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SUMMARY

Detail-oriented Quality Assurance (QA) Professional with 15 years of extensive auditing experience in clinical trials, clinical research, and pharmacovigilance. I have demonstrated expertise in ensuring compliance with both international and local regulatory requirements, showcasing a commitment to quality assurance and pharmacovigilance within the pharmaceutical industry. My background emphasizes a strong foundation in regulatory compliance and operational excellence.

Key Skills:

- Have a strong knowledge of pharmacovigilance (PV) regulations, guidelines, and policies; possess awareness of Good Clinical Practice (GCP), Good ,Manufacturing Practice (GMP) and 21 CFR Part 11 requirements, as well as an understanding of clinical trial methodology and GCP
- Demonstrate knowledge of ICH-GCP/GLP and other national and international regulations governing clinical trials, with experience in clinical research organizations.
- Exhibit the ability to work independently and consistently in a fast-paced environment.
- Show a strong ability to prioritize tasks, manage multiple projects simultaneously, and meet deadlines.
- Build and maintain good working relationships with both internal and external customer groups.
- I have experience supporting domestic and international regulatory agency site inspections, ensuring adherence to guidelines set forth by agencies such as the FDA and EMA.
- Possesses communication skills to drive quality enhancement discussions with internal stakeholders and external customers, fostering continuous improvement.

Professional Experience:

Manager Quality Assurance Pharmacovigilance, (Jul 2022 – till date)
Vigilare Biopharma Pvt Ltd, **Hyderabad.**

- Lead and continuously coach, guide and develop the Quality Management Systems.
- Establish and run the QMS network for GMP (Good Manufacturing Practices and GPV (Good Pharmacovigilance Practices) areas and drive interactions with all functions within the commercial Operations through the defined process.

- Develop, implement, and maintain quality system documentation (SOPs, WIs, templates, forms) adhering to QMS requirements and regulations
- Coordinate and oversee quality and compliance monitoring for safety signals, key medical safety information (like product labeling and ICSRs), and other pharmacovigilance areas to support a robust GVP Quality Management System.
- Manage the QMS documentation activities to ensure the documentation follows processes and procedures agreed with Global QMS, including document review to ensure a high standard of documentation is in place.
- Identify Continuous Improvement opportunity for Quality Management System
- Investigate and respond to Corrective and Preventive Action (CAPA) and work with Operations to obtain evidence of deliverables and facilitate effectiveness checks as needed to ensure CAPA closure.
- Assist in the preparation, execution, as well as the drafting and tracking of responses to external audits and inspections.
- Ensure that the Periodic Review management is in place and effective to reduce the number of overdue documents within the QMS.
- Overseeing the quality assurance processes related to pharmacovigilance activities, including monitoring the accuracy and completeness of adverse event reports, case processing, and documentation.
- Act as a subject matter expert for selected Quality processes and collaborate with the respective Process owner to ensure GxP compliance of the processes and tools within own remit.
- Ensure the establishment and continuous operation of quality oversight programs to monitor pharmacovigilance (PV) compliance and maintain high standards
- Author/review respective QMS documentation.
- Establish and maintain community/network of Subject Matter Experts or Single Points of Contact and drive interactions with corresponding Functions. Establish strong partnership with key stakeholders.
- Support BD projects and initiate new projects
- Maintain knowledge of current industry trends and Health Authority expectations.
- Provide support for QMS Operations inspections by actively participating in and leading client audits.

Assistant Manager Quality Assurance Pharmacovigilance (May-2017 – Jun 2022)
Vigilare Biopharma Pvt Ltd, **Hyderabad.**

- Initiate/Develop/Review/Update departmental procedural documents such as SOPs and Training Guidance.
- Collaborate effectively with authors, reviewers, approvers, and trainers. Ensure pharmacovigilance activities are carried out in accordance with controlled documents.
- Responsible for global PV Safety Data Exchange Agreement activities. Serve as the liaison between BD global PV and associated business partners or vendors.

- Expertise in the process of SDEA management with third party commercial partners and service provider and ensuring compliance with relevant regulations and Standard Operating Procedures (SOPs).
- Project management of activities for PV department. Organize and moderate meetings and author minutes'/discussion summaries for PV related activities.
- Perform regular trending of quality results to identify potential trends.
- Effectively manages workload to ensure overall compliance with PV standards and timelines with other PV sub-functions and relevant personnel to discuss quality issues and identify timely solutions.
- Ensure complaint records and applicable complaint handling documents are complaint with Good document practices (GDP).
- Ensure required audits are performed and reported in accordance with QA requirements, and on time.
- As needed, assist in review and contribution to PV Quality and Compliance-related SOPs, Work Instructions and Job Aids.
- Participate in the continuous process improvement effort within the function to identify gaps and advise management accordingly
- Maintaining track of quality information like organization chart, deviations and review of on-going process of deviation and deviation forms for requirement of CAPA
- Responsible for approval of the investigation initiation and closure for the market complaints for the report received from the clients.
- Co-ordination of training for team as per respective controlled documents.
- Facing periodic audits of PV system internally and support audit and inspection activities as needed. Ensure that the team works in accordance with approved company operating policies, procedures, practices and methods.
- Facilitate client audits / regulatory inspections, as assigned.
- Perform other quality related tasks or initiatives as assigned.
- Ability to travel up to 50%.

GCP Quality Assurance Assistant Manager (SEP 2016-APRIL 2017)
Vigilare Biopharma Pvt Ltd, **Hyderabad.**

- Ensure that all processes contributing to the performance of a clinical trial are conducted properly. For on-going studies, ensure that the trial is being performed according to protocol and applicable regulations, guidelines, and standards at clients facility
- Review of all study related documents and reports. Ensure regulatory rules are communicated through corporate policies and procedures.
- Ensure that investigator, vendor, facility and system audits are conducted. Communicate any critical compliance risks noted from these activities to senior management.
- Identifying training needs of the employees and arranging trainings from externals and escalation of critical audit findings to Quality Manager/ line manager

- Responsibilities as assigned by the line manager.

GCP Quality Assurance (Auditor) Associate (August 2011-March 2015)
GVK Biosciences Private Limited, Hyderabad.

- Preparation of quality assurance systems and implement them at Clinical Research Center. Planning and Conducting of internal and external vendor audits, preparation of audit report and ensuring compliance.
- Inspection of Clinical Pharmacology Units and Clinical Labs for the GCP Compliance. Monitoring of entire BA/ BE studies related activities.
- Handling & maintenance of change initiations / change controls related to changes in process, methods, SOPs, facility, documents, systems.
- To participate actively in regulatory audits & customer audits and to responsible to make the compliance to the audit points in accordance to GCP
- Review of Protocol, ICFs, Ethics Committee documents, DCGI approvals etc. before initiation of the Clinical Research project.
- Review of Clinical Raw data Clinical study reports, AE and SAE Forms.
- To assure that clinical studies are conducted in accordance to SOPs, compliance to Protocol requirements and guidelines applicable.
- Responsible for monitoring all activities of Clinical Research Center to assure compliance to applicable regulations and guidelines.
- Provide advice on quality and GCP issues to the Investigator and Customers.
- Audit of all aspects of clinical research studies protocol compliance Clinical data, planning and conduct of BA/BE studies, Clinical reports in compliance with intended submission country guidelines.
- To ensure complaints investigation and CAPA are implemented & to ensure that deviations and Incidences are investigated and resolved.

GCP Quality Assurance Auditor (December 2009 to July 2011)
Vimta Labs Ltd, Cherlapally, Hyderabad

- Assist Manager-Quality Assurance in preparation and revision of SOPs and in imparting SOP training
- Archive all historical SOPs, raw data, final method validation and study reports and other necessary documents
- Determine that no deviations from approved protocols or standard operating procedures are made without prior authorization and documentation
- Review the final biostudy reports to assure that such reports accurately describe the methods and SOPs and that the reported results accurately reflect the raw data of the conducted biostudy.

GCP Quality Assurance Associate (August 2008 to November 2009)
Wellquest Clinical Research Ltd (A Division of Piramal Healthcare Limited), Hyderabad

- Maintain the training records of personnel and issue raw data forms and log books. Archive SOPs, study related documents and log books and audit clinical data.
- Assist Head-Quality Assurance in facility audits and tracking corrective and or preventive action plan. Assure adherence to GCP/GLP guidelines and applicable regulations, to file and maintain QAU records and reports

Education Qualification:

- M. Tech Biotechnology with 70% from Jawaharlal Nehru University.
- B. Pharmacy with 64% from Osmania University, Hyderabad

Training /Conference attended

- Online training on Lean Six Sigma White Belt by Management and Strategy Institute on April 2020
- Online training on Introduction to drug safety and Pharmacovigilance by Biopharma Institute on May 2020
- Attended GxP training on computer System Validation conducted by Anthem GxP solutions Pvt. Ltd. 15 May 2014.
- Attended a "Good Clinical Laboratory Practices" conducted by Gvk Biosciences Pvt. Ltd, Hyderabad, 14 May 2014
- Attended a "Good Clinical Practice" conducted by GVK Biosciences Pvt. Ltd, Hyderabad.
- Attended a workshop on "Good Clinical Practice" conducted by Wellquest Clinical Research (A Division of Piramal Healthcare Limited) Hyderabad, 23-24th July 2009.
- Undergone training in Clinical Data Management and SAS training program during Dec 2007 to Feb 2008 Clinnova Labs, Hyderabad.
- Participated in the 55th Indian Pharmaceutical Congress 2003, Chennai conducted at Sri Ramachandra Medical College and Research Institute
- Undergone training in handling of instruments like UV–Visible Spectrophotometer (Double beam), Gas chromatography (GC), High Pressure Liquid Chromatography (HPLC) & FTIR spectroscopy at Chandra Labs, Kukkatpally, Hyderabad during 11-12-2006 to 15-02-2007

Registration/License:

- Registered with Andhra Pradesh Pharmacy Council, Hyderabad (Registration No.41860/A1).

All above details are true and correct to the best of my knowledge and belief.