

Education:

Bachelor of Engineer (I.T) 2007
R.G.P.V University (Bhopal)
Medicaps Inst of Tech & Mgmt,
Indore (M.P.), India

Companies:

1. Tata Consultancy Service Ltd.
2. Mahindra Special Services Group
3. Wipro Ltd (erstwhile CITI Technology Services)

Respective Clients for each company:

1. Pfizer Inc (Dec2011 – Till date)
2. Mahinda and Mahindra (5 Months)
3. Citibank Inc (3.4 Years)

Certifications:

- ITIL v3 Foundation
- Lead Auditor for below –
 - ISO/IEC 27001:2005 Information Security Management System (ISMS)
 - ISO/IEC 20000-1:2011 Information Technology Service Management (ITSM)
 - ISO 22301:2012 Business Continuity Management System (BCMS)

Domain Knowledge:

Pharmaceutical, BFSI, FMCG (including Datacenter)

Roles:

QA Program Manager, Project Manager, CSV Consultant, Test Lead, ISMS Analyst, QA Analyst

Work Areas:

CSV, Quality Assurance, Testing, Risk Management & Compliance, RCSA, Risk profiling, Change Management, Audit, ISMS, Testing, Periodic Reviews

SDLC Methodologies:

Waterfall, Agile, SCRUM

Quality Standards/Systems:

CSV, CSA, ISO, CMMi, ITIL, Six Sigma

Platforms:

Veeva, Trackwise, SFA, Documentum, SAP, ERP, CRM, Mobile, iRep, Tableau, Archer, SharePoint

Projects:

New Application, Data Migration, Enhancement, Decommission

Tools:

HP ALM/QC, Confluence, JIRA, BOX, Trackwise, Documentum, Archer, SharePoint

Skills Summary

Dynamic and motivated professional with around 13 years of experience, working in areas of Quality Assurance, Computer System Validation, Risk Management and compliance, Quality Control, Audit and Assessment, Information Security Management System. Consistently recognized for exceptional project management, client relationship and leadership skills with a proven track record of managing multiple projects with multiple stakeholders. Possess years of successful experience executing and consulting, streamlining internal processes, maintaining accurate documentation and facilitating positive relationships with IT systems end users, colleagues, third party vendors and key business partners. Proficient in the implementation, management, and decommissioning of a diverse variety of computer systems in accordance with regulations including GxP, 21 CFR Part 11. Commended for efficiency, priority management, and communication skills.

- Excellent written and verbal communication, Interpersonal and Project Management skills
- Solid Knowledge in Project Management, Quality Assurance (QA), Risk Management and Compliance, Computer System Validation (CSV, including 21 CFR Part 11, GxP Validation), ISMS implementation and sustenance, Quality Control, Risk Control Self-Assessment (RCSA)
- Extensive understanding of Software Development Life Cycle (SDLC), Software Test Life Cycle (STLC), ISMS, BCP/DR, Vendor Assessment
- Experience of working in Agile, Scrum, waterfall model software development environment
- Good hands-on experience in New applications, Enhancements, Data Migration, Decommission/Divestiture projects
- Experience & knowledge of Change Management, Risk assessment, Periodic review, CAPA, Deviation
- Comprehensive knowledge of the methods, techniques, and process of system validation and verification
- Hands on experience in testing validation process of large and sub systems
- Good expertise in developing, reviewing and guiding team on Project (including Validation) deliverables
- Solid experience in developing and executing Test Strategy/Plans/Protocol
- In Depth experience in creating, maintaining and reviewing Requirement Traceability Matrices (RTM) to measure the testing progress
- QA/Testing expertise includes Integration, Functional, System, Regression, End to End & UAT
- Expert in reviewing defect tracking meetings with the team members & project development team
- Information Security Policy Management, Supporting development & maintenance of corporate Information Security related policies and procedures
- Conducting information security assessment of information systems as per our methodology
- Track, coordinate, and resolve issues identified in and related control, compliance, or risk work
- Documents risk analysis and controls and evaluates control design and continuous control improvement
- Maintaining familiarity with industry trends and security best practices
- Demonstrated capabilities to quickly gain a detailed understanding of a process to optimize efficiencies, reduce cost, and improve quality
- Detail oriented ability to work independently and collaboratively with the team members
- Capable to work independently with minimum supervision, as well as in an interactive team environment

