SUMAIYA SHARIEF

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Objective	● Looking for a position that offers me an opportunity for advancement in my career endeavors, where I can utilize my skills and abilities in the areas of Research, Development, Clinical Research, and Pharmaceutical organization. ● I would like to strive for the benefit of the Organization with my ability and hard work and dynamic career, which bring laurels to the organization and boost up my career skills.

Last Position Held:

★ Quintiles Clinical research organization
Date of Employment: 09/2014 - 05/2016
Job Title: Associate Operations Specialist (pharmacovigilance- lifecycle drug safety)
Key Responsibilities: ADR/AE Reporting and Recording.
* Processing of ICSRs in Argus and SCEPTRE Safety Database after triage.
* Coding of events, indications and patient history based on MedDRA 18.01.
* Capture Adverse Event related to the drugs reported by the patient/consumer for seriousness criteria
* Handling the case calibration.
* Data entry for ICSRs in SCEPTRE Safety Database
* Authenticate accuracy of Serious Adverse Event and Product Complaint captured by the agents as per SOP while doing peer review.
* Using CPD and WHO-DD for coding of drugs.
* Raising queries on safety related issues to update the FU information as required.

★ Manage and process expeditable adverse events to the required standard and submit them to the client and the regulatory agencies (if required) within the agreed/stated timelines.

★ Assist with the overall Clinical Safety and/or PV&DSS operations associated with products including the entire adverse events process: which may include safety data collected from clinical trials and/or post marketing setting (i.e., unsolicited reports).

Other Clinical Experiences:

CRC at Zentrum fur Medizinische Forschung (ZMF), LKH, Graz, Austria. 2011 - 2012.

Was posted in the Department of Endocrinology and Metabolism and specialised in Diabetics.

- Was involved in the **Bioequivalence study of NN**** and Huminsulin.**
- Was involved in the study which **Investigates the PK and PD Differences between**

Liraglutide and NN******

Job Responsibilities

- Maintenance of all the documents required for the start, conduct and end of the study.
- Maintenance of all the correspondence between the investigator and the sponsor and vice versa.
- Maintaining a regular contact with investigators or other site staff members during the course of studies, to ensure all the proceedings are agreed upon with protocols and time schedules, and that the data is being recorded accurately.
- Preparation and maintenance of the training record for the internal purposes
- Preparation of all required documents for the screening visits and the follow ups.
- Filling of CRFs which later are dispatched for data management.

INTERNAL MONITORING

- On-Site & In-house monitoring as per monitoring plan in order to check & ensure compliance with study management, protocol GCP & other requirements at all assigned sites.
- Monitor study-related documentation ICD, Source Data CRF, Drug accountability logs at the site to check & ensure the completeness & accuracy with compliance to protocol GCP, & regulatory.
- Identify and assist in reporting SAEs to sponsors and regulatory authorities coordinate in generating CRF data and all other activities with the clinical research team.
- Reporting of study progress at regular intervals, to the study manager.

STUDY CLOSE-OUT

With comprehensive overview of study relevant documents, retrieval of CRFs, Complete Drug accountability & Destruction of the documents.

Areas of interest:

- To play an important role in providing adequate, accurate, and timely drug information to patients, families and the professional staff
- To promote selection of rational drug therapy and support formulary development process by consulting with medical staff
- To make effective contribution of my knowledge in the field that meets the expectations of the organization.

M.Sc 2008-2010	Holding a Post Graduate Diploma in Clinical Research Management and M. Sc. in Clinical Research, both from the Institute of Clinical Research, Bangalore. ● Comprehensive knowledge on various clinical research guidelines like ICH- GCP, Schedule Y and other practical aspect ● Successfully completed GCP and SOP training in the current organization and awarded certificate for the same. ● Study area Pharmacology, Drug Discovery & preclinical studies, Clinical trial Management, Bioethics, IRB, QM&FDA, ICH-GCP, Data Management, & Medical writing, ● Master Thesis To assess the risk factors of Polycystic Ovarian Disease (PCOD) Bangalore, India.
Study area	Pharmacology, Drug Discovery & preclinical studies, Clinical trial Management, Bioethics, IRB, QM&FDA, ICH-GCP, Data Management, & Medical writing,
Master Thesis	To assess the risk factors of Polycystic Ovarian Disease (PCOD) Bangalore, India. **(Operational Tasks)** ● Preparation of Protocol, Case Report Form and Inform Consent Form ● Obtaining approval from ethics committee. ● Attaining the sample size by recruiting the patients from different medical centres, and obtaining inform consent. ● Collecting various articles relevant to the study from online journals. ● Obtaining the results and analysing them using various statistical tools and concluding the whole study on the basis of the results.

B.Sc 2005-2008	Bachelors in Biotechnology from Bangalore University, Bangalore, India	
Degree	Bachelors B.Sc	
Study area	Botany, Chemistry , Biotechnology, Different Labs	
Pre University 2003-2005	Baldwins Women's Methodist College.	
Secondary Education 2003, ICSE.	St. Francis Xavier's Girls High School.	

· **Achievements**

- Participated as volunteer in Pulse Polio National Immunization Programme in Bangalore.
- Obtained NCC-A Grade Certificate of a Cadet Rank in Schooling

Teaching experience:

- Clinical research to nursing students in Karnataka Nursing college for 6 months
- English to foreign nationals in Success English Academy for 2 years

PERSONAL INFORMATION

Languages Known.

English	Fluent
Urdu	Mother Tongue
Hindi	Fluent
German	Moderate

Date of birth	10 July'1987, Bangalore, India
Nationality	Indian
Marital status	Married
Hobbies	Reading, Travelling, learning New languages.

I, hereby Declare that the above mentioned information and details are true to my knowledge.

Thanking You,
Sumaiya Sharief.
Bangalore, 29.10.2018