

Srinivas Reddy
Validation QA Analyst
Email: srini00423@gmail.com

Edison, NJ
Ph: 732-648-7176

Profile

- Over 18 years of Pharmaceutical, Manufacturing, Media, and Federal Government, Telecommunications experience in Computer System Validation and Quality & Compliance, and QA Lead.
- Ability to prioritize, organize, plan and manage multiple tasks efficiently and having Excellent written and verbal communication skill and strong leadership qualities.
- Evaluates validation activities and documentation to ensure that they meet FDA standards, User Requirements, deliverables such as Validation Plan, Test Plan Protocols, Validation Summery report, Risk Assessments Reports,
- Experience in generating, reviewing, and executing validation and change control documents, authoring SOPs, Protocols (IQ, OQ, PQ) of Process Control Systems
- Expertise in development of QA project deliverables, such as System and UAT design test scripts and System, UAT test protocols, and Summery Report for System and UAT
- Experience in FDA regulations, Validation, and SOX, GxP compliance requirements as they relate to the validation protocols and IQ (installation qualification), OQ (Operational Qualification), and PQ (Performance Qualification).
- Experience in 21 CFR Part 11 820 Electronic Signatures, Electronic Records, and GAP analysis remediation plan requirements
- Good Exposure in Change Management, Change Control, and Review, Edit and Approve, Execute Test scripts
- Exposer to CAPA, GAMP guideline approach and development of **Standard Operating Procedures (SOP's)**
- Ability to work on multiple projects in a fast paced environment experience in SDLC Methodology Waterfall, Agile
- Excellent understanding of Ascendant / ASAP methodologies, and other ERP
- Good communication and inter-personal skills, accustomed to work in a team environment with tight schedules and capable of working efficiently under pressure, manage multiple project

Technical

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| Operating Systems: | Windows 95/98/NT/2000/XP, UNIX, MS DOS |
| Languages: | SQL, PL/SQL, C++, ABAP/4, AND XML |
| Databases: | Oracle 8i /9i, 10g SQL Server 2000, DB2, MS Access |
| GUI: | Developer 2000, (Forms 4.5, Reports 2.5), Visual basic 5.0 |
| ERP: | SAP R/3 4.5, 4.6C, ECC 5.0, 6.0 FI, SD, MM, CRM, FSCM, HR |
| Scripting: | VB Script, 4 Test Language, TSL, UNIX Shell Scripting |
| Browsers: | Internet Explorer, Netscape, Navigator, |
| Interfaces: | ALE, EDI/IDOC, Web Methods, Ariba, Siperian, Prism |
| Tools: | Test Director, HPQC, Clear Quest, Rational Tool, TrackWise, OTIS, SharePoint |

Experience/Project Work

Ortho Clinical Diagnostics (OCD)
Raritan, NJ
Role: Validation QA Lead
Project: Foundation

Sep'15-Present

- Ortho Clinical Diagnostics (Ortho) is a global leader of in vitro diagnostics. Ortho serves two primary industries in the medical field: clinical laboratories, by producing platforms and assays that test for a variety

of diseases. Ortho Clinical Diagnostics (Ortho) is separated from the J&J, and the OCD data has been migrated from J&J to OCD Foundation project.

Responsibilities/Deliverables:

- Author, Review and approve SDLC Validation documentation deliverables such as Compliance Plan, Compliance Analysis, and Risk Assessment, Test Plan, Test Scripts, and Compliance Reports different stream applications for OCD Foundation project
- Ensure compliance with 21 CFR Part 11, 211, 820 requirements and predicate GxP standards through integrated quality reviews of all computer system validation processes, procedures and documentation
- Review and execute documenter's validation deliverables like User Requirements, Functional Specification, Technical Design Documents, and Traceability Matrix, Reports make sure that all the J&J needed information was being migrated with the OCD framework and following GAMP/GAMP 5 guide lines.
- Review and Approve System and UAT Pre/Post Execution Test Scripts, and approving the Defects in RQM Tool
- Guide IT and Business stakeholders collaboratively with project teams, providing CSV guidance and support to project and/or base business support teams in the resolution of validation documentation corrections and/or test defects
- Interacted with IT and Business stakeholders on internal OCD global regulations focused on the implementation of Foundation Project and advice on risk based validation, regulatory gaps and adherence to internal SOPs
- Review and Approve PRT (Production Readiness Testing) scripts in production environment.
- Review, Edit and Approve change controls forms for normal and emergency changes
- Developed Standard Operating Procedures (SOPs)
- Support change control processes for the Quality Operations group, evaluating change control documentation, release mgmt., data changes, testing for compliance and GXP impact
- Provided Compliance and deliverables input as and when needed by the manager
- Monitoring systems and processes to ensure compliance with standard operating procedures, audit compliance and industry best practices moving the organization towards a positive risk management.
- Create and implement training documents like QC Guidelines and Q&C Presentations document for the testing team for global audience
- All fundamental component of a Quality Management system documents upload/ housed in OTIS tool
- Interacted with off-shore teams across the globe to ensure compliance requirements were met during testing phase

