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PROFILE: The ability to establish new projects in Pharmacovigilance by combining resourcefulness and problem-solving skills. The technical and academic knowledge to consistently deliver improved research and production results. The manager dedicated to quality, continuous improvement, and bottom-line objectives.

QUALIFICATION HIGHLIGHTS

- Communication with client regarding conventions and other case related queries and country wise guidelines.
- Proven project management abilities with capacity to design, plan and implement ideas from conception through completion; able to manage multiple responsibilities without compromise to quality
- Communication with the Sponsor and IEC, Monitors and External Agencies for Clinical Trials
- Outstanding interpersonal skills; equally comfortable communicating one-on-one or addressing large audiences. Ability to handle technical queries and information.

AUDITS FACED:

- 3 Kazakhstan Regulatory Audit
- 2 USFDA Audits
- 3 MHRA Audits
- 25 client Audits

AREA OF INTEREST:

- End to End Pharmacovigilance

PROFESSIONAL ACCOMPLISHMENTS

- Recognized as efficient resource to the newly joined associates and as a must in crucial period and extensive achievement in creating Standard Operating Procedures.

CAREER HISTORY

1. Ethicare Clinical trial services (Oct 06, 2022, till date)

Assistant manager (Pharmacovigilance)

Job description:

- Part of the Client Primary meetings for work transition and MSA signing
- SDEA and TA preparation and Business development Assistance
- Billing and Invoice of complete Pharmacovigilance profile from ICSR, Signal, REMS and MIS
- PvPMP finalization and work allocation from Vendors to the Team
- Overlooking the Aggregate, signal and RMP process

2. APCER life sciences (Mar 06, 2017, Sep 30, 2022)

Team lead (Pharmacovigilance)

Job description:

- ICSR assignment and its completion within timeline. Preparation and presentation of daily efficiency data, monthly performance of team, and guidance on improvement part
- Case Allocations, daily, weekly, and monthly Compliance reports, Working status and Billing data preparation and verification
- SME for all type of cases and client calls summarization for team (Literature, Clinical, regulatory, post marketing surveillance and spontaneous)
- Reconciliation of Mailbox, PQC, Follow-up queries, Vendor, and trial cases data.
- Data correction confirmation and CAPA on deviation, Training and Quality compliance, and suggestion on SOP improvement
- Web meetings: responsible for attending web meetings with clients to get new/update regarding the coding conventions, database update/enhancement, Client's SOPs, and new product information

- Prioritization of cases on basis of country where the case is to be submitted.

3. Sciformix technology solutions (Oct 12, 2015, Feb 28, 2017)

Safety Data Analyst (Pharmacovigilance)

Job description:

- case processing (Clinical, post marketing surveillance and spontaneous)
- Software: SCEPTRE
- Data entry and Processing the direct reported customer terms in database and promoting them to reporting
- Checking validity of case, Drug selection, MedDRA linking, assessing labeling of events and Narrative writing & others (communication with operational physicians, Subject matter experts (SMEs)), Quality reviewers and Sponsor).
- Responsible for completion of day-to-day work within agreed SLA (service level agreements)

4. Cognizant technology solutions (Sep 16, 2013, Sep 21, 2015)

Junior Data Analyst (Pharmacovigilance) (Drug safety specialist)

Job description:

- Oncology case processing (Clinical, post marketing surveillance, spontaneous and literature)
- Software: ARGUS
- Case book-in and Case triaging and Data entry and case management for cases in database.
- Maintaining pear client communication related to cases processing.
- Responsible for creation, follow up, and closure of AE related queries with client or relevant department as applicable.

5. Cliantha Research Limited *(known as BA Research India Ltd.)* **(June 21, 2011, Dec 06,2012)**

Junior research associate

- Managing the dermatological clinical studies with proper arrangements and executing the logistics of the studies along with Investigators.
- Managing the Bioavailability and Bioequivalence Trials [BA-BE Trials] of different phases.
- Supervising a technical study staff to conduct of the study as per the standards laid down in the in-house SOPs in collaboration with the Investigators and study director.
- Ensure timely conduct of trials and comply with GCP, Declaration of Helsinki, SOPs and applicable regulatory requirements.

EDUCATIONAL ACHIEVEMENTS, CERTIFICATIONS & SKILLS

- **Master of Science in Clinical Research**-I.C.R.I , Ahmedabad**- 71 %**
- **P.G.D. in Pharma Buisness Management-** I.C.R.I , Ahmedabad- **68 %**
- **Bachelor of Pharmacy (B.Pharm)** A.P.M.C.C.P.E.R, Himatnagar, India (2009), Hemchandracharya North Gujarat University, India**-66.15 %**
- **Dissertation**: Thesis entitled Oral Mucosal Drug Delivery
- **Three** months internship at YASH MEDICARE pvt. Ltd, Himatnagar, India

Certificates:

- Complicated oncology training of client protocols
- Certified Registered Pharmacist from State Pharmacy Council Gujarat, India **Certificate No. G-33360**
- Deep Knowledge about the cumulative irritation scale - Adhesion Scoring Knowledge

Skills:

- CERTIFIED MEDDRA CODER
- Computer Skills - MS office, Word, Excel, Power point, database knowledge, Excellent organization, planning and problem-solving abilities.

References: Will be available on request.