Krunal Pastagia
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Summary:

- Possess a Bachelor of Science in Computer Science coupled with over 15 years of experience in Lab Informatics, Computer Systems Validation, Technical Writing, and Business Analysis within the pharmaceutical industry, including roles at Merck, BMS, Johnson & Johnson, and Eli Lilly & Co.
- Demonstrates exceptional communication and interpersonal abilities, adept at managing multiple responsibilities efficiently in fast-paced, time-sensitive environments. Proven readiness to embrace new challenges to achieve or surpass objectives.
- Proficient in developing Deviations, CAPAs, and conducting non-conformance assessments.
- Offers strong expertise in System Administration, Validation Lifecycle, and Quality/Validation consultancy for regulated enterprise systems like SAP ERP, Track and Trace, Veeva Vault (QualityDocs, QMS), TrackWise (CAPA, CCM), LIMS, Empower, as well as standalone systems including UV-VIS, FTIR, Mettler Toledo Tiamo, Perkin Elmer, among others.
- Skilled in authoring, reviewing, and modifying documents pertinent to Computer System Validation Lifecycle, such as Validation Master Plans (VMPs), Standard Operating Procedures (SOPs), URS, FRS, DQ, FAT, SAT, Installation Qualification (IQs), Operational Qualification (OQs), Performance Qualification (PQs), and Validation Summary Reports (VSRs).
- Extensive experience utilizing HPALM and JIRA across validation and testing phases.
- Proficient in FDA regulations, GAMP5 guidelines, and GxP (GCP/GLP/GMP) standards.
- Substantial background in 21 CFR Part 11 compliance and audit trail validation processes.

Education:

- **Major:** Computer Science
- **Degree:** Bachelor of Science
  New Jersey City University, Jersey City, NJ
- Certified Scrum Master (CSM)

Skills:

- System Validation Oversight
- Standardization and SOP Development
- Vendor and Infrastructure Management
- Innovation and Continuous Improvement
- Change Management
- Process Improvement
- Project Management

Applications:

- Microsoft Office
- Lotus Notes
- Maximo,
- SAP
- GMP
- Trackwise
- HP-ALM,
- Docspace
- Master Control
- Jira

- Confluence
- CelDox
- Service Now
- Compliance Wire
- Empower
- Veeva Vault

Professional Experience:

SME IT GxP Systems/Quality Support **10/24 to Present**
SCA Pharma

- Perform QA review and approval of validation documents, Process Validation, Equipment Qualification (IQ/OQ/PQ), and Computer System Validation (CSV).
- Ensure all validation activities comply with regulatory standards, including FDA, cGMP, GxP, and 21 CFR Part 11.
- Provide QA oversight during validation execution, including protocol review and discrepancy resolution.
- Sign off as IT Quality on validation documents to ensure compliance with internal and regulatory requirements.
- Support audits and regulatory inspections by ensuring documentation readiness and compliance.
- Collaborate with cross-functional teams, including engineering, manufacturing, and quality, to achieve validation and compliance goals.
- Provide on-going to support to Master control and other lab Systems.

IT Quality Compliance **12/23 to 05/24**
Eisai, Inc

- Conduct comprehensive gap assessments to identify key control gaps in IT compliance, enabling the development of future-state control matrices and the implementation of routine testing and review procedures tailored to varying levels of risk.
- Develop an IT compliance risk assessment framework alongside periodic review processes to evaluate regulatory, commercial, organizational, inherent, and residual IT compliance risks effectively.

SME IT GxP Systems **03/22 to 10/23**
CMIC CMO USA

- Acted as the operational lead for existing systems, holding regular meetings with business partners and vendors.
- Collaborated with Business and QA Project Management teams to ensure clear understanding of ITES compliance deliverables, project status, risks, and issues.
- Managed change requests, initiated controls, and coordinated system patches, ensuring quality and seamless integration across platforms.
- Monitored IT system performance to optimize cost and productivity, recommending infrastructure improvements.
- Supported IT project management in implementing solutions according to governance processes.
- Worked with subject matter experts to align operations, analyze compliance data, and drive improvements while reducing operational risks.
- Developed and refined SOPs and a validation framework to standardize organizational practices.
- Conducted Risk Assessments and ensured FDA compliance for new GxP system designs, performing monthly data integrity checks on QC Lab and Manufacturing Systems.

