### PROFESSIONAL SUMMARY

* 5+ years of experience in techno-functional roles: Led GxP CSV initiatives for traditional on-premises as well as cloud IT systems for large corporations as well as medium and small firms in the Life Sciences industry.
* In depth understanding of 21 CFR Part 11, EU Annex 11, and CSV regulations across the globe.
* Completed multiple implementation life cycles for different versions of Oracle ERP systems in the roles of Quality Lead as well as Validation Lead.
* Performed end-to-end validation cycles: retrospective validation, baseline validation for large Pharmaceutical, Biotech and medical devices clients in North America and EU Regions.
* Detailed understanding of digital transformation, program management, Quality Management Systems (QMS), and IT regulatory compliance.
* Successfully delivered in the roles of IT Quality Lead, GxP Validation Lead, and GxP Business Analyst.
* Thorough understanding of strategic development of quality systems, validation processes and standard operating procedures.
* Experience in GxP Change Control, risk assessment, test protocols for IQ/OQ/PQ, incident management, deviation management, CAPA, summary reports, and overall GxP compliance.
* Worked extensively on Sprint/Kanban boards using JIRA and modern cloud project management platforms.
* Strong and practical leader with excellent communication, collaboration, and problem-solving skills.
* Known for integrity, trust, quick learning ability, authenticity, and ability to design win-win solutions that consistently meet / exceed stakeholder expectations.
* Efficient team worker as well as independent performer.

### WORK EXPERIENCE

* **GxP Validation Engineer, ValiMation Inc, Philadelphia, PA, USA August 2017 – January 2021**

* Led GxP Validation for multiple enterprise IT Systems (on-premises and cloud).
* Delivered validation artifacts including requirements, risk and compliance assessments, specification, test plans, test scripts (IQ, OQ, PQ), trace matrix, test reports, incident reports, deviation reports, CAPA, and validation summary reports.
* In depth knowledge and knowhow of the industry standard Quality Management Systems (QMS) configured using various platforms like JIRA.
* Contributed to change control lifecycles. Documented change progress, change actions, linked documents, and change artifacts.
* Prepared configuration specification for security configurations, workflow configurations, operations configurations and system metadata. Assisted system administrators for system configuration and setup of new GxP IT applications.
* Developed and documented Risk Management strategies for 21 CFR Part 11 compliance.
* Responsible for managing the end to end process for documenting, approving, and implementing changes in the ETQ Global Change Control (GCC) system.
* Delivered end-to-end validation for Veeva CRM and delivered test plans, test protocols (IQ/OQ/PQ), test execution reports, test incident reports, deviation reports, trace matrix, CAPA, and summary reports.
* Worked with Subject Matter Experts and System Owners to gather information and investigate issues in creating CAPA Records and driving CAPAs to closure.
* Contributed to test plan and test strategies for cloud data storage validation.
* Developed and managed GxP system lifecycle documentation (URS, FRS, IQ, OQ, PQ, SAT, FAT, CLIA), data sheets, schedules, and performed execution of validation tests, and authored final validation reports.
* Supported the review of new systems and modifications to existing systems to ensure the compliance with current validation and regulatory standards.
* Provided technical and investigational support in troubleshooting and resolving IT system configuration issues.
* Performed root cause analysis for quality problems and updated respective CAPAs.
* Worked as liaison between Quality and IT teams.

**21 CFR Part 11, Validation Projects for Life Science Customers of ValiMation:**

**ValiMation’s Validation for Veeva:**

**Responsibilities:**

* Led design and development of end-to-end regression and performance test scripts for Veeva.
* Interacting with Technical team, Business team, Validation team and developers for resolving application issues as well as proper implementation of changes to the application.
* Led validation to coordinate and deliver Validation Plans, Risk Assessments, Requirement Specification, IQ/OQ/PQ Protocols, Trace Matrix, Test Execution Reports, and Summary Reports. Also coordinated the changes (CRs) and CAPA in the in the GxP environment.
* Worked with business team to develop User Acceptance Testing (UAT) strategies, developed UAT plan and UAT test scripts.
* Built reports in Veeva for generic usage: Metrics on document usage, life cycles, unused/aborted documents, access requests.
* Reviewed quarterly upgrade release notes for Veeva systems and performed risk and compliance assessments.
* Assisted users in performing UAT testing. Coordinated logging, tracking, and closure of incidents/defects.
* Veeva Upgrade Validation Activities: Defined processes for release validation for major upgrades and patch releases: Compliance and Risk Assessment, Upgrade Testing, Change Control, and revision of validation artifacts.
* Developed a FRS review and analysis document.
* After the initial validation, I continued working as Validation Engineer for the validation of new releases and upgrades of the system.

**ValiMation’s Johnson & Johnson Vision Care(JJVC):**

**Responsibilities:**

* Contributed to the development of Master Validation Plan
* Focus on the Computer System Validation of the applications that were being used in the manufacture of products.
* Perform individual Validation Assessment, Risk Assessment, 21 CFR Part 11 Gap analysis from a GMP perspective.
* Ensured applications were compliant with 21 CFR Part 11 and Part 820.
* Assist the client team members during the formal execution of OQ/PQ.
* Reviewed all the Validation deliverables as given by the Vendor.

**ValiMation’s ServiceNow:**

**Responsibilities:**

* Led ValiMation’s team in charge of developing a “continuous” validation managed service for ServiceNow Apps.
* Interact with the Business community for understanding the Business Process and creating the User Requirements and Functional Requirements.
* Developed a risk analysis document.
* Developed Validation plan, FRS, IQ/OQ/PQ protocols, OQ/PQ scripts.
* Reviewed project deliverables and guided teams working on project documentation and Compliance issues.
* After the initial validation, I continued working as Validation Engineer for the validation of new releases and upgrades of the system.

**Validation of Learning Management System (LMS):** The project scope included validation of GxP Learning Management System (LMS) used for training of the employees. Drafted LMS Manual, User and Admin SOPs, templates, and guideline documents.

**Responsibilities:**

* Managed business needs and client objectives to meet project timelines.
* Conduct training sessions for Test Script Authors, SME’s, and Testers.
* Guided project teams in regard to adherence of processes and procedures and FDA guidelines.
* Guided the teams in meeting Documentation Policies and Procedures as part of their training.
* Find the gaps within the Policies and Procedures that pertained to the Validation and manage employee trainings accordingly.
* Interacted with the Project Manager and Subject Matter Experts for developing comprehensive training program.
* After the initial validation, I continued working as Validation Engineer for the validation of new releases and upgrades of the system.

**Validation of JIRA Issue Tracking and Ticketing Cloud Platform:** This project involves validation of JIRA used for tracking of projects, and issues involved within the project.

**Responsibilities:**

* Developed validation strategy, a detailed project plan and qualification framework (test approach, test cases, test data templates, automation models, and frequency and scope of incremental testing).
* Assign task to team members based on user stories and guide the team members in meeting the project timelines.
* Developed validation deliverables as needed and log Issues within the application and track them till their completion.
* Developing the process flow diagrams as part of PQ development.
* Interacted with Quality management members to discuss compliance gaps within the systems and procedures.
* Conducted weekly meetings to report the progress of the project.
* After the initial validation, I continued working as Validation Engineer for the validation of new releases and upgrades of the system.
* **GxP Validation Engineer, PRAD Machine Tools October 2015 – July 2017**
* Led validation of Oracle ERP: Delivered Validation Plans, Risk Assessments, Requirement Specification, IQ/OQ/PQ Protocols, Trace Matrix, Test Execution Reports, and Summary Reports. Also coordinated the changes (CRs) and CAPA in the GxP environment.
* Researched and identified opportunities to utilize QA best practices, guidelines to improve system productivity, scaling and monitoring.
* Worked with Subject Matter Experts (SME) for various ERP modules. Prepared business use cases and functional requirements for their respective modules.
* Worked with system admins and architects to understand the integration interfaces of the Oracle ERP systems for other enterprise applications.
* Reported project status/progress to the executive leadership, worked with Scrum Masters and diverse teams to manage scheduled deliverables.
* Assisted users in performing UAT testing. Coordinated logging, tracking, and closure of incidents/defects.
* Prepared flow charts, mapping documents, detail design documents, production support guides, software configuration guides, and reference documents.
* Performed system validation testing and generated validation reports.

### TECHNICAL EXPERTISE

* **Productivity Tools:** MS Office expertise, Office 365, MS Project, MS SharePoint, Confluence
* **Document Management Systems:**  Teamcenter (SIEMENS software), TrackWise, IQVIA SmartSolve, Veeva PromoMats, Veeva MedComms
* **QA and Test Management:** HP Quality Center, Smartsheet, ServiceNow, JIRA
* **ERP** **Systems:** Oracle ERP, SAP ERP
* **Quality & Compliance Management:** 21 CFR Part 820, 21 CFR Part 11, EU Annex 11, Data Lake, Process Validation, PLM, CAPA, Continuous Improvement, Good Manufacturing Practices (GMP), GAMP 5, ISO 13485, Process Failure Modes and Effect Analysis (PFMEA)

### CERTIFICATIONS

* Certified Six-Sigma Green Belt from Wayne State University, Detroit, Michigan, May 2018

### EDUCATION

* **University of Pune, Maharashtra, INDIA, May 2015**

Bachelor of Engineering in Mechanical Engineering (First Class with Distinction)

### LinkedIn PROFILE

* [https://www.linkedin.com/in/varun-rukadikar](about:blank)