KAVYA R M

kavyamallapur5@gmail.com +91 9901460892

PROFILE

Biotech and clinical research professional with experience in quality assurance, regulatory affairs, business development, and project coordination. Skilled in clinical study audits, SOP control, CAPA support, and regulatory documentation. Proficient in EDMS, Excel, and coordinating tasks across project timelines. Experienced in lead generation, CRM-based client management, and customer engagement across academic and corporate sectors. Strong understanding of GCP, GMP, GDP, and clinical documentation workflows.

PROFESSIONAL EXPERIENCE

03/2025 – 04/2025 **Business Development Associate** Bangalore, India
Learning Lab Research Institute
- Building and maintaining strong customer relationships.
- Managing customer data and sales records using CRM tools.
- Using CRM tools to generate, track, and manage leads efficiently.
- Building partnerships with schools, colleges, and corporate training institutes to expand LLRI's product reach.
- Understanding customer needs and providing tailored product recommendations.

02/2025 – 03/2025 **Junior Business Development Associate** Bangalore, India
Learning Lab Research Institute
- Generating and qualifying leads through calls, and online channels(WhatsApp).
- After qualifying leads, hand them over to the senior team for further processing.

11/2023 – 12/2024 **Regulatory Affairs Associate (Freelancer)** Kolkata, India
AyuMantra
- Managed regulatory documentation projects for individual drug products.
- Created structured reports including ingredient quantities, usage, age restrictions, and disclaimers.
- Compiled scientific data for accuracy and compliance with regulatory guidelines.
- Formatted finalized documents using MS Word for submission-ready PDF output.
- Ensured timely, compliant submission of documents across multiple projects.

04/2023 – 10/2023 **Trainee Quality Assurance** Bangalore, India
Notrox Research Pvt Ltd
- Coordinated study audits from initiation to close-out, ensuring GCP and SOP adherence.
- Reviewed clinical study reports for data accuracy, completeness, and compliance.
- Issued controlled documents (SOPs, logbooks, forms) and supported CAPA tracking.
- Conducted system audits and validated equipment performance against protocols.
- Supported QA activities across study timelines and built foundations for project coordination.

01/2022 – 06/2022 **Intern** Bangalore

Stelis Biopharma

- Reviewed Batch Manufacturing Records (BMR) and Batch Packaging Records (BPR) ensuring regulatory compliance.
- Managed document control and archival through Electronic Document Management System (EDMS).
- Maintained Good Documentation Practices (GDP) in alignment with ALCOA principles.
- Performed water sampling, environmental monitoring, gram staining, and membrane filtration techniques.
- Documented microbiological and environmental data using Microsoft Word and Excel.
- Proficient in handling lab instruments: weighing balances, meters, probe sonicators, and centrifuges.
- Ensured laboratory activities aligned with Good Laboratory Practices (GLP) and GMP standards.

EDUCATION

08/2018 – 06/2022 **KLE Technological University** Hubli, India

B.E - Biotechnology

SKILLS

- **Project Coordination:** Task tracking, documentation management, cross-functional collaboration, project reporting
- **Regulatory Compliance:** Managed end-to-end coordination of regulatory documentation projects for individual drug products, organizing data inputs, structuring content, and ensuring timely submission of compliant reports.
- **Quality Assurance:**Experienced in coordinating project timelines, managing study documentation, conducting system audits, qualifying equipment, and supporting inspection readiness.
- **CRM & Operations:** Proficient in lead generation, client data handling, workflow coordination using CRM platforms
- **Tools & Software:** JIRA (basic), Trello (basic), EDMS, MS Excel (Pivot Tables, Charts), MS Word, PowerPoint, Google Workspace
- **Soft Skills:** Detail-oriented, a strong communicator, and effective in team-based, deadline-focused environments.

CERTIFICATES

Good Clinical Practice (GCP)
NIDA Clinical Trials Network

Project Management Fundamentals-Simplilearn
(Includes PM lifecycle, process groups, JIRA, Trello, task tracking)

LANGUAGES

- English
- Hindi
- Kannada