Supriya Dattatraya Khade

Scientific Writing Lead

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Location: Pune

Summary

A postgraduate in Masters in Pharmacy (Pharmacology) with over 7.7 years of specialized experience in pharmacovigilance, focusing on Medical Writing and Aggregate Report Writing. Seeking an opportunity to leverage my expertise in these areas to contribute to organizational growth while further advancing my professional skills and knowledge. Eager to expand my proficiency in pharmacovigilance and explore new facets of the field to support both personal and organizational development.

Skills

- External Team Collaboration - Ability to communicate scientific and/ or medical information in a clear and concise manner with clients as well as internal colleagues
- Proficiency in Word, Excel, and PowerPoint
- Excellent Communication Skills
- Ability to work in a team with diverse backgrounds
- Agile learner
- Trainer and mentor
- Flexibility, Problem Solving Skills, Organization Skill

Total Work Experience: 7.7 years

Indegene Pvt. Ltd., Bengaluru, Karnataka, India – Aug 2024 – Till Present

Scientific Writing Lead

- Managed two projects with different clients, delivering reports as per requirements.
- Training and mentoring new joiners as per client's requirement, identifying knowledge gaps and conducting additional refresher training as and when required
- Managed team performance, with a focus on onboarding and developing new team members, as well as overseeing the progress of those reporting to me.
- Led continuous process improvements to enhance content quality.
- Provided guidance to ensure consistency in project deliverables, including content, format, style, and compliance.
- Authored and reviewed Periodic Signal Analysis Report (PSAR) and Aggregate reports including Periodic Benefit Risk Evaluation Reports (PBRERs), Addendum for Clinical Overview (ACOs), Canadian Annual Summary Reports (CARs) and China Feedback Safety Data Analysis Report (CFSDAR) and managing the full

document lifecycle while ensuring quality, timeliness, and compliance with internal/client SOPs and regulations. All other responsibilities remain the same as previously outlined.

Key responsibilities:

- Attended and supported audit inspections.
- Provided guidance and support to team members on client-defined project processes, ensuring consistency, completeness, and compliance with format, style, and content standards.
- Assisted in Generative AI literature testing.
- Trained and mentored new team members.
- Provided monthly metrics and ongoing feedback to team members.
- Served as the primary point of contact for resolving report-related queries and securing client confirmations.
- Delivered refresher training to the team as needed.
- Developed training plans for new joiners.
- Managed transition activities during project exit.
- Monitored daily project activities, including leave management.
- Evaluated team performance during appraisals.
- Updated CVs and job descriptions as team members joined or changed roles

Indegene Pvt. Ltd., Bengaluru, Karnataka, India – Aug 2021 – Till Jul 2024

Senior Associate – Scientific Writing

- Trainer (internal and client side), and responsible for mentoring new joiners, identifying gaps in knowledge for individual team members, and conducting further trainings as required
- Authoring and review of Periodic Signal Analysis Report (PSAR) and Aggregate reports including Periodic Benefit Risk Evaluation Reports (PBRERs), Addendum for Clinical Overview (ACOs), Canadian Annual Summary Reports (CARs) and China Feedback Safety Data Analysis Report.
- Responsible for the entire life cycle of the document and accountable for maintaining quality and timeliness, and compliance to internal/client SOPs and regulations.
- Keeping track of variation (SmPCs, PRAC or CMDh updates) filed or submitted for respective regions.
- Exposure estimation for scheduled and non-scheduled reports based on (assessment for different formulation, indications etc.)
- Keeping track records of completed/ongoing interventional or noninterventional trial data for inclusion of its data.
- Assessment/analysis of signal/safety topics/HA issue sections. (Creating search strategy for risk/signals)
- Conducting literature search for authoring various aggregate reports.
- Conducting Kick-off meetings whenever required, which includes identifying and reaching out to the required stakeholders, ensuring the meeting is conducted by the specified due date, ensuring all essential topics are covered and closed, capturing, and sending out the meeting minutes, etc.
- Performing allied activities like generation of line listings and summary tabulations from Argus database and client specific database
- Providing inputs for Benefit/risk evaluation sections (sections 17 and 18)

- To Draft and Review documents on a timely manner, liaise with subject specific stakeholders, set up review comments resolution meetings when needed, facilitate QC process, ensure documents are submission-ready before facilitating approval and handover over of the document to clients.
- Discuss project details and obtain clarification on specific questions/issues/gaps with project POC.
- Ensure that clinical documents adhere to current global standards regulatory guidelines and are in accordance with electronic publishing standards.
- People management, especially for the new team members.
- Responsible for continuous process improvement in the team for developing better quality content.
- Providing guidance and support to all team members on a project. Ensuring consistency and completeness of information, format, style, content, and compliance.

Employment History

Covance Scientific Services and Solutions Pvt. Ltd., Pune, Maharashtra, India – Nov 2018 to Aug 2021

Medical Writer / Scientific Safety - Science Specialist I (internal title change as of Oct 2020**) –** Nov 2018 – Till Present

- End-to-end authoring and Peer review of Canadian Annual Safety Reports (CAR) and PBRERs
- Writing subject narratives for adverse drug reactions and serious adverse events
- Line listings and Summary tabulations generation
- Literature extraction, review, and selection
- Conducting search on various regulatory websites
- Hands on experienced on Argus Safety database and Embase, PubMed literature database
- Any additional activities as per the project requirement or manager's discretion on completion of relevant trainings.
- Responsible in implementing and promoting use of consistent, efficient, and quality processes to meet timelines and deliverables according to requirements and standard operating procedure.
- To ensure compliance of operations with governing regulatory requirements.

Ipca Laboratories Pvt. Ltd., Mumbai, Maharashtra, India – Dec 2017 – Oct 2018

Drug Safety Executive – Dec 2017 – Oct 2018

- Drafting of aggregate reports including PBRER, and the PADER.
- Writing subject narratives for adverse drug reactions and serious adverse events
- Retrieve worldwide data from the Supply Chain Management database
- Literatures extraction, review, and selection from Embase and suggested authenticated websites
- Line Listings generation from Argus Safety database
- Draft and analyze ICSR cases in the aggregate reports.

Drug Safety Associate – Apr 2017 – Nov 2017

- Individual case safety reports (ICSR) processing in Argus database
- ICSR Narrative Writing
- Literature extraction from Embase database
- Validity checks for extracted literatures as per selection criteria
- Booking valid cases into Argus Safety Database

Language Capabilities

- English (Level 5)
- Hindi (Level 5)
- Marathi (Level 5)

Education

- Masters in Pharmacy (Pharmacology), Nagpur University, Maharashtra, India.
- Bachelor in Pharmacy (B. Pharm) Nagpur University, Maharashtra, India.
- Diploma in Pharmacy (D. Pharm) Nagpur University, Maharashtra, India

Signature: *Supriya* Date: Jan-2024