KOMARAPALEM VAMSHI KRISHNA
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PROFILE SUMMARY

Experienced quality professional with 9.0+ years seeking assignments in computer system validation, QA complains for growth-oriented organization in pharmaceuticals and IT Consulting firms or similar domains.

- Expertise knowledge of FDA regulations, EU guidelines, CSV, GAMP Guidelines, QA and product development process. Knowledge on V-model of validation for GxP Projects for Life science, pharmaceutical and healthcare industry. Significant exposure in maintaining & ensuring stringent adherence to quality standards, norms & practices, identifying gaps and implementing CAPA.
- Developing, Reviewing, Validating and Monitoring of Test scripts, Test plans & Test cases based on URS from clients. Effective handling of OOS, OOT, Incidence and non-conformance occurred during validation and audits.
- Expertise in Preparation of Validation Plan and protocol, Validation Report, SOP writing and revision.
- Abilities in Data management & validating various quality documents using software's in pharmaceutical companies. Hands-on experience in product validation for taking stringent quality measures and organizing quality awareness programs in the organization.
- Exposure in Validation, Qualification, Requalification and Decommissioning of Product.
- Abilities in implementing quality plans with focus on optimum utilization of resources with minimum cost.

CORE COMPETENCIES

- Raising defect in Jira defect tracker and communicating with development team to resolve the defects.
- Exposure to GxP, GAMP, USFDA, EU guidelines, 21CFR Part 11, EU Annexure 11 for pharmaceuticals industry.
- Responsible for implementing Quality principles (ALCOA+) during Project.
- Implementation of (LIMS) and Execution to monitor end to end activity of analysis and reporting of results.
- Responsible for curation and review of quality and validation documents with assurance of GxP compliance, adherence to safety policies.
- Responsible for knowledge sharing to new Joiners on projects and Standard operating Procedure.
- To review the master document of product Qualification & Validation.
- Reviewing of market complaints of Products, investigation and implementation of Global CAPA.
- Preparation of Validation protocols, Revision of SOPs, and training modules.
- Handling of Change Control, Non-conformances (Incidences, OOS & OOT).
  Implementation of QMS for Assuring Quality at manufacturing & Testing platform.
- Responsible for maintaining compliance in manufacturing and quality functions.
- Responsible for Putting ideas and suggestions to top management with respect to process & projects.

ORGANIZATIONAL EXPERIENCE

Syngene international limited
Senior Executive
Oct 2021 – Till Date

Talluri pharma limited
Executive
Sep 2020 – Sep2021

Serin formulation Pvt Ltd
Senior Executive
Apr-2016 – Sep 2020

ACADEMIC DETAILS

M.pharmacy (Pharmaceutics)
Kakatiya University
(2013-2016)

IT SKILLS

- Laboratory Information Management System (LIMS) – Labware V7
- SAP
- Track wise for Handling Change Control & Non-Conformance.
- Quality Management System (QMS)
- LMS
- MS Office

CERTIFICATIONS

- Certification Course three months Diploma course in Computer system validation (CSV)& Computer software Assurance (CSA) from Pharma connection
- Certificate course in Agile from My great learning academy
- Certificate course in Scrum Master from Simplilearn
- Diploma course in ISO 9001 -2015 from Alison
- Diploma Course in ISO 27000 from Alison
- Diploma course in ISO 13485-2016 from Alison
- Diploma course in ISO14001-2015 from Alison

PROFESSIONAL STRENGTH

Team player. Time management

DECLARATION

I hereby declare that the above written particulars are true to the best of my knowledge and Belief.

Komarapalem Vamshi Krishna