GM, Detroit

July'14 – Aug'15

Role: SAP QA Lead

Project: Production Support

GM motors upgrade the system version from existing version to higher version and made enhancements to the system for 34 countries. After went in to live it was hypercare for one year and the project was production support

Responsibilities/Deliverables:

- Reviewed Test Scope, Business Requirements, and Business Process Procedures and developed the lean Test plan, Test Strategy
- Prepared QA effort estimation for phase wise, Development, QA, and PROD
- Gathering the Change request Business Requirements specification and wrote the Regression Test Strategy.
- For effective Regression testing conducted meetings for impact analysis along with Developers, Functional Analyst, and Business Analyst to identify Regression Requirements, and Regression Test Scenarios.

- Pre-Approved Regression and Integration test cases/scenarios uploading in for HP Quality Center/ALM.
- Reviewed Test scenarios and Test Data to sufficient for cover all the possible test scenarios for Integration, Regression in QA environment.
- Developed Requirements coverage matrix, developed detailed Regression, Integration test scripts/test cases, and defined expected test cases.
- Reviewed and approved OTC testing scenarios which were executed in HPQC,. OTC process Scenarios like inquiry, quotation, sales order, cash order, rush order, deliveries, transfer orders, post goods issue, billing and release to accounting..
- Reviewed and approved defects in HPQC

CMS Energy, Jackson, MI
Project: BTS
Role: SAP QA Lead

Feb'12- June'14

Consumers Energy, one of the nation's largest combination utilities, provides electric and natural gas service to nearly 6.5 million of Michigan's 10 million residents with the help of nearly 7,500 employees. It is upgraded SAP and Non SAP application, Interfaces

Responsibilities/Deliverables:

- Reviewed project Scope, Project Plan, Business, Functional, Technical Requirements and Process Design documents, and writing Test Strategy, and phase wise Test Plans
- Responsible for reviewing and approving of all aspects of testing scenarios including Integration Testing, End to End, and Regression testing, UAT, SAP/Non SAP projects .
- Reviewed project documentation to become familiar with the scope and purpose of the project, as well as understanding of the process and functionality being tested
- Reviewing and approving pre-approvals and post-approvals of test scripts in HP Quality Center.
- Conducted defects triage meetings to discuss all open defects and track them to closure and approve
- Managed Traceability matrix to ensure that test case coverage meets requirements to ensure 100% test coverage.
- Reviewed and approved Change Control Forms to move the transports to Quality Environment, Production Environment
- Worked with testing resources to drive all testing deliverables to completion
- Managed all QA project aspects ensuring that QA is the gatekeeper to the production environment

USDOI, Herndon, VA
Role: IV&V Lead
Project: FBMS

Aug'11- Jan'12

US Department of the Interior (DOI) is implementing a Financial and Business Management System (FBMS), integrated suite of software applications that helps the DOI to manage a variety of business functions

Responsibilities/Deliverables:

- Reviewed the FBMS Approved User Acceptance Test Plan (UAT),which Specify testing overview, testing approach, testing strategy, roles and responsibilities and scope of testing
- Verified and Validated requirements traceability and requirements to test cases, and BPPs
- Reviewed defects and verify that the defect description, resolutions, and validations are clearly stated

- Validated the test cases documentation for completeness and accuracy after the successful completion of a test run.
- Validated that the test steps are recorded and actual results coincide with expected results as documented.
- Participated and provided feedback on Test Readiness Reviews to the IV&V Manager.
- Prepared the DEEP DIVE Report submitted to IV&V Project Manager.
- Participated in the Daily Workstream Review Board (WRB) meeting, which reviews the defects, determine Enhancement vs. Defects, Assign Priority.

Forest Laboratories

Oct'10 – July'11

Commack, NY

Project: SFA

Role: Validation QA Analyst

Forest Laboratories, Implemented CRM Sales Force Automation (SFA) Application. It is a Sales Representative Mobile device (FRxsell) Application, to manage day to day activities, and Information update includes addresses, affiliations, sales data, shipment records and transfer records. Sales representatives can detail their sales calls, record sample disbursements and capture physician signatures on their mobile device. Associated with planning and performing sales calls, inventory management for samples/voucher, sample and voucher distribution, patient coupons. And signature capture for sample/voucher distribution.

