L.LOGIDHASAN

SDM Specialist

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918428428478 Chennai, India

GitHub LinkedIn

Skills

Python, Data Visualization, SQL, LLM,

Machine Learning, Deep Learning, Selenium web scraping, Power BI, MongoDB, BeautifulSoup, Django, HTML, Web Designing

Education

Master of Pharmacy (Pharmaceutic), PGP College of Pharmaceutical science and Research Institution, 2011 -2013 | Namakkal

Bachelor of Pharmacy, Pallavan Pharmacy College 2007 -2010 | Kanchipuram

Diploma in Pharmacy, SRM College of Pharmacy 2004-2006 | Chennai

IIT-M - Artificial Intelligence and Machine Learning
IIT-M GUVI, Chennai
Oct-2023 – Jun-2023 | Chennai

Certificates

Profile

Experienced in Safety Data Management with 10+ years. Capable of managing all types of cases (clinical trial cases, spontaneous cases, and literature cases).

In-depth knowledge of Good Pharmacovigilance Practices (GVP) modules, ensuring compliance with regulatory standards.

Proficient understanding of International Council for Harmonisation (ICH) guidelines, contributing to the development of safe and effective pharmaceutical products.

Professional experience and responsibilities:

Pfizer Inc (Apr 2018 – present | Chennai)

Hands-on experience in processing multiple License Parties' reports, Health Authority reports, and drafting narratives for literature, PMS, clinical trials (including SUSAR), and Spontaneous ICSRs (Individual Case Safety Reports) as per regulatory guidelines.

Act as subject matter expert and liaise with key partners regarding safety data collection and data reconciliation

Review, analyze, prepare, and complete safety-related reports within scope to determine the safety profile of Pfizer's products and to meet regulatory requirements.

Review processed cases to verify accuracy, consistency, and compliance with process requirements, and review case data for special scenarios.

Accenture Services Pvt Ltd (Jun 2014 – Apr-2018 | Chennai)

Working on ARGUS safety database server for End to End ICSR case processing.

Receive information on adverse events, perform initial checks, search database to prevent duplicate entries, create case files, and initialize received drug safety reports in the DS&E tracking tool and/or safety database.

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

Use medical dictionaries and business guidance to code medical history, drugs, and adverse event terms. Prepare narratives summarizing the essential details of the case.

Ensure accurate and consistent coding of medical history, drugs, and adverse event terms by using WHO DD and MedDRA dictionaries.

Assess adverse event reports for seriousness, causality, and expectedness as per the labeling documents CDS, EMEA, Investigator Brochure/Basic Prescribing Information/US package insert.