SANDEEP LAXMAN BORDE

CONTACT:

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Objective -

- Drug development process – New drug goes through to be brought to market - Discovery and development, preclinical research, Clinical research, FDA review, FDA post market safety monitoring.
- Regulatory Compliance – It include variety of laws regulation and guidance documents. Clinical trials, IND application, GMP, Investigational device Exemption.
- I have experience as a data migration specialist with a background in regulatory affairs, data migration, and data validation within the pharmaceutical industry.
- demonstrated expertise in managing complex data migration projects, ensuring data integrity, and implementing regulatory compliance processes and specializes in IDMP implementation, Veeva Vault data migration, XEVMPD submissions, and using tools such as Liquent Insight and SPOR systems.
- Experience leading the migration of regulatory data, enriched data sets, and mapped information to support IDMP projects while coordinating with key stakeholders to meet compliance requirements.
- I have strong experience in managing large-scale data migration and enrichment projects across global markets, ensuring high data quality and accuracy through rigorous QC processes.
- Proficient in tracking regulatory activities, conducting data cleanup operations, and resolving system discrepancies using GPP tools. ability to streamline data processes and support lifecycle management has been integral to maintaining the consistency and reliability of regulatory information systems.

Education

Bachelor's of Pharmacy (B-Pharma)

Specialization -Science

Year: 2011-2014

Grade: 62.15% (first class)

Professional Skills:

- Data Migration
- Data Enrichment
- Data Mapping
- XEVMPD submission
- Implementation of IDMP
- Veeva vault data migration.
- Liquent insight tool System (GI)
- Insight for viewing System
- EV (Eudravigilance Web)
- Veeva vault system
- SPOR System
- XEVMPD sheets.

PROFESSIONAL EXPERIENCE -

Genpact Pharma Pvt Limited **DEC 2022 to SEP 2024**
Lead associate - Regulatory affairs

Takeda Client

- Development and implementation of organizational technical learning strategies.
- To provide support and coaching on regulatory information management (Regulatory requirements, IDMP, xEVMPD) to the regulatory team.
- Identification of key learning needs for the organization through the department and handling IDMP (identification of medicinal projects) implementation projects (PRISM and GRACE), OMS values analysis, and tagging regulatory activities.
- Data mapping: responsible for collecting data from multiple sources, i.e., xEVMPD, SMPC (summary of product characteristics), PIL (patient information leaflet), and SPOR data (SMS, PMS, OMS, and RMS) updated in the Excel sheets.
- Data Migration: Migrate all data in the Veeva system. Responsible for the creation of applications, events, registrations, regulatory objectives, and submissions in the Veeva vault system and maintaining the lifecycle of the registered product.
- Highlights or identify gaps in existing RIMS functionalities
- Responsible for providing training or coaching where required to new joiners.
- Proactively involved in quality discussion about all processes.
- Completed all assigned project tasks and trainings within target timelines with high quality.
- Report extracts by using multiple data and circulation to multiple stakeholders to support their day-to-day activities.

Teva Pharm India PVT. Ltd. **Jul 2017 to Dec 2022**

Regulatory Affairs Associate I – Data Migration, Data Management, data clean up

- Performed quality control (QC) and data integrity checking as part of the RIM Central Data Services operations to confirm the accuracy and completeness of the Teva Global Registration database.
- Worked on different projects such as US project, Canada project, ROW market and Europium countries markets for data migration, data enrichment, data clean up, annual reports activity, e-CTD submission in liquent insight system (GI), GPP tool system, XEVMPD submission, and Veeva vault system.
- Tracking of registration activities and status to be delivered on demand that meet internal business needs and RA requirements.
- **Data Migration and Data Enrichment (Teva Products)**
  Pre-approval: Responsible for creating applications, events, and registrations in the global insight tool system. (eCTD submission)
  Post approval: To collect data from multiple sources from the regulatory team and stakeholders and update the PDS (product detail sets, package sets, labeling, storage conditions, indications, and manufactures) and maintain and update other events as per regulatory requirements (i.e., post approval requests) in the GI system (Liquent Insight Tool system) and Veeva system.
- Ensure correct data entry in line with SOP.
- **XEVMPD (Extended Eudra Vigilance Product (Article 57 Database)**: Electronic submission and maintenance of different types of medicinal products; addition of any object or substance in XEVMPD via XEVPRM; EV code will be generated. Importance of the xevmpd to support the pharmacovigilance activity in EU.
- Contributing to IDMP data management activities like OMS, RMS, and data catalogue.
- Provide best practices and updated guidelines to team support their day-to-day activities.
- **Data gap analysis and clean-up**: This process is used only for the addition of missing data in the GI tool system.
- Worked with IT and/or vendors on software problem resolution, escalation, and enhancement.
- Communication with the external team and resolving queries related to the application and raising tickets as per requirements.
- Reports circulation to multiple stakeholders to extract information on global registration status of products to support their day-to-day activities.
- **GPP tool** - to remove duplication and multiple data entry errors in the GI tool system.
- Data validation: ensure accuracy and integrity of data before its use in business operations.
- Standardized data collection protocols and maintaining the lifecycle of registered products.

- Interacting with the global regulatory team for submission and collecting information to maintain good data management for different countries.
- Trained new team members on register software and given trainings with the help of PPT presentations.

India bulls Foundation pvt ltd and Shree Swami Samarth Medical Shop

Jan 2015 to Dec 2017
Pharmacist

- Dispensed medicine to the patients with the help of prescription.
- To answer incoming calls and respond to clients' queries.
- Maintained records of delivery of goods to customers. Handled clients' complaints professionally, ensuring timely delivery of medicine to the customer.
- Ensured that all documents were completed accurately and in a timely manner.

Tools -

RIMS (global Liquent Insight - TEVA), Insight for viewing, Wisdom, xEVMPD, Basic understanding about Veeva vault, MS Office –Word, PPT, SharePoint, teams.

Skills -

- Good grasping power and Active listening
- Positive attitude and Critical thinking
- Problem solving
- Regulatory reporting, Operational excellence, database
- Data and Project management

Licence –

Registered with Medical licences of Maharashtra.

Declaration -

All information in this resume is right and truthful to the best of my knowledge and faith.