Responsibilities/Deliverables:

- Developed Compliance Plan and Compliance Analysis and Compliance Reports Test Plans, and Architecture Design.
- Reviewed and executed validation deliverables User Requirements, Test Plan Protocols, Test Summery reports, Procedures, traceability matrix, error/defect reports
- Reviewed and approved Test templates which contains Plans, Test Scripts, Test Data, Execution Instructions, Test Description, Process Objectives, Test Script ID for uploaded in to the Quality Center
- Validated and Verified OQ/PQ Formal, CRF, and 21 CFR Part 11 FDA guidelines documents, and GxP, Compliances, electronic records and signatures
- Guide IT and Business stakeholders on internal Forest Labs and global regulations focused on the implementation of Sales Force Application (SFA) and advice on risk based validation, regulatory gaps and adherence to internal SOPs.
- Validated OQ/PQ Formal Test Scripts, developed the OQ/PQ protocol and test summery reports
- Coordinated with SME, Business Owners, Development team for resolution of Issues, and problems approving the defects
- Reviewed Pre-Post approval for the test case documentation for completeness and accuracy after the successful completion of a test run, and followed the GDP(SOP)
- Verified test steps are recorded and actual results coincide with expected results as documented as per test plan, and followed the GTP (SOP)
- Verified and Validated requirements traceability and FDS requirements to test cases,
- Reviewed and approved defects and verify that defect description, resolutions, and validations are clearly stated

USDOJ, Herndon, VA

July'10- Sept'10

Project: FBMS

Role: IV&V/Tester

US Department of the Interior (DOI) is implementing a Financial and Business Management System (FBMS), integrated suite of software applications that helps the DOI to manage a variety of business functions

Responsibilities/Deliverables:

- Reviewed the FBMS Approved User Acceptance Test Plan (UAT), which Specify testing overview, testing approach, testing strategy, roles and responsibilities and scope of testing
 - Verified and Validated requirements traceability and requirements to test cases, and BPPs
 - Reviewed defects and verify that the Defect description, resolutions, and validations are clearly stated
 - Complete Formal Assessments Review of the quality/completeness of the FBMS
- Integration Test results
- Validated that the test steps are recorded and actual results coincide with expected results as documented.
 - Participated and provided feedback on Test Readiness Reviews to the IV&V Manager.
 - Prepared the DEEP DIVE Report submitted to IV&V Project Manager.
 - Executed , Integration, Functional, Regression test scripts and recorded the results and uploaded in to CQ (ClearQuest)
 - Participated in the Daily Workstream Review Board (WRB) meeting, which reviews the defects, determine Enhancement vs. Defects, Assign Priority.

Warner Bros, Burbank, CA

Oct'09- June'10

Project: Cosmos

Role: QA Lead

Warner Bros. has two leading category distribution units, Domestic Television Distribution (WBDDTD), and International Television Distribution (WBITD), together, these entities are responsible for the distribution of Warner Bros., Entertainment and Media. It has thirteen units around the world, and using different legacy systems for Create and Maintain deals. Warner Bros has initiated to implement a single system with SAP CRM IPM 7.0 and ECC 6.0

Responsibilities/Deliverables:

- Prepared test plans, which specify testing overview, scope, testing approach, testing strategy, roles & responsibilities and scope of testing
- Coordination with SME to develop System testing, UAT Testing scenarios
- Reviewed Uploaded the Test Cases, Requirements, Test Plan, Test Data in Quality Center
- Monitored Test Progress and communicating status and issues to the Manager
- Reviewed the Test Cases, Integration End to End test Scenarios, and completeness of Test results
- Assisted Functional Team leads , Technical Team leads in coordination of test activities
- Reviewed and approved pre-post approval , Formal testing, and Regression testing
- Conducted Defect Meetings, assign prioritization of defects and escalate to Project Manager, if necessary
- Responsible for monitoring test matrix and communicating status and issues to the Test Manager

Johnson & Johnson

June'08-Sep'09

Health Care Systems, Piscataway, NJ

Role: CSV QA Analyst

Project: SOM – OTC

US Region Order-to-Cash (OTC) is a major Johnson & Johnson strategic initiative to integrate 24 separate transactional systems into a single, regional system for 14 participating Medical Devices & Diagnostics companies in the United States, the initiative will create common processes in the “order-to-cash” cycle from the time a customer places an order through delivery of the product and final payment. This includes processes and systems used for Accounts Receivable, Order Management, Warehouse Management and Transportation Management.

