Pranidhi Chauhan

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CAREER OBJECTIVE

A Registered Pharmacist with hands-on experience in Clinical Research. Seeking for a challenging position where I will get a chance to utilize my knowledge and my experience to attain organizational goals and provides an opportunity for my personal and professional

SUMMARY OF EXPERIENCE:

Pharmacovigilance including triage, data entry and validation of Individual Case Safety Reports (ICSRs) of various case types (spontaneous, clinical studies literature and solicited programs), Literature and Regulatory intelligence screening, Submission of ICSR, MICC.

PROFESSIONAL EXPERIENCE:

COD Research, Ahmedabad, India-

(01-Jan-2022 to Till Date)

Job Responsibility-

- Receipt of incoming case information via project specific mailbox/fax/phone line daily or via an automated SAE notification e-mail and/or EDC system per project requirements and review of same.
- Compliance check activities for medical information management system
- Tracking and triage of case information for processing.
- Prioritize incoming AE/SAE information for further processing and confirm receipt, as required from multiple sources like spontaneous, clinical trial, literature, legal, regulatory, business partners, etc.
- Identify potential 2-day, 7-day, 15-day, 30-day and 90-day alerts or as per regulatory/Client requirements.
- Consults/Communicates with multiple internal and external stakeholders (e.g. sponsor / medical monitor /pharmacovigilance physician) to decide on action and/or additional steps to provide complete narratives to the sponsor/client or any other requirements.
- Conduct active follow-up for clarification and missing case details with reporter (e.g. site / clinical study team / HCP / patients / caregiver, etc.)
- Enter initial and follow-up information in the safety database according to the project requirement as required.
- Perform coding for all required medical/drug term according to given coding dictionaries and applicable coding guidelines.
- Develop case narratives, per project specific templates.
- Provides final narrative and/or CIOMS form/ MedWatch form/ XML/ Line listing generated to the client, as applicable.
- Perform quality review of cases, as applicable and provide feedback to case processor and/or medical reviewer.
- Data retrieval from safety database and EDC system, as applicable.

- Perform/co-ordinate expedited reporting according to project-specific requirements.
- Participate in audits and regulatory inspections in co-operation with QA, as needed.
- Generate validated ad-hoc reports as well as periodic reports from the safety database, as requested.
- To maintain the project specific e-folders as per the study requirements, as applicable.
- Establishment and Maintenance of the Clients' Pharmacovigilance system master file (PSMF) for the products.
- Screening and evaluation of literature articles received from various search engines (such as PubMed, Embase, Local journals, etc.)
- Screening and evaluation of various regulatory authority portals (such as EMA, MHRA, etc.) for receipt of regulatory cases.
- Identification and triaging of case reports from literature and regulatory sources.
- Performing literature search for aggregate reports and signal detection, as applicable.
- Prepare PADER, PSUR, DSUR, RMP, Signal management documents, PSMF and others, as applicable.
- Overview of medicinal product safety profiles and any emerging safety concerns, as applicable.
- Provide input into the preparation of regulatory action in response to emerging safety concerns (e.g. variations, urgent safety restrictions, and communication to patients and healthcare professionals), as applicable
- Review and preparation of SOPs, training materials, providing inputs to SOPs. Any other responsibilities assigned by the manager or management.

PAREXEL International, Mohali, India

Drug Safety Associate

(04-Jan-2021 to 04-Jul-2021).

Management of Individual Case Safety Reports (ICSRs) of all case types which includes:

• Triage of ICSRs to determine whether they qualify for expedited reporting or not and the timelines within which they need to be submitted to the regulatory authorities

• Registration of ICSRs into safety databases

• Conducting duplicate searches prior to registration and identifying potential duplicates

• Managing duplicate cases appropriately

• Data Entry of ICSRs in the safety database, including determination of the expectedness of the adverse events against various labelled documents (such as SPC, CDS, IBs etc.) writing case summaries, accessing causalities.

