - 1(2) OCT-DECEMBER 2011
- Participated in Young Innovator's Choice Competition (YICC) held during 11th - 14th January 2010 at Institute of Chemical Technology (ICT), Deemed University (under section 3 of UGC act, 1956), Mumbai
- Participated in Annual Extension Activities for not less than 120 hours related to Information Technology Project in the Academic Year 2009-2010
- 57th rank at Junior Level in National Level Pharmacy Talent Search Examination-2009 (online) held on 1st March 2009

LANGUAGES KNOWN

English | Hindi | Marathi | Gujarati

PERSONAL DETAILS

Gender	Female
Date of Birth	22 April 1989
Marital Status	Married
Nationality	Indian
Permanent Address	11, Karuna Society, Nava Vadaj, Ahmedabad - 380013, Gujarat. India.

DECLARATION

I hereby declare that the information furnished above is true to the best of my knowledge.

Place: Ahmedabad

Roma Ajit Pandit