CURRICULUM VITAE

SAURABH VIJAYRAO NIWAL

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A pro-active, passionate and skilled Pharmacovigilance Specialist with a view to utilize my interest, credentials and work experience in case processing, narrative writing and literature searching/reviewing. A thrive to learn new skills for influencing them around positively, subsequently adding value and growth to the company.

SNAPSHOT

- Working in healthcare industry (Pharmacovigilance) with an overall experience of 10 Years
- Worked as Senior Safety Scientist II (Role-Team Lead) in Pharmacovigilance department at Qinecsa/Bioclinica solutions (1.2 year).
- Earlier worked as a Senior Process Associate in Pharmacovigilance department in Tata Consultancy Services (5.3 Year).
- Earlier worked as a Junior data analyst in Pharmacovigilance department in Cognizant technology solutions (3.2 years).
- Earlier worked as lecturer at SBG College of Pharmacy, MSBTE, Pulgaon in year 2012.
- Work as M pharm research fellow for the year 2010-2012, SGBA University, Amravati.
- Completed industrial training in Clinical Research Department, at Serum Institute of India Ltd. Pune on Post marketing surveillance study of H1N1 (live, attenuated) influenza vaccine in 2011.

ON-JOB EXPERIENCES& RESPONSIBILITY

AS TEAM LEAD RESPONSIBILITY:

- Ensure all serious and non-serious ICSRs (individual case safety report) are processed by the team members as per regulatory timelines and service level agreements.
- Provide feedback to the team members for findings, ensure the corrections have been performed and document the results.
- Ensure team members plan, organize, and manage daily work to meet service level time lines and deliverables.
- Ensure compliance with Business policy and contractual requirements of the company.
- Perform appraisal for the whole team periodically.

ASSOCIATE LEVEL RESPONSIBILITY:

- Receive information on adverse events, perform initial checks, search data base to prevent duplicate entries, create case in Argus data base.
- 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 AE reports including review for completeness and accuracy.
- Perform labeling for serious and non serious cases.
- Responsible for completion of day to day work.
- Use of MedDRA and business guidance to code medical history and AE terms.
- Use of Company Drug Dictionary (CDD) and WHO dictionary for coding of drugs.
- Prepare narrative summarizing the essential details of the case.
- Work with clinical safety scientist to improve quality.
- To coordinate with internal team to obtain necessary information required for day to day operations.
- Maintaining data as per the customer guidelines

- Identify clinically relevant information missing from case report and facilitate its correction.
- Process current incoming cases in order to meet timelines

SCHOLASTICS

- Master in Pharmacy in pharmacology from P. Wadhwani College of Pharmacy, SGBA University, Amaravati in 2012 with 69.44%.
- Bachelor in pharmacy from IPER, RTMNU Nagpur, 2010 secured 59.45 %.
- HSC from Maharashtra state board, Nagpur division in 2006 with 60 %.
- SSC from Maharashtra state board, Nagpur division in 2004 with 67.46%.

RESEARCH PROJECT

Title : To study the effect Aloe Barbadensis in gastrointestinal complication using diabetic rats.
Technique : Pharmacological, Biochemical, Pathological, Analytical.
Description : Effectiveness of Aloe Barbadensis on GI emptying, Intentional transit, Change in Blood parameters, body weight gain and physical activity of animals.

KEY SKILL SETS AND QUALITIES

- Familiar with tools and software utilized in Pharmacovigilance (PV) Drug safety ICSR i.e., Argus (Version 7.0.5 and Advanced Version) - A pharmacovigilance safety database is the central repository for individual case safety reports ICSR.
- Handled Bio connect Enterprise sales force application for Source documents repository accession, operate IRPC application for Source documents repository accession and Documentation Specialist.
- MEDRA coding - Medical Dictionary for Regulatory Activities is a clinically validated international medical terminology and WHO Dictionary.
- Ms-Office (Advance Excel, Macro, Excel and Outlook integration, MS-PowerPoint, MS-Word), Internet applications, search engines, advance features of MS Teams, etc.
- Possesses qualities of a good team player by effectively handling relationship with colleagues, key stakeholders on project teams, customers, line management, etc
- Strong written and verbal communication skills considering cultural differences of Results and detail-oriented approach to work delivery and output.
  Good problem-solving skills
  Good planning, time management and prioritization skills
  Conflict management
  Attention to detail and accuracy in work
- Bear knowledge of clinical trial conduct, and skill in applying applicable clinical research regulatory requirements i.e., Good Clinical Practices (GCP), ICH guidelines and Regulatory authorities.

PERSONAL DOSSIER

Date of Birth: 18thFeb1988
Address: Gandhi Chowk, Pulgaon :-442302.
Languages: English, Hindi and Marathi

DECLARATION

I hereby declare that the above written are true to the best of my knowledge belief.

Saurabh Niwal