Key Values & Achievements

- 14 "TCS Gems" awards, 'Star of the Month' along with appreciation certificate across the tenure in TCS majorly for significant contribution, excellent support for projects and special initiatives
- 'BT PGS GRC Validation Team' received "BEST TEAM award for Quarter 2 – 2018".
- Worked as PforceRx Test Lead on special client request due to excellent support during initial phase of project. Also, was invited to support UAT sessions conducted in Turkey and Czech Republic
- 'BT Q&C Commercial Team' received "BEST TEAM award for Quarter 3 – 2012".
- Received "SHINING STAR award of Quarter 1 – 2009" for outstanding individual contributions towards customer satisfaction.
- Received "FEATHER IN MY CAP" award on 26th November 2010 for whole-hearted effort, sincerity & dedication that ensured client satisfaction.
- Received several 'RAVE' awards for consistent performance from the management
- 'Received appreciation for brilliance and hard work from CTS management as well as clients on numerous occasions.

Project Experience

Employer: TATA Consultancy Services Ltd. (Dec 2011 – Till Date)
Client: Pfizer Inc. (Dec 2011 – Till Date)
Current Program: Risk Management and Compliance
Role: QA Program Manager
Location: Mumbai/Indore, India (Aug 2019 - Mar 2020, Nov2020 onwards) & Walton Oaks, Surrey, UK (Mar 2020 – Oct2020)

- Overall responsibility for delivery of RM&C Program with various Statement of Work/ s (SOW) and Service Level Agreement (SLA)
- Acting as a primary interface to customer for all matters that can affect the baseline, schedule and cost of the services project
- Defining the scope of testing within the context of each project / release / delivery
- Preparing/revising project plan for testing, budget/effort and schedules and advise on test strategies for various engagements
- Managing project schedules, identifying risks, overall effectiveness of service delivery and clearly communicating status to project stakeholders
- Reviewing test strategies, test plans and test results, and consult with test lead(s) on resources, schedules and milestones
- Interact with management for appropriate staffing for each engagement
- Evaluate all customer complaints for quality and escalate issues if required and provide training to all project teams and perform required audits and perform root cause analysis and recommend preventive and corrective actions
- Managing all communication with business partners and senior management to achieve all project objectives and manage multiple functional areas
- Procure tools and conduct training for test team and aim for continuous process improvement
- Identify and assign roles to team members, set clear goals for direct reports and monitor performance
- Track competency gaps that exist among team and ensure closure of competency gaps
- Provide testing frameworks and guidelines to projects
- Provide guidance to project resources on applicable use of the methodology and project organization for testing
- Driving process improvement, leading with Agile methodology transformation
- Providing an active role in mitigating impediments impacting successful team completion of Release/Sprint Goals

Program: Validation and Compliance, Pfizer Global Supply (PGS) (Customers Business Line)

Role: Computer System Validation (CSV) Project Manager

Location: Peapack, NJ, USA (Nov 2015 – Jul 2019)

Projects: Below is the list of projects supported during this tenure

1. iMEX Program (Digital Transformation) - Integrated Mfg Excellence, using latest technologies like Microsoft surface hub, Smartglasses etc to enable digital transformation
2. Legacy Pfizer Complaints Systems (PCOM) – Documentum based, including data migration from acquired company complaint systems
3. Complaint Intake Triage (CITI) – Trackwise based solution, replacement of PCOM with Data Migration
4. EnterpriseOne (E1) – JD Edwards

During my tenure in this program I was part of various critical, high valued and high visibility projects. Along with project responsibilities, I was additionally SPOC for validation services for managing billing, resources, serve as SME and 1st level escalation points for any issues/concerns faced by clients.