• Data Validation i.e. cross checking against source documentation.

• Under training in MedDRA coding in accordance with "MedDRA Term Selection: Points to consider".

• Maintaining a good working knowledge of the AE safety profile of assigned drugs/class of drugs, Reference Safety Information documents, data entry conventions and guidelines, aggregate reporting conventions and guidelines, client's procedures and international drug safety regulations including: - ICH guidelines on safety and efficacy

• GVP Modules

• FDA guidelines

• CIOMS

• New EU PV legislation - EU-GDPR

• Maintaining an awareness of global reporting obligations and organizing workload to ensure compliance with internal and regulatory timelines for adverse event reporting.

PROFESSIONAL QUALIFICATION:

PG DIPLOMA- Institute of Clinical Research India- Medanta Institute of Education

& Research (ICRI-MIER), 2019-2020.

B.PHARM- Roorkee College of Pharmacy, Uttarakhand Technical University,

Dehradun, 2015-2019, 70.0%

ACADEMIC CREDENTIALS:

Intermediate- CBSE, Angel's Academy Sr. Sec. SCHOOL 2015, 66%.

Matriculation- CBSE, Angel's Academy Sr. Sec. SCHOOL, 2013, 72%

RESEARCH EXPERIENCE:

1. Project Title: Industrial Training (2018).

Company: PURE AND CURE HEALTH CARE PVT.LTD (AKUMS) SIDKUL.

Duration: One Month

2. Project Title: Internship Training (2 Months)

Company: Medanta-the Medicity, Gurugram.

PV SKILLS:

Knowledge of medical terminology, Concepts associated with patient safety, ADRs (evaluation, monitoring, prevention and management), DSMB, Surveillance methods , CIOMS Forms, Case processing, Signal Detection, Causality assessment, Methods in causality Assesment, ADRs reporting, AE&SAE Reporting, SUSAR, Indian regulations, WHO International drug monitoring programme, PvPI, Management of ADRs, Medication related event, Regulatory terminologies, Terminology of PV, Role of health care professional in PV, phases of clinical development programme, Drug discovery and development, MedRA And standardized MedRA Queries, Drug event monitoring, Communicating with regulatory agencies, GCP in Pharmacovigilence studies, Drug safety evaluation in special population, CDSCO and Pharmacovigilance, D And C ACT And schedule Y, Difference in Indian And Global Pharmacovigilance requirement, Who drug dictionary, ICH E2 A & E2E guidelines, Guidelines and regulations (ICMR, ICH-GCP, INDIAN-GCP, IND).

CERTIFICATIONS:

• Registered pharmacist in Uttarakhand pharmacy council

• GCP certified

• UMC certified

- Certified in Intro to Pharmacovigilance, Signal Detection and causality
- Assessment, Statistical reasoning and algorithms in PV by Uppsala Monitoring Centre, Sweden.

SOFTWARE KNOWLEDGE –

ARISg, Oracle-Inform EDC for eCRF entry, Pvedge, clenovo, eudravigilance, Web trader (ICSR submission).

CORE STRENGTH:

• Good interpersonal skills (listening skills, patience and handle situations in a calm and composed way), Good time Management, Ability to work independently, guided by procedures, with appropriate support, Good team player (Share the work among the team members and helping the team meet the deadlines), Good communication skills (written and spoken English) with ability to clearly, articulate the message without causing any confusions, Good organizational skills and strong attention to detail, with proven ability to handle multiple tasks efficiently and effectively.

TECHNICAL SKILLS:

Handling Lab Equipment/Instruments, Good skills in science experiments, SOP writings, CRF designing, ICF designing, Strong analytical, clinical data interpretation skills , Good understanding of preclinical and clinical scientific information, Good secondary research skills advanced search options in Google, Proficient in MS Office (e.g., Word, Excel, PowerPoint)

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

Pranidhi Chauhan.