M/S Shruthi Manjunath,
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(PMP Certified), (Six Sigma black belt)

Summary

Highly skilled and dedicated clinical researcher with a proven track record of designing, executing, and managing complex clinical trials. Proficient in various methodologies and regulatory guidelines, adeptly applying technical expertise to ensure data integrity and patient safety. Demonstrated ability to analyze and interpret clinical data, providing valuable insights to support evidence-based decision-making. Exceptional proficiency in GCP (Good Clinical Practice) standards, ICH (International Council for Harmonisation) guidelines, and adherence to ethical principles. Strong collaborator and effective communicator, adept at fostering productive relationships with cross-functional teams and stakeholders. Committed to advancing medical knowledge and improving patient outcomes through rigorous and innovative clinical research.

Skills

1. Clinical Trials and Research, Clinical Trial Support, Clinical trial Protocols, RAVE EDC, RAVE X EDC, Oracle (TAO), Red Cap, Imed Net, Veeva Vault eTMF, Veeva Vault shared Investigator Protocol (SIP) Medical DataReview, Regulatory Submission, Project Management eCOA

WORK EXPERIENCE:

Sl No	Company Name	Designation	Date Of Joining	Ending Date
1	Vipragen Biosciences Pvt Ltd	Deputy Manager	Jan 2020	Present
2	IADFAC Laboratories Pvt Ltd	Product Manager	Jan 2017	Dec 2019
3	Karnataka Antibiotics Private limited	QC Analysts	Jan 2012	Oct 2015

Roles And Responsibility Present (Jan 2020)

- Site Monitoring: Conduct on-site visits to clinical trial sites to assess the overall site performance, verify data accuracy, and ensure adherence to the study protocol, GCP, and applicable regulations.
- Investigator and Site Management: Identify and evaluate potential investigators and study sites, conduct feasibility assessments, and establish positive relationships with site personnel.
- Study Documentation: Review and maintain essential study documents such as informed consent forms, case report forms (CRFs), regulatory documents, and site communication records.
- Source Data Verification (SDV): Perform SDV to ensure that the data recorded in the CRFs

accurately reflects the source documents and is in compliance with the study protocol.

- Subject Recruitment and Enrollment: Collaborate with sites to identify and enroll eligible study participants in a timely manner, ensuring that enrollment targets are met.
- Safety Reporting: Monitor and report adverse events (AEs) and serious adverse events (SAEs) to ensure patient safety and regulatory compliance
- Protocol Compliance: Ensure that all activities at the site are conducted in accordance with the approved study protocol, and any deviations are appropriately documented and reported.
- Data Collection and Query Resolution: Work closely with site staff to collect and resolve data queries, ensuring the accuracy and completeness of study data.
- Study Progress Reporting: Provide regular updates on site status, enrollment progress, and any potential issues to the project team and sponsor.
- Regulatory Compliance: Assist in preparing for regulatory inspections and audits by maintaining site inspection readiness and ensuring compliance with relevant regulations and guidelines.
- Training and Support: Provide training and support to site personnel on study procedures, documentation, and regulatory requirements.
- Study Closeout: Facilitate the closeout process, ensuring that all required documentation is collected, and study-related activities are appropriately concluded.
- Continuous Improvement: Identify areas for process improvement and implement best practices to enhance the efficiency and quality of clinical trial conduct.

Roles And Responsibilities as Regulatory Affairs in Medical Devices, Pharmaceuticals, special chemicals, Agrochemicals, Nutraceuticals, Cosmeceuticals'

- Regulatory Compliance: Ensuring that all products manufactured and distributed by the company comply with relevant regulations and guidelines set forth by the respective regulatory authorities (e.g., FDA, EMA, Health Canada, EPA, etc.).
- Product Registration: Preparing and submitting applications for product registration, marketing authorizations, and permits to regulatory agencies, and managing the process through to approval.
- Regulatory Strategy: Developing and implementing regulatory strategies that align with business objectives, ensuring timely market access for new products while maintaining compliance.
- Product Labeling and Advertising: Reviewing and approving product labeling, packaging, and advertising materials to ensure they meet regulatory requirements and are truthful and non-misleading.
- Quality and Safety Compliance: Collaborating with Quality Assurance teams to ensure that products are manufactured, tested, and distributed in compliance with applicable regulations and quality standards.
- Regulatory Submissions: Preparing and submitting regulatory documents, such as Investigational New Drug (IND) applications, New Drug Applications (NDA), Premarket Notifications (510(k)), Technical Dossiers, etc.
- Post-Market Surveillance: Monitoring and reporting adverse events, complaints, and safety issues related to the products in the market to regulatory agencies as required.
- Regulatory Intelligence: Keeping up-to-date with changes in regulations and guidelines in the relevant industries and regions, and advising internal stakeholders on their impact on the business.
- Regulatory Audits and Inspections: Assisting with internal and external regulatory audits and inspections, addressing any findings, and implementing corrective and preventive actions.
- International Regulatory Compliance: Ensuring compliance with global regulations in markets

where the products are sold or distributed, and managing international registrations and approvals.

