**SHRUTI SATYA ANTHATI**

**Computer System Validation Consultant**

**SUMMARY**

* Over 5+ years of strong experience as a Computer System Validation Consultant (CSV Consultant), and Quality Assurance in pharmaceutical, and Medical Device Industries.
* Excellent in Project Planning, Gathering / Reviewing/ Gap analysis of requirements, Design specifications, and creating Master Validation Plans.
* Extensive working knowledge of the Validation Life Cycle;  expertise in developing the following validation deliverables – Risk Assessments, Regulatory Assessments, 21 CFR Part 11 Assessments, Gap Analysis documents, Validation Plans, Qualification Protocols, Validation reports, IQ/OQ/PQ test scripts, Deviation/Incident Reports, Change Controls and Problem Reports.
* Experience in performing 21 CFR Part 11 Gap Analysis, Risk Analysis, and developing Remediation Plans.
* Extensive hands-on experience and knowledge of Food and Drug Administration (FDA) regulations (particularly 21 CFR Part 11/ 210/ 211/ 820) qualification-testing protocols (IQ, PQ, OQ).
* Extensive working knowledge of Software development Lifecycle (SDLC)
* Understanding of Industry standards like ISO 9000/01
* Experience in GxPs (GMP, GCP, GLP). GAMP guidelines, Validation process, and QA Strategies.
* Experience in managing the Change Controls for GxP system enhancements/changes and ensuring that the systems are maintained in a validated state.
* Excellent experience in validating a wide variety of applications and infrastructure - Business Intelligence Reports, Excel spreadsheets, Electronic Document Management Systems, Track Wise, and LIMS.
* Experience in developing test scenarios, test cases and test scripts, and testing standards.
* Competent in analyzing business and workflow, performance issues, and evolving strategies for Load Tests, Stress Tests, and User Acceptance Tests.
* Experience with test management tools such as Quick Test Professional (QTP), HP Application Lifecycle Management (ALM), and HP QC.
* Good understanding of Root cause analysis, Corrective, and preventive action (CAPA), and Failure Mode Effect Analysis (FMEA).
* Performed Independent Validation and Verification testing to test credit approval modules.
* Good mentoring skills, analytical skills, and presentation skills with strong communication skills.
* Hardworking, self-starter, and consistent performer.
* Capable of working both as a team member and independently.

**EDUCATION:**

Masters in Health Informatics

Bachelors in Pharmacy

**Technical Skills:**

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| **Key Skills** | Validation, IQ, OQ, PQ, Good Manufacturing Practices (GMP), CRF Part 21 Regulations (21 CFR Part 11/210/211/820), Gap Analysis and Remediation, Audit Objectives and Scope,Validation Plan and Protocols (Prospective, Process, and Concurrent), Risk Analysis, Quality Assurance, Requirements Analysis, Test Plan Development and Implementation, User Acceptance Testing, Regression Testing, System Testing, Integration Testing |
| **Applications/Tools** | SharePoint, MS-SQL, JIRA, HP Quality Center 10.00, HP ALM 11.52, eQMS, DMS, LIMS(LabWare), LMS (Learning Management System), TrackWise8, Veeva - Electronic Document Management System (eDMS), E-Log System, Advanced Maintenance Management System (AMMS), Spreadsheet Validation |
| **Business Tools** | MS Visio, MS Project, Microsoft Office |
| **Database/ Server** | SQL, My SQL Server |
| **Testing / Bug Tracking** | JIRA, HP ALM, HP Quality Centre, QTP, WinRunner |
| **Operating System** | Windows (7/10/11), macOS |

**WORK EXPERIENCE**

**Xellia Pharmaceuticals, Bedford, OH**

**Validation Analyst, May 2022 - Present**

Xellia Pharmaceuticals (“Xellia”) is a specialty pharmaceutical company developing, manufacturing, and commercializing anti-infective treatments against serious and often life-threatening bacterial and fungal infections. Company’s evolution, Xellia Pharmaceuticals focuses its R&D investments within inhalable and injectable product technologies, generating an innovative pipeline of value-added anti-infective medicines intended to enhance patient care, providing convenience and ease of use for healthcare professionals.

**Responsibilities:**

* Involved in the implementation and validation of Advanced Maintenance and Management System (AMMS) and Labware LIMS (Ver 5). Performed paper-based testing and testing using HP ALM. Responsible for validating Track Wise 8.5 – Change Control Management and CAPA modules.
* Performed Computer System Validation Assessment for the Trackwise system to identify the validation deliverables for the project implementation
* Authored and reviewed the validation-related documents such as Validation Plan, User Requirements Specification (URS), Functional Specification (FS), Design Specification, Test Plan, Requirements Traceability Matrix, Test cases, Test Results, and Validation Summary Report.
* Performed high-level Risk Assessment, 21 CFR Part 11 Assessment, and Detailed Risk Assessment for the GxP computerized systems.
* Documented Installation Qualification (IQ), Operational Qualifications (OQ), and Performance Qualifications (PQ) and Deviations using standard templates.
* Reviewed and updated end-to-end validation documentation for Track wise (CAPA) to ensure compliance with company policies and procedures.
* Performed review of the following deliverables – Regulatory Assessments, Risk Assessments, Validation Master Plans, Qualification Protocols, Design Reviews, User/Functional Specifications, IQ/OQ/PQ, Validation Summary Reports, Final Reports, Gap Analysis/Remediation Plans, User Manuals and Training Materials.
* Developed applicable test cases for Operational Qualification testing, System testing, and User acceptance testing.
* Tracked defects encountered during testing and reported using ALM and paper-based manual testing.
* Responsible for Peer review of test plans, and test scripts and executing them for validation testing.
* Performed Dry runs and executed test protocols, System Integration Testing to verify that the integration of different LIMS modules has been successful and report interface errors.
* Authored all change control requests for all changes/enhancements by using Trackwise.
* Reviewed proposed changes and performed impact assessment to identify the validation requirements necessary to maintain the system's validation status after execution of the change.
* Performed GAP analysis and initiated CAPA as required and developed remediation plans to mitigate non-compliance.
* Ensured all change control requests were in the process of being reviewed to have the appropriate documentation and/or prerequisites that were required.

**Environment**, HP ALM 11.52, QTP, HP Quality Centre, FDA 483, Trackwise, EDMS, DMS, LMS, LabVIEW, LIMS, AMMS, 21CFR parts 11, 210,820, cGMP, GLP, GDP, HIPAA, SharePoint, MS-SQL, MS Office Suite, JIRA

**Alkermes, Wilmington, OH**

**Validation Analyst, September 2021 – April 2022**

Alkermes focuses on the development of innovative medicines that seek to address the unmet needs of people living with serious mental illness, addiction, and cancer. As a fully-integrated, global biopharmaceutical company, we apply our scientific expertise and proprietary technologies to develop products that are designed to make a meaningful difference in the way patients manage their diseases.

**Responsibilities:**

* Involved in the Global Implementation and Validation of CAPA, and CCM workflow; Reviewed and updated end-to-end validation to ensure compliance with company policies and procedures.
* Prepared documentation for all aspects of the Computer Systems Validation (CSV) lifecycle, under FDA regulations including 21 CFR Part 11.
* Hands-on review of the following deliverables – Regulatory Assessments, Risk Assessments, Validation Master Plans, Qualification Protocols, Design Reviews, User/Functional Specifications, IQ/OQ/PQ, Validation Summary Reports, Final Reports, Gap Analysis/Remediation Plans, User Manuals, and Training Materials.
* Developed OQ and PQ test cases for Track wise and IRMS
* Coordinated the execution of Operational Qualifications Test Scripts with different modules and specifications.
* Wrote IQ, OQ, and PQ and developed Data migration protocols, and conducted the dry run in Quality Center.
* Developed Detailed Risk Assessment documentation for managing the risk levels used before the validation of the system.
* Developed Trace Matrix document for mapping the URS, FS, DS (Design Specification), IQ, OQ and
* Proficient with Corrective Action Preventive Action (CAPA) workflow including Investigation, Investigation Task, Action, Request, Request Extension, and Closure phases.
* Conducted reporting and tracking of defects using the Quality Center.
* Developed and maintained Traceability Matrix documents of all systems.

**Environment**, HP ALM 11.52, QTP, HP Quality Centre, FDA 483, Trackwise, EDMS, DMS, LMS, LabVIEW, LIMS, AMMS, 21CFR parts 11, 210,820, cGMP, GLP, GDP, HIPAA, SharePoint, MS-SQL, MS Office Suite, JIRA

**Granules India, Hyderabad, India**

**Validation Consultant, June 2019 – August 2021**

Granules India is a vertically integrated, high-growth pharmaceutical product manufacturing company based in Hyderabad, India. We manufacture high-quality API, FD, PFI, and Specialty Products with a focus on customer-centricity, and bringing quality, reliability, and sustainability through affordable drug options.

**Responsibilities:**

* Analyzed user requirements document and system specification document.
* Developed, implemented, and executed test methodologies and plans to ensure software product quality.
* Created test plans and detailed test cases using the Quality center.
* Tracked changes made to the requirements, tests, and defects using the Quality center.
* Created documents to comply with the appropriate FDA regulations including 21 CFR Part 11 requirements.
* Worked on Traceability Matrix.
* Created and reviewed IQ, OQ, PQ protocols, and Master Validation Plan.
* Developed a Validation Master Plan for this custom-designed software as an integrated system along with the associated instruments.
* Conducted Risk Analysis meetings to analyze the risk involved in implementing the Track Wise system in the existing business process.
* Prepared Traceability Matrix to define the relationship between requirements, design specifications, and test scripts.
* Involved in GAP analysis for user requirements verification and devised a remediation plan.
* Automated Test scenarios for GUI, Functionality, Boundary, Security, and Regression Testing.
* Performed Data Migration Policy.
* Coordinate the activities in the SDLC with a focus on system analysis and maintenance activities.
* Technical involvement with projects, support during audits, and collaboration with vendors.
* Wrote and executed test cases to validate user requirements and exercise all system functions.
* Provided Validation strategy documents which involved project overview, development approach, roles and responsibilities, validation approach, and deliverables.

**Environment**, HP ALM 11.52, QTP, HP Quality Centre, FDA 483, Trackwise, EDMS, DMS, LMS, LabVIEW, LIMS, AMMS, 21CFR parts 11, 210,820, cGMP, GLP, GDP, HIPAA, SharePoint, MS-SQL, MS Office Suite, JIRA

**Leucine Bangalore, India**

**Validation Consultant, August 2017 – May 2019**

The Product Defect Tracking System (PDTS) is an enterprise solution, with a configurable workflow. PDTS enables customer representatives to enter product complaint information online in real time, while on the phone with the customer. PDTS supports trending analysis (to be used by the QA department) and the summarized findings for regulatory reporting and history files.

**Responsibilities:**

* Developed detailed project plan including WBS, project key milestones, resources allocation, project interim report, and communication matrix.
* Validated the application following FDA regulations and checked to ensure compliance with 21 CFR Part 11, 820, 210, and 211 requirements
* Prepared, reviewed, executed, and summarized validation protocols (IQ, OQ, PQ) for IT/computerized systems; Ensured validation efforts were conducted in an appropriate and timely manner. Involved in document control and change control management
* Assisted in Ranking the risks associated with functions executed in the system based on the severity of impact on product quality, the probability of a hazard occurring, and the probability of detecting a given hazard.
* Verification, clarification, and sign-off of the functional requirements/functional specification.
* Developed fully documented test and validation plans, preparation, and execution of IQ, OQ, documentation of Test and Validation reports, OOS, UAT documents, and Traceability Matrix.
* Supervised and approved a complete set of UAT test scripts (using WinRunner and Test Director) to ensure completeness of the implementation and the end-to-end functionality.
* Played a key role in project issues such as release management, change management, scope control, and requirements prioritization.
* Developed SOPs and Compiled Training Manuals for the new working environment.
* Document strategy for maintaining the Validated State.
* Detailing FDA’s approach to compliance issues, including the FDA 483 Observations, and summarizing the outstanding problems and issues.

**Environment:** HP ALM 11.52, QTP, HP Quality Centre, FDA 483, Trackwise, EDMS, DMS, LMS, LabVIEW, LIMS, AMMS, 21CFR parts 11, 210,820, cGMP, GLP, GDP, HIPAA, SharePoint, MS-SQL, MS Office Suite, JIRA