Rajesh Kumar Babu
Senior Veeva Vault Developer

SUMMARY

Veeva Vault Clinical professional with 3 years of experience in configuring and customizing the Veeva Vault platform to meet specific organizational needs. Proficient in user security setup, object and document configuration, lifecycle and workflow customization, configuration migration, and record/document import using the Loader tool. Experienced in VQL, REST APIs, Java SDK, and integration scripting. Strong understanding of GxP compliance and validation frameworks, including 21 CFR Part 11, EU Annex 11, GMP, GCP, and CSV. Skilled in ITSM tools such as ServiceNow and Jira, with experience authoring and maintaining knowledge base articles to enhance user support and self-service capabilities.

PROFESSIONAL EXPERIENCE

PRANA LIFE SCIENCES	Dec 24-Present

Project: Biogen – Veeva Vault Clinical Operations Suite
Role: Senior Veeva Vault Developer

- Implemented configuration changes and resolved Level 3 (L3) enhancement requests across CTMS modules, ensuring alignment with evolving business and regulatory requirements.
- Managed metadata updates, including picklists, object fields, and layout configurations to support enhanced data capture.
- Customized document types, lifecycles, and workflows to automate review/approval processes and ensure compliance with clinical documentation standards.
- Configured Vault object relationships and reference constraints to improve data integrity and streamline user navigation.
- Designed entry actions, user actions, and workflow steps to enhance operational efficiency and reduce manual workload.
- Collaborated with cross-functional stakeholders (QA, Clinical Ops, IT) to gather requirements, evaluate impact, and implement compliant configurations.
- Authored technical documentation including Compliance Risk Assessments, URS, FRS, Validation Plans, and Design Specifications in line with GxP practices.
- Participated in validation efforts by drafting and executing IQ/OQ/PQ testing and capturing validation evidence.
- Supported UAT execution by providing system demos and post-implementation support to ensure smooth adoption.
- Delivered hypercare support and managed defect resolution and change requests through structured release cycles.

Project: Novartis – Operations Support for Veeva Vault Clinical Suite

Role: Veeva Vault Support Engineer

- Resolved Level 2 (L2) support tickets for Veeva Vault Clinical Operations, ensuring minimal downtime and swift issue resolution.

- Utilized ServiceNow for efficient tracking, prioritization, and closure of support requests while maintaining clear communication with end users.

- Implemented configuration updates such as user role changes and permission adjustments based on validated business requirements.

- Executed change requests to inactivate security profiles in compliance with access control policies.

- Created and customized reports in ServiceNow to deliver insights on ticket trends and system performance to leadership.

- Troubleshot and resolved technical issues across CTMS and eTMF modules, supporting ongoing clinical operations.

- Collaborated with cross-functional teams to identify recurring issues and shift suitable responsibilities to L1.5 support.

- Contributed to Continual Service Improvement (CSI) initiatives by recommending and implementing process improvements.

- Authored and maintained knowledge base documentation and user guides, promoting user self-service and reducing support volume.

- Participated in retrospectives and team meetings to enhance support processes and knowledge sharing.

TECHNICAL SKILLS

- **Veeva Vault Modules:** CTMS, eTMF, Quality
- **ITSM Tools:** ServiceNow, Jira
- **Languages & Queries:** Apex, VQL, SOQL, SOSL, JavaScript
- **Integration & Automation:** REST API, Java SDK, cURL, MDL
- **Reporting & Workflow Automation:** Power BI, Power Automate
- **Documentation & Support:** Knowledge Base Articles, User Guides, Validation Documentation

EDUCATION

- 2011 – Bachelor of Engineering (CS), Dhaanish Ahmed College of Engineering-Anna University, Chennai
- 2014 – MBA (Sales & Marketing), Leadership Institute of AIMS-University of Mysore, Mysore

CERTIFICATIONS

- **Veeva Vault Platform Associate Administrator**
- **Certified SAFe® 6 Practitioner**