As the CSV Consultant below were general roles and responsibilities across projects:

- Clearly communicate the validation strategy and facilitate all aspects of a risk-based life cycle approach for Computer System Validation projects
- Work closely with IT, Business, Regulatory Affairs, and Quality to develop, coordinate and execute Validation documents and strategies
- Participate in the development, implementation, execution and adherence to validation procedures and methods related to computer systems validation (CSV)
- Ensure that the Validation / Qualification and quality systems are working in accordance with any changing and current regulations
- Recommend acceptance of the computer system, as determined from the CSV tasks performed on the system
- Create, Review or approve the relevant documents on validation processes including Strategy, Protocol, Testing, Defect Management, Change Management, Documentation Control etc
- Reviewed, identified and remediated legacy CAPA's for proper content
- Compliance review and assessment of current state of validations in preparation for Internal audits including Periodic Reviews and External inspections
- Ensured that GxP regulated computer systems were in full compliance with federal regulations, company policies & SOPs
- Writing, executing, reviewing Validation protocols like IQ, OQ, PQ for Computer System Validation (CSV), developing Standard Operating Procedures (SOPs) and Work Instruction (WI)
- Prepare data migration plans including migration risk, milestones, quality and business sign-off details
- Manage assigned risks and monitor potential impacts as part of the data migration plan
- Develop best practice, processes, and standards for effectively carrying out data migration activities
- Perform source system data analysis in order to manage source to target data mapping

Program: Validation and Compliance, Pfizer Global Supply (PGS) (Customers Business Line)
Role: Computer System Validation Analyst
Location: Mumbai, India (Apr-Nov 2015)
Project: PGS Tableau

Support and work along with clients Validation Specialist in providing consultancy to project teams (Clients customers in PGS BL) to acquaint them with expected organizational and regulatory quality standards hereby ensuring quality and compliance in deployed products.

- Perform in-depth requirement analysis and gathering with application end users
- Work with the project team to develop specified business requirements from inception to completion
- Developed project backlog and sprint backlog from requirements and run daily sprints. Tracked and monitored tasks and team collaboration using agile tool Jira
- Produced Business Integrated Model diagrams, business mappings, performed data analysis for functional requirements documentations
- Develop, maintain and review deliverables such as Requirement Specification Verification (RSV) documents, validation plans, user requirements, functional specifications, verification protocols, test scripts and summary reports
- Perform test case execution, defect management and defect reporting
- Monitor and control the quality of deliverables to the customer by stringent quality assurance checks and engaging stakeholders to ensure the project deliverables are certified compliant and are up to the compliance and audit standards currently in effect
- Onsite/offshore co-ordination with the testing and development teams

Program: Risk Management and Compliance, Commercial (Customers Business Line)
Role: QA Consultant (also Test Lead, for PforceRx project on special client's request)
Location: Walton Oaks, Surrey, UK (May 2014 – Apr 2015)
Major Project: PforceRx and Operational Data Store

Provide consultancy to project teams (Clients European customer in Commercial BL) to acquaint them with expected quality standards hereby ensuring quality and compliance in deployed software application. Major project worked during this was PforceRx (Veeva CRM) as Quality Consultant and Test Lead. Was invited to PforceRx UAT session in Prague and Istanbul as Compliance consultant and Test Lead, attended UAT session in Istanbul.

Along with responsibilities as Quality Analyst handled previously, following were additional responsibilities as QA Consultant:

- Actively involved in Vendor Assessment (VCAS), Compliance Requirement Set (CRS) dispositioning co-ordination with project stakeholders
- Prepare weekly report from QA (and Test lead) team to highlight risk and issues for project milestones
- Provide Consultancy to team with respect to RFC\Change Management Process
- Record, Monitor deviations for unmet processes and requirements. Monitor the deviations at regular intervals and proceed towards their closure
- Ensure QA presence at the time of Go/No Go meeting for application deployment
- Authoring Compliance summary report upon project completion
- Prepare and conduct training for good documentation practices before UAT workshops
- Manual UAT Test Scripts Archival (Hard copies) for Audit & Inspection purpose

Program: Risk Management and Compliance, Commercial (Customers Business Line)
Role: QA Analyst
Location: Mumbai, India (Dec 2011 – Apr 2014)
Project: Multiple projects from APAC, EU and AMER geographies

Support and work along with clients Quality Specialist in providing consultancy to project teams (Clients customers in Commercial BL) to acquaint them with expected quality standards hereby ensuring quality and compliance in deployed products. Worked on multiple projects from various geographies during this time.

- Interact with Project team to understand the scope/purpose of project.
- Assist and guide project team on creