46/182 Government ‘E’ Colony,
Opp, Amber cinema, Bapunagar
Ahmedabad, 380024
9978367715
Kirdhirvaghela@gmail.com

KIRAN VAGHELA

Career Objective

To secure a challenging position where I can effectively contribute my skills combined with knowledge in positive growth of my carrier and organization.

Relevant experience in Pharmacovigilance

- Torrent pharmaceutical Limited – Scientist-II Global PV from 04-Oct-2021 to present.
- Lambda Therapeutic Research Ltd. As research associate from 17-May-2021to 14-Sep-2021.

Roles and Responsibility

- Prescribing Information: Preparing and ensuring the quality of prescribing information and then uploading it to the appropriate relevant platforms.
- Skilled at producing and ensuring the quality of a variety of aggregate reports, including
  - Periodic safety update reports (PSURs)
  - Risk management plans (RMPs)
  - A risk evaluation and mitigation strategy (REMS)
  - Periodic adverse drug experience reports (PADER s)
  - Development safety update reports (DSURs)
  - Periodic benefit-risk evaluation reports (PBRERs)
  - Drug Safety Report (DSR), Clinical Overview (CO) and Safety Evaluation Report (SER).
- Spontaneous Reporting: Proficient in managing the spontaneous reporting process for adverse events (AE), product quality complaints (PQC), and medical inquiries (MI) and Health hazard evaluation (HHE). Skilled in receiving, triaging, and documenting spontaneous reports in accordance with regulatory guidelines and internal procedures. Experience in assessing the seriousness and causality of reported events, conducting follow-up investigations, and coordinating with cross-functional teams for resolution. knowledge of pharmacovigilance principles and adverse event reporting requirements, including timely submission to regulatory authorities.

- Quality Check of Signal Detection: Ability to conduct complete quality checks of signal detection activities within pharmacovigilance and drug safety processes. Skilled in reviewing and validating signal detection outputs, ensuring accuracy, completeness, and adherence to regulatory guidelines and best practices. Strong attention to detail and ability to identify and resolve any discrepancies or errors in signal detection outputs.
- Master Product Datasheets: Proficient in creating and maintaining comprehensive and accurate product datasheets. Skilled in gathering and organizing and updating product information from various sources.
- Processing and quality review of ICSRs originating from clinical, spontaneous, literature and legal sources.
- Distribution of cases for QC among the team members on a regular basis.
- Compliance Monitoring: Skilled in tracking and monitoring compliance of submissions to meet client and international regulatory requirements.
- Literature QC, Medical information call center (MICC), Track wise (change control form) SAP (Systems, Applications & Products in Data Processing).
- Support PVRP for oversite of pharmacovigilance service provider PVSP activities

Technical Skills & Abilities

- Work with Global PV
- Microsoft office, word, excel, power point.
- Time management and problem-solving abilities.
- Multitasking, adaptive to any environment.
- Willingness to learn and team work.
- Strong written and verbal communication
- Punctual
- Quality oriented approach
- Excellent attention to details.

Academic Qualifications

M.PHARM	GTU	L.M.Collage of pharmacy	87%	July 2020
B.PHARM	GTU	SSPC, Zundal	70%	May 2018

Personal Information

- DOB: 04-Jan-1996
- Marital Status: Single
- Language: Hindi, English & Gujarati (Speak and write)
- Hobbies: cocking, traveling, reading
- Permanent address: Gujarat, Ahmedabad 380024.

Declaration:

I do hereby declare that the above stated particulars are true, complete and correct tothe best of my knowledge.

Kiran.B.Vaghela