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|  |  | Ajay Kumar Agrawal  Project Management / CSV  **Industry Preference**- Pharma | |  |  | | --- | --- | | +91-9594708386 |  | | ajaybangalore@rediffmail.com |  | | Mumbai |  | | https://www.linkedin.com/in/ajay-kumar-agrawal/ |  | |
|  | **Profile Summary**   * Visionary Thinker, Change Manager & Risk Taker with **over 16 years** of rich & extensive experience in **Project Management and Quality Management** with Pharma industry * **Strong leadership** & **people management skills**, leveraged in leading high-performing teams and engaging with key stakeholders for directing collaborative efforts towards transformation of the organization’s vision into reality * Successfully faced various **USFDA, MHRA, TGA, ANVISA, ANVIMA, International Client audits** * Vast experience in **GXP, 21 CFR part 11, GAMP 5, Annex 11, ALCOA, Data Integrity** and other compliance requirements and adherence * Gained exposure in **Global IT quality systems creation, rollout, and management** including Global IT Policy, SOPs, Procedures * Managed **Computer Software Assurance** Project and **Robotic Process Automation** implementation in user access management & production process * Proficient in conception, planning and performing Computer Systems Validation (CSV) in regulated environment; excellence in using knowledge of FDA cGMP and related regulations and guidelines, and specific knowledge of computer validation methodologies and principles to perform CSV on a variety of systems and programs * Ensured project deadlines and performance standards are met while communicating status accordingly; contributed and collaborated on CSV activities for enterprise level (multi-site projects), lab and manufacturing systems * Strong leadership & people management skills, leveraged in leading high-performing teams and engaging with key stakeholders for directing collaborative efforts towards transformation of the organization’s vision into reality   **Managerial Skills**   * Executive Leader & Motivator * Visionary & C-level Advisor * Decision Maker & Strategist * Communicator & Team Player * Proactive Planner & Change Agent   **Education**   * **Executive Program in Management** from IIT Mumbai XIII batch year 2016 * **M.Pharma** from Al-Ameen College of Pharmacy, Bangalore in 2006 * **B.Pharma** from SSITM College, Aligarh U.P Agra University in 2003   Others Courses-   * Scrum Master Certification in Feb’20 * Software Testing from SQC Infotech, Chandigarh | | **Core Competencies**    Project Management  Quality Management  Computer System Validation  ERP Validation  Digitalization  IT Infrastructure Qualification  Risk Management & QMS  Cyber Security Compliance  **Technical Skills**   |  |  | | --- | --- | | MS Office, MS Projects |  | | MS Access, MS SQL, FoxPro |  | | HPALM, JIRA, X-ray, Confluence, Trackwise, Service Now |  |   **Knowledge Purview**   * Spreadsheet Validation * SDLC & Quality Management Systems (CAPA, Deviation, Change control) * GAMP Guideline * GxP Analysis, Gap Assessment and 21 CFR Part 11 of USFDA in Validation * Validation of AI, RPA Bot & IMMERSIV Technology application |
|  | **Work Experience**  **Since Dec’20 with Infosys Consulting, Mumbai as Sr. Consultant**  **Key Result Areas:**   * Leading a team of 20-40 person and working as Project Manager and Project Quality Manager for Pharma IT application for Novartis projects * Providing overall leadership to the entire project team including managing deliverables of other functional team leaders * Spearheading project budgeting, timelines, vendor management, project sponsors and stakeholder management * Defining Validation Strategy and stakeholder management * Supporting testing team during test cases execution * Authoring key project deliverables like Validation Plan and Validation Report * Handling various projects like IQVIA Salesforce, Master Document Management, SAP, Trackwise and Integration project * Reviewing and approving SDLC documents and traceability matrix as per GAMP 5 guidelines * Creating end user training material and ensuring that end users were trained before handover of application to business and operations * Ensuring that project was executed with zero non-compliance   **Highlights**   * Set-up CSV practice for organization including recruitment, training, and deployment of CSV team spread across multiple locations in India * Managed more than 50 GxP CSV related to Project Management * Rolled-out Enterprise applications (SAP, LIMS, MES) as per GAMP 5 through multi-stakeholder partnerships and accountability framework   **Feb’19–Feb’21 with Sun Pharma Ltd., Mohali, Punjab as Manager- IT -CSV**  **Key Result Areas:**   * Worked as Project Manager for IT application (Project Charter, Project Plan, Budgeting, Project Timeline and Stakeholder Management) * Led CSV activities and service assurance testing in-line with requirements of internal procedure & regulatory requirements * Managed infrastructure qualification of Hardware/Servers/Infrastructure Apps/Tools * Maintained categorization of Off-the-shelf validation categories * Created, managed, and maintained validation of GxP computerized systems such as SAP, LIMS and so on * Provided Qualification/Validation protocol and report oversight * Managed creation of Installation Qualifications, Operational Qualifications and Performance Qualifications and other GAMP 5 document generation * Participated in CSV effectiveness and improvement initiatives   **Previous Experience**  **Dec’16-Feb’19 with Pfizer Ltd., Aurangabad, Maharashtra as Assistant Manager – CSV-IT**  **Highlights:**   * Ensured quality and compliance of GMP electronic system used in different area like Pharmacovigilance   **Jun’14–Dec’16 with Watson Pharma, Ambernath, Thane as Executive -CSV-QAA**  **Highlights:**   * Ensured quality and compliance of GMP electronic system used in different area like Labs, Manufacturing and enterprise level systems * Provided IT CSV support for agency audits including multiple international agencies at one time * Managed CSV Contractors for a variety of project implementations across Enterprise Applications   **Jun’12-Jun’14 with USV Ltd., Navi Mumbai as Sr. Executive – Quality Assurance**  **Highlights:**   * Maintained and developed CSV, Quality Management System Framework for worldwide implementation   **Feb’08–Jun’12 with Reliance Life Sciences, Rabela, Thane as Sr. Executive – Quality Assurance**  **Highlights:**   * Steered execution of Process Validation, Cleaning Validation & Utility Qualification protocol activity * Rendered services as a validation lead for global/site IT validation projects * Designed overall computer system validation strategy * Worked with IT and User Groups to evaluate change control requests for GxP systems * Conducted regular compliance internal audits, part 11 compliance assessment, provided guidance & support and ensured closure of audit findings with the help of the desired team   **Sep’06–Jan’08 with Biocon Ltd., Bangalore as Executive- Quality Assurance** | | |
| **Personal Details**  Date of Birth- 31st July 1981  Languages Known- Please Mention  Permanent Address- House # G-11, New Gopal Puri, Aligarh, UP – 202001  Present Location Ho. No. B5-304, Arihant Arshiya, Kalapur Toll Naka, Khopoli, Dist. Raigarh, Maharashtra- 410203 | | | |