Responsibilities/Deliverables:

- Develop compliance strategy for Medical Device Regulatory Information management system. Author Compliance Analysis, Compliance Plan, Compliance Reports ; provide quality review on all other SDLC deliverables
- Reviewed all the Validation deliverables URS, FDS, and FDS ensured documentation consistency across all project deliverables
- Create and implement training documents like QC Guidelines and Q&C Presentations document for the testing team for global audience
- Reviewed and approved Pre and Post Approved System and UAT scripts in HPQC
- Prepared System and UAT Test Summary Reports routed for wet signatures and uploaded in to SharePoint
- Developed Traceability Matrix and mapped URS, FDS, and PDD, to Test Scripts
- Support Change Control and periodic releases like Normal and Emergency changes
- Ensured System test scripts and UAT scripts were mapped with System Protocol, and UAT protocol
- Reviewed Pre-Post approval for the test case documentation for completeness and accuracy after the successful completion of a test run, and followed the GDP(SOP)

Avaya, Basking Ridge, NJ

Feb'08 – May'08

Role: QA Lead

Project: Enhancement

The automation feature of billing late payment fees has been decommissioned in SAP. Automation will streamline the process of billing late payment fees and bring a consistent experience across Avaya customers. It links to the Avaya goal of “Strong Financial Position”.

Responsibilities/Deliverables:

- Reviewed existing Business Process Procedures and requirement analysis, Test Plan, Test Scope, and Test strategy, Work plan, Test Environment, Test Design and Execution of Testing Tools.
- Created Test Data for Auto Cash functional testing three different payment types (Lockbox, EDI, and Credit Cards)
- Created new payers with T.Code XD01 and assigned selection rule to the payer in the company code data payments transaction screen
- Developed debit memos with T.Code VA01 and tested accounting document show debit to A/R at the payer, credit to Revenue, and credit to sales tax payable.
- Created txt.file and executed FTP in Unix to simulate receipt of the lockbox file from the Bank
- Reviewed all scenarios as per functional requirements selection rule on the customer master. If paid amount matches the invoice, an overpayment clear the invoice residual open (DZ15), and if an underpayment clear the invoice but put residual in open (doc type DZ, Posting Key 06)
- Reviewed Configured Prototype Creation for Late Payment fees Dunning Procedures as per business requirements.

Johnson & Johnson
Bridgewater, NJ
Role: CSV QA Analyst
Project: Enhancements

Dec'07- Feb'08

J&J was reengineering certain intercompany billing processes to improve efficiencies across its affiliates. This project includes the implementation of limited FI, SD and MM enhancements in SAP Financials and the deployment of new processes.

Responsibilities/Deliverables:

- Develop Compliance Analysis, Compliance Plan, Architecture Design, Test Plan, Test Scripts, and Compliance Reports different stream applications for J&J reengineering intercompany billing enhancements project
- Ensure compliance with 21 CFR Part 11 and 820 requirements and predicate GxP standards through integrated quality reviews of all computer system validation processes, procedures and documentation
- Reviewed and approved Validation documents URS, PDD's, FS, Configuration document, TDS for various SAP modules like sales order management, material management, Finance
- Reviewed and approved System, UAT pre-post test scripts.
- Developed System Testing, UAT Testing protocols and Summery report and routed for approvals
- Support change control processes for the Quality Operations group, evaluating change control documentation, release mgmt., data changes, testing for compliance and GXP impact
- Guided J&J business, technical and testing teams in regards to meeting Validation requirements
- Provided Compliance and deliverables input as and when needed by the manager
- Developed PRT (Production Readiness Transaction) document and reviewed test scripts and approved.
- Prepared Traceability Matrix mapping URS, FRS and Test Cases.

Nestle, Minnetonka, MN
Role: CSV QA Analyst
Project: Upgrade from 4.6 to 6.0

Feb'06- Nov'07

HealthCare Nutrition offers complete nutritional solutions for people with specific illnesses, disease states or the special challenges of different life stages. Nestle Nutrition strives to offer high quality and great tasting products which provide clinically Proven benefits to those with special nutritional needs.