- Assisted in vendor qualification and managed infrastructure projects to maintain a secure IT environment.
- Aligned GxP system needs with business objectives to optimize resource allocation and efficiency.
- Collaborated with stakeholders to develop policies and procedures for managing SaaS applications and server-based solutions.
- Administered computer GxP systems (e.g., Tiamo, FT-IR, UV-Vis, Malvern, Solo-VPE, Waters Empower), network and systems administration, and data storage solutions, conducting research to enhance user satisfaction.
- Provided standards and best practices for GxP system change management and project execution to ensure consistency and quality.
- Developed and managed system documentation, including specifications, SOPs, and training materials, to enhance user understanding and compliance.
- Supported GxP and Non-GxP network connectivity and servers, establishing segregated domains for data separation.
- Led organizational change management efforts to support GxP system compliance, fostering continuous improvement.
- Prioritized and resolved application issues, escalating to vendor support when necessary.
- Managed vendor activities, including contract negotiations, licensing, and renewals.
- Interfaced with the CSV group to lead validation activities, reviewing and approving CSV documentation to ensure IT systems met security and compliance standards. Performed UAT/PQ as needed.
- Ensured all IT equipment (GxP and Non-GxP) was installed and tracked according to asset management procedures.
- Developed training materials and knowledge items to facilitate user adoption of new technologies.
- Ensured computer systems validation adhered to 21 CFR Part 11 guidelines, including audit trails, electronic signatures, and data integrity.
- Provided configuration support for key systems, including user management, backup/restore, disaster recovery, and archival processes.
- Led and managed internal and external consultants in GxP systems management to deliver business capabilities.

SME of IT GxP Application **11/20 to 03/22**
Torrent Pharma

- Managed system validation quality aspects, including updates and migrations, ensuring seamless integration across development platforms.
- Improved IT system lifecycle and validation procedures to boost efficiency.
- Successfully implemented and deployed GxP IT systems.
- Participated in the annual budget cycle with finance and the Overseas Leadership team to submit budget requests for new technology implementations.
- Led and managed a team of skilled direct reports to deliver business capabilities.
- Developed and refined SOPs and the validation framework to standardize practices across the organization.
- Perform QA review and approval of validation documents, Process Validation, Equipment Qualification (IQ/OQ/PQ), and Computer System Validation (CSV).
- Served as a Subject Matter Expert (SME) in computer systems, security, network, systems administration, databases/data storage systems, and phone systems – both on-premises and cloud-hosted solutions.

- Facilitated User Acceptance Testing (UAT) and conducted system integration testing.
- Created documents and on-demand reports for compliance activities, including patching, deviations, audits, and issue management.
- Revised IT SOPs to ensure alignment with IT procedures and industry best practices.
- Generated precise and standardized reports with key insights to communicate operational performance to the IT leadership team.
- Assisted with firewall installation and configuration to ensure data security.
- Established and maintained system administration guides and IT policies.
- Supervised and managed external vendors for other sites.
- Provided local support for on-site desktops, A/V, help desk, lab computers, label printers, handheld mobile devices, scanners, etc.
- Contributed to User Requirements to ensure GxP IT systems meet 21 CFR Part 11 and IT security requirements.
- Ensured Data Integrity on QC Lab Systems, including standalone, enterprise, and manufacturing systems.
- Handled IT change controls and assisted with QA/GxP change controls, UAT, and PQ activities.
- Established and updated disaster recovery plans, ensuring daily backups.
- Acted as a liaison for GxP technology enhancements, roadmap, and capacity planning.
- Managed resource allocation, strategy, and project/program planning for GxP IT systems.
- Provided audit support for internal and external audits.
- Evaluated technology solutions for adherence to 21 CFR Part 11, data integrity, and regulatory requirements.
- Managed all GxP administrator passwords for computer systems and smart equipment.
- Implemented site-wide policies and procedures for commissioning, qualification, and validation, including computerized system validation.
- Identified critical operating systems security updates and implemented changes.
- Assisted in the technical design and implementation of new GMP systems and infrastructure.
- Ensured availability and conducted technical maintenance and support activities, including adding users, backup/restoration, disaster recovery, and archival.