- Risk Assessment and Mitigation: Conducting risk assessments for products and proposing risk mitigation strategies to ensure product safety and compliance.
- Clinical Trial Support: Assisting in the preparation and submission of clinical trial applications to regulatory authorities, and ensuring compliance with clinical trial regulations.
- Regulatory Training: Providing training to cross-functional teams on regulatory requirements and changes that may impact product development, manufacturing, and distribution.
- Interfacing with Regulatory Authorities: Acting as the point of contact for regulatory agencies, responding to queries, and participating in meetings with regulatory authorities as needed.
- Regulatory Strategy for New Product Development: Working closely with R&D teams to provide regulatory guidance during the development of new products to facilitate timely market entry.

Competencies, skills and abilities:

- Clinical Research Knowledge: Strong understanding of clinical research principles, protocols, study designs, and relevant regulations (e.g., ICH-GCP, FDA guidelines) to conduct trials ethically and in compliance with standards.
- Attention to Detail: Meticulousness in reviewing and verifying data, source documents, and study-related documents to ensure accuracy and adherence to protocol.
- Communication Skills: Effective verbal and written communication to interact with site personnel, investigators, and sponsors, as well as the ability to write clear and concise reports.
- Organizational Skills: The ability to manage multiple tasks, prioritize work, and meet deadlines while maintaining attention to detail.
- Critical Thinking: Analytical and problem-solving skills to identify issues, address challenges, and make informed decisions during the conduct of clinical trials.
- Ethical Conduct: Strong commitment to maintaining patient confidentiality, protecting participant rights, and ensuring data integrity.
- Adaptability: Flexibility to work in a dynamic and changing environment, adapting to different study protocols, therapeutic areas, and technology tools.
- Time Management: Efficiently managing time and resources to complete site visits, monitor data, and meet study milestones.
- Interpersonal Skills: Building positive and productive relationships with site staff, investigators, and team members, fostering a collaborative work environment.
- Medical Terminology: Familiarity with medical terminology to understand patient medical histories and communicate effectively with medical professionals.
- Computer Literacy: Proficiency in using various software applications and electronic data capture (EDC) systems used in clinical research.
- Regulatory Compliance: Knowledge of regulatory requirements and guidelines applicable to clinical trials, ensuring adherence during study conduct.
- Problem-Solving: Ability to identify potential issues or challenges in trial conduct and proactively seek solutions.
- Patient-Centric Approach: Demonstrating empathy and understanding to ensure the safety and well-being of study participants.
- Team Player: Collaborating effectively with cross-functional teams, including project managers, data managers, and medical monitors.
- Site Management Skills: Skills in assessing and managing clinical trial sites, including site initiation, monitoring visits, and site closeout.

- Negotiation Skills: Ability to negotiate with investigators and site personnel on study-related matters while maintaining a positive working relationship.
- Risk Management: Identifying and mitigating potential risks associated with study conduct to protect patient safety and data quality.
- CRAs play a vital role in the successful execution of clinical trials, and possessing these competencies, skills, and abilities contributes to their effectiveness in ensuring the integrity of clinical data and advancing medical research.
- Maintenance of individual training records (Vipragen Biosciences or client related) and completionof all designated required training.

Knowledge And Experience

- Experience with clinical trials, or managing documentation
- Good understanding of procedures and concepts within own technical/subject area and a proficientknowledge in other related areas.
- Prior experience in an international environment.
- Strong command of written and spoken English language

Technical Skills :

Oracle, SAP, ERP, CRM, AWS Azure, VB+, SQL MSQL

Education Details:

B.SC Biotechnology GPA 8.3% (2010)

M.SC Biotechnology GPA 8.5% (2014)

Personal Details

Name	Shruthi Manjunath
Husband	Manjunath Kolbal
Nationality	Indian
Language	Kannada, English, Hindi, Telgu Tamil

Regards

Shruthi Manjunath