CURRICULUM-VITAE

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Objective:

To obtain a challenging role in Pharmacovigilance that will capitalize on my technical, analytical and managerial skills for professional growth in a continuous learning and challenging environment.

Work Experience:

Organization Name	Location	Designation	Duration
Tata Consultancy Services	Mumbai, Maharashtra	Business Process Lead	Dec 2013 till date
Cognizant Technology Solutions	Mumbai, Maharashtra	Junior Data Analyst	May-2011 to Nov-2013

Roles and Responsibilities:

Tata Consultancy Services (Dec 2013 - till date)

Working in TCS Drug Safety department and associated with the processing of Individual Case Safety Report (ICSR) in the safety database of client. Currently working on ARISg safety database.

Review of literature articles to identify type of report (spontaneous, study and non-interventional cases) and assessing the validity of cases.

Ensure quality of literature review and reporting. Performing the quality review of the citations that are processed by DSA of accuracy of data entered in data base as per source document, identifying clinically significant information missing from initial reports and ensuring its collection processors.

To attend client meetings, client teleconferences as required and to take sessions to the DSA's on recent updates in the process and answer all the queries of the cases.

Also Accountable for handling ICSRs disposition of valid items into ARIS from IRT for further processing in ARISg (case initiations).

Responsible to carry out Quality review activity by performing accurate data capture for individual case safety reports which can be spontaneous, clinical, NIP and NIS cases. Draft and QC of Narrative writing as per regulatory format.

Sending MEDdra requests as needed and discussing with operation physician team regarding the amendment/split and raising queries regarding the events.

Accountable for performing the appropriate clinical assessments (including the assessment of seriousness, labeling and company causality for each adverse event) adhering to SOPs/other controlled documents and regulatory requirements.

Assuring and maintaining compliance with regulatory and local/global SOP timelines using proactive workflow management.

Developing and maintaining knowledge of the appropriate disease biology areas and associated client's product knowledge.

Identifying potential SUSAR's cases and process them on priority.

Raising queries to Safety Responsible personnel for missing information.

Generation of HCP and Non-HCP follow up letter for required cases.

Accountable for been part of mentoring and has also coached new associates in the process and also backup for the team activities.

Cognizant Technology Solutions (May-2011 to Nov-2013)

Hands on experience on ARGUS safety data base, MedDRA, WHO DD, individual case safety report (ICSR), narrative writing, including literature reports, Spontaneous reports and post marketing surveillance reports.

Receive information on adverse events, perform initial checks, triaging of cases, search database to prevent duplicate entries, create case file and initialize received drug safety reports in the tracking tool and/or safety database

Ensure scientific rigor through accurate, complete and consistent data entry of adverse event reports from source documents with emphasis on timeliness and quality.

Evaluate and finish processing of expedited and non- expedited AE reports, including review for completeness and accuracy.

Prepare narratives summarizing the essential details of the case.
Identify clinically relevant information missing from case report and facilitate its collection (in consultation with medical staff as required) by preparing follow-up request as needed.

Book –in case in Argus Affiliate and Reconciliation of all cases received.

Escalate critical calls to concerned managers/clients.

Liaise effectively and maintain good relationship with the clients and internal/external contacts.

Academia:

- 2011 post graduate Diploma in Clinical Research from Academy for Clinical Excellence, Bombay College of Pharmacy, Mumbai
- 2011 post graduate Diploma in Drug Regulatory Affairs from I.P.E.R, Pune
- 2010 Bachelor's Degree of Pharmacy from Mumbai University

Pharmaceutical Plant training:

30 days of training associated with complete study of injection and oral of manufacturing plant at Pharmax India pvt. Ltd Ghatkopar

Other Skills:

- Good verbal and written communication
- Willingness to learn
- Good Team member

Computer Skills:

- MS- Office: MS-Word, MS-Excel, MS PowerPoint
- Operating system: Windows98, XP, Vista, Windows7

Activities & interests:

Listening to music, cooking

Personal Outline:

Date of Birth: 18 May 1987
Marital Status: Single
Language Proficiency: English, Hindi, Marathi, Gujarati
Address**:** 3/Apna Ghar Tenent, Opp. Pankaj (A) bldg., Nr. Roa Hotel, LBS Marg, Ghatkopar (West) Mumbai 400 086.

Declaration:

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

(Anjali Lalji Sonkar) Date: