

CURRICULUM VITAE

Ajit Dattatray Tekale

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OBJECTIVE:

- A result-oriented professional with **7+ years of Qualitative** experience in the fields of **Computer System Validation, Quality assurance & compliance, QMS, Title 21 CFR Part 11, GAMP5, Computer System Assurance, EU annexure 11, cGxP(cGMP, cGDP, cGLC) etc.**

PROFESSIONAL EXPERIENCE:

- Currently working as CSV Senior Consultant in HCL Tech, Bangalore (Feb 2023 to till date)
- Worked as CSV Consultant, Harjai Computers Pvt. Ltd. Mumbai (Nov 2022 to Feb 2023)
- Worked as CSV Consultant, Valsyner Consultancy services Pvt. Ltd. Pimpri, Pune. (Feb 2022 to Jul 2022)
- Worked as CSV Engineer, Antara Technology. Chinchwad, Pune. (Dec 2021 to Feb 2022)
- Worked as Officer QA (Validation & QMS), Glenmark Lifesciences Ltd. Kurkumbh, Daund, Pune. (Aug 2021 to Sep 2021)
- Worked as Junior Executive QA (Validation & QMS), INDOCO Remedies Ltd. Patalganga, Panvel, New Mumbai. (Oct 2020 to May 2021)
- Worked as Senior Executive QA (Validation & QMS), Cipla Ltd. Bangalore. (Aug 2018 to Sep 2020)
- Worked as Production Officer, Godrej Astec life sciences Ltd. Mahad, Raigad, Maharashtra, India. (May 2018 to Jul 2018)
- Worked as Production Officer, Privi Organics Ltd. Mahad, Raigad, Maharashtra, India. (Jan 2016 to Apr 2018)

GxP Computer System Validation:

- Expertise in validation of enterprise-wide Quality IT systems using established Computer System Validation (CSV) methodology such as GAMP5 and FDA guidelines.
- Exposure in Computer System Validation Life Cycle 'V' model, Waterfall and Agile methodology.
- Experience with validation/ testing tools like HPALM, qTest, JIRA, etc.
- Providing training to Validation resources on CSV approach based on project.
- Preparation, Review and Authorization of Validation Deliverable like GxP assessment, User Requirement Specifications (URS), Compliance Analysis, Compliance Plan, Traceability Matrix, Functional Specification, Design Specification, Compliance Summary Report, IQ/OQ/PQ Test Protocols & Reports, SRC, etc.
- Highly proficient with all the phases of SDLC (System Development Life Cycle) process.
- Handling of Change Management, Defect Management, CAPA Management, Business Process Management, User Story Management, Risk Assessment, 21 CFR Part 11 Assessment etc.
- Participation in CAB meetings, User Story Review Meeting, Daily Stand-Up Meetings, etc.
- Periodic Evaluation of Computer Systems against 21 CFR Part 11.
- Implementation of IT Security Controls to the GxP Systems in the facility.
- Conduct of Internal Quality Audits and follow up audits to ensure the compliance with regulations.
- Routing and Approving validation deliverables document in Adobe sign.

Tools Handled:

- JIRA, qTest, Asset Management, TRU Vault, Tru Enovia, SOLMAN, DAISY, SAP, One Identity Manager, EDMS, Trackwise, LMS, Cipdiox, Complince-wire, Summit, LIMS, MES, HMI, etc.

CSV Projects Handled:

- Track-wise, ERP, MES, Mercury SAP migration project (ECC), SAP-LIMS Interface project, SAP (MM, QM&PP), LMS, eDMS.

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- Prepared and review SDLC documentations.

Quality Management System:

- Review of Operational SOP, identifying the areas of quality failures and advising on systems and process changes for quality improvement.
- Preparation and Review SOP as part of periodic review or Version change.
- Performing Periodic review of system as per schedule.
- Handling and management of Deviations, CAPAs, incidents and change control management.
- Conduct of internal audits as per the IMS standards to ensure the compliance.
- Co-ordinate for conduct for Management review meetings at regular intervals.
- Review of Calibration and validation related documents and activities.
- Review of instrument/equipment qualification documents.
- Well verse with ALCOA+ and data integrity principle.

Regulatory Audits:

- Faced/ Co-ordinated regulatory Audit from USFDA.

Vendor Audits:

- Audited RAW material supplier units.
- Audited Calibration / validation units.

Educational Qualification:

- **B.E. CHEMICAL** from Pune university in 2015.
- **Advance Diploma in Industrial Safety (ADIS)** from Mumbai University in 2018.
- Technical certification- **Lean Six Sigma Green Belt** from TUV SUD South Asia certified.

DECLARATION:

Herby, I declare that the above information furnished by me is true to the best of knowledge and belief.

(Ajit D. Tekale)