Responsibilities/Deliverables:

- Develop compliance strategy for Medical Device Regulatory Information management system. Author Compliance Analysis, Compliance Plan, Compliance Reports ; provide quality review on all other SDLC deliverables
- Create and implement training SOP documents and uploaded into SharePoint.
- Ensured the applications were validated as per 21 CFR Part 11 and 820 requirements and predicate GxP standards through integrated quality reviews of all computer system validation processes, procedures and documentation
- Review and approve URS, FRS, and TDS, Configuration documents, multiple SAP modules WRICEF
- Analyzed the gaps in the Vendor documents and reported to the team
- Developed a risk analysis document and Reviewed pre-post approval test scripts and approved in HPQC

- Conducted weekly meetings to report the progress of the project
- Interacted with SME's to understand business process for the development of OQ/PQ
- Resolved the deviations encountered during the OQ/PQ phase and prepared Summary Report

Nielsen Media, NY
Role: SAP QA Tester- FICO
Project: Enhancements

Dec'03 - Jan'06

The Nielsen company, formerly known as VNU Group B.V., is global information and media company with leading market positions and recognized brands in marketing information, (ACNielsen), media information (Nielsen Media Research), business publications (Billboard, The Hollywood Reporter, Ad week) and trade shows, the privately held company is active in More than 100 countries, with headquarters in Harlem, Netherlands, and New York.

Responsibilities/Deliverables:

- Reviewed Business Process Procedures and Blue Print and did requirement analysis, and Developed Test Strategy
- Developed Test Scripts and Test cases and sent to Business for review and approval
- Involved in all stages of testing process functional testing, regression testing, and integration testing, and User Acceptance Testing (UAT)
- Reviewed Test Cases verified actual results against expected results.
- Identified and documented all issues and defects to ensure application software functionality
- Manually tested Lockbox Configuration like Lockboxes (OB10), Lockbox Control Parameters,(OBAY), Lockbox Posting data (OBAX) verified the output results with Business Requirements
- Manually tested Liquidity Forecast, Cash Management, and Cash Concentration and It Source Symbols (OT05), Planning Levels (OT14), and Planning Groups (OT13) Internal MM and SD Transactions to Planning Levels (OT47), Treasury Groupings (OT17), Treasury Grouping Headers (OT18), and Treasury Updates (OT29), validated and verified GUI process meeting with as expected results.

Energy East, Portland, ME
Role: QA Analyst
Project: SAP Implementation

Oct'02 - Nov'03

Energy East, The utility holding company distributes electricity and natural gas in four northeastern states through subsidiaries Berkshire Gas, Central Maine Power, Connecticut Natural Gas, Maine Natural Gas, New York State Electric & Gas, Rochester Gas and Electric, and Southern Connecticut Gas. Overall, Energy East serves 1.8 million electricity customers as well as 900,000 natural gas customers

Responsibilities/Deliverables:

- Developed test plans, which specify testing overview, testing approach, testing strategy, roles & responsibilities and scope of testing
- Developed System Test cases, UAT and got them approved from IT/Business, and uploaded into Test Directory Tool
- Created Test Data sheets for Recruitment, Gross Payroll, Net Payroll, Time Management, and Benefits, Compensation Management for functional testing

- Manually performed positive and negative testing in the all segments
- Monitor testing progress and influence the timely completion of testing and analyze and report testing results
- Conducted training and developed documentation for end-users for UAT testing over the conference call
- Reported Defects and maintained test results using TestDirector.

Home Depot, GA
Role: Functional
Project: Enhancement

Nov'99 – Sept'02

Responsibilities/Deliverables:

- Configuration expertise focusing in areas of Asset Accounting (AA), General ledger (GL), Accounts Payable (AP) and Accounts Receivable (AR).
- Involved in collecting business blue print documentation, customization, and configuration and in depth understanding of business process relating to SAP Finance, Integration with SD, MM modules.
- Configured FI Enterprise Structure includes Company Code, Business Areas, Function Areas and Fiscal year Variant.
- Configured General Ledger include chart of accounts, G/L accounts, Sample accounts, Field status groups, Posting Key and Sales/use tax assignment, Automatic Account Determination.
- Configured Document Type, Tolerance groups, Number ranges and Financial Statement versions
- Configured ALE/IDOC setting for Inbound and outbound Idocs, Message Handling
- Configured Accounts Payable includes Vendor Master Data, Vendor Groups, House Banks, Payment Program and Recurring entries, Credit memos, and Special GL.
- Configured Accounts Receivable including Customer Master Data, Customer Groups, Terms of Payment, Interest Calculation, billing, and Dunning, Incoming Payments, and Cash Discounts.
- Asset Accounting (AA) including Asset master data, Asset Classes, Chart of Depreciation, Depreciation areas, Depreciation keys, Depreciation postings, Depreciation Calculation methods

Education:

Masters Business Computers,
 PG Diploma in Computer Application,
 Diploma in Client/Server Technology,