Validation Engineer /IT GxP Consultant **06/20 to 02/22**
Spark Therapeutics (The FDA Group)

- Acted as the interface to the CSV group and participated in validation activities, reviewing and approving CSV documentation from an IT perspective to ensure CSV deliverables and IT systems met security and compliance requirements; performed UAT/PQ when necessary.
- Provided input to User Requirements to ensure GxP IT systems met Part 11 and IT security requirements.
- Managed the initialization and completion of IT change controls; assisted with activities related to QA/GxP change controls.
- Designed disaster recovery plans.
- Served as a liaison for GxP technology enhancements, roadmap development, and capacity planning.
- Managed resource allocation, strategy, and project/program planning for GxP IT systems.
- Provided audit support for internal and external audits.
- Demonstrated understanding of GxP requirements and the ability to translate regulatory requirements into technical solutions.
- Evaluated technology solutions for adherence to 21 CFR Part 11, data integrity, and regulatory requirements.
- Responsible for maintaining all GxP administrator (full permission) passwords for computer systems and smart equipment.

- Ensured that all GxP IT equipment (e.g., workstations, printers) was installed and tracked according to IT asset management procedures.
- Configured/assisted with firewall installation and configuration to ensure data security.
- Maintained system administration guides and IT policies.
- Assisted with the installation and configuration of GxP systems to ensure compliance with 21 CFR Part 11; configured systems for 21 CFR Part 11 compliance (e.g., audit trails, electronic signatures, security role configuration, permissions, and password configuration).
- Identified critical operating system security updates; evaluated and implemented operating system changes.

Validation Engineer **01/20 to 01/21**
Akorn

- Designed, developed, and implemented an audit trail review program for computerized systems to ensure compliance with regulations and company standards.
- Established protocols for systematic and comprehensive audit trail reviews, covering all relevant system activities.
- Collaborated with cross-functional teams to identify key risk areas and prioritize audit trail reviews.
- Provided training on audit trail review procedures, fostering a culture of compliance.
- Liaised with internal stakeholders and external auditors to facilitate transparent audit processes.
- Implemented continuous improvement initiatives for the audit trail review program.
- Managed metadata reviews for administrative activities and laboratory data systems.
- Collaborated with end-users and process owners for system reviews and validation activities.
- Worked with IT Application Support for system maintenance and change controls.
- Conducted GMP audits of manufacturing and packaging sites, reporting findings and recommendations.
- Managed data security and continuity requirements.
- Facilitated periodic assessments of laboratory systems for compliance.
- Managed system master data addition, verification/validation, and troubleshooting of analytical methods/instruments.
- Served as the business process administrator for laboratory software.
- Enforced company compliance and safety requirements.
- Provided technical support for investigations.
- Participated in data migration and verification protocols.
- Reviewed and approved CSV documentation to ensure security and compliance.
- Conducted validation assessments of laboratory systems.
- Performed routine queries and audit trail reviews of computerized systems.
- Managed authorized user lists and documentation for IT changes.
- Initiated and executed change control within laboratory systems.
- Coordinated with vendors to resolve application issues.
- Created, revised, and executed standard operating procedures.
- Actively participated in implementing new equipment and compliance initiatives.
- Reported system risks observed during reviews.
- Ensured timely completion of Quality events or CAPA items.

Validation Engineer /IT System Administrator & Compliance **09/19 to 01/20**
Wuxi AppTec

- Led improvisation efforts in IT infrastructure related to the laboratory system applications to improve the overall efficiency and effectiveness.
- Responsible for the technical support during the computerized system issue trouble shooting.
- Responsible for the day-to-day support of IT infrastructure of regulated systems.
- Central point of contact for all regulated system support issues reported to the IT helpdesk

- Responsible for regulated systems user management, security management, backup/restore and disaster recovery.
- Performed validation in accordance to FDA and Pharma regulations also checked to ensure that they are compliance with 21 CFR part 11, 210 and 211 of multiple Quality computer system validation projects, assisted in the planning and organization of these projects required to achieve group and corporate objectives.
- Provided support of preparing, reviewing, approving and implementing system changes and enhancements.
- Worked with QA/Validation/end users to analyze their processes and needs and employ comprehensive knowledge to assist in decision-making.
- Interfaced with sponsor and regulatory audits as directed by management.
- Maintained records and documentation for areas of responsibility as required by SOPs.

Sr. Validation Engineer **09/17 to 09/19**
BMS

- Led the SAP upgrade to SAP S4/Hana and reviewed and approved test scripts in HP ALM.
- Drafted and reviewed Computer System Validation Lifecycle Documentation (User Requirements, Configuration Specs, etc.) for SoloVPE, Vi-Cell, Plate Readers, iCE3 Protein Analyzer, etc.
- Configured the system according to User Requirement Documentation.
- Provided technical and validation support for the initiation of computer systems.
- Assisted in the development of standard operating procedures related to validation and technical administration of computerized systems.
- Reviewed, approved, and provided input on system validation documents.
- Aligned validation activities with corporate policies and regulatory standards by collaborating closely with diverse teams.
- Interfaced with system owners, IT, QA, and vendors related to computerized system validation projects.
- Implemented Robocopy within the system.
- Created Instrument IDs/Child IDs in BMRAM to document proper system calibration.
- Supervised vendors for calibration, preventative maintenance, and qualification functions.
- Perform QA review and approval of validation documents, Process Validation, Equipment Qualification (IQ/OQ/PQ), and Computer System Validation (CSV).
- Administered standalone lab software, as well as enterprise software like BMRAM (Blue Mountain Regulatory Asset Management), ELN (electronic laboratory notebook), and Waters Empower 3 Chromatography Data Acquisition System.
- Performed system administration, support, user account setup, and maintenance activities for scientific systems.
- Assisted with IT projects related to laboratory software implementation, upgrades, and support.
- Created GxP documentation for IT, such as SOPs, Configuration Specifications, and change controls.
- Collaborated with end-users and business capability managers to understand, verify, and develop IT requirements for laboratory systems or enhancements.
- Interpreted business goals and requirements to devise technical solutions.
- Acted as a liaison between the business and IT service providers to coordinate enhancements, provide integration, and resolve issues.
- Worked in a GxP environment utilizing Celdox and ServiceNow.

Validation Consultant **05/16 to 05/17**
Johnson & Johnson (Sogeti)

- Established various validation deliverables per Computer Validation Life Cycle, Software Development Life Cycle
- Reviewed validation deliverables for websites, mobile and web apps in HP ALM Quality Center following GXP and GDP guidelines.
- Wrote and Maintained Validation deliverables such as design specifications, business requirements Change Control/Validation Summary Report.
- Created/Reviewed business requirements, user stories and test cases/test scripts
- Worked in agile/scrum environment utilizing HP-ALM, Docspace and Jira.

QC Computer Validation Specialist **02/07 to 05/16**
Imclone Systems (Eli Lilly and Company)

- Performed validation in accordance to FDA and Pharma regulations also checked to ensure that they are compliance with 21 CFR part 11, 210 and 211 of multiple Quality computer system validation projects, assisted in the planning and organization of these projects required to achieve group and corporate objectives.
- Drafted and review computer system validation lifecycle documentation (Plans, Requirements, Protocols, Requirement Traceability Metrics, Summaries, etc). Execute IQ/OQ/PQ protocols. Validated SoloVPE, Vi-Cell, Plate Readers, iCE3 Protein Analyzer etc.
  Provided technical/validation support for the initiation and management of change controls related to QC computer systems.
- Assisted the QC laboratories with the selection and implementation of computerized systems within the QC laboratories, as well as upgrades to existing systems.
- Assisted in the development of standard operating procedures relating to validation/technical administration of QC computerized systems.
- Interfaced with system owners, IT, QA and vendors related to QC computerized system validation projects.
- Performed Periodic Reviews of Validated Systems.
- Wrote and updated department Job Plans & Work Orders. Scheduled and planned preventive maintenance work, both in-house and contractors. Interfaced with engineering to assist with the scheduling and planning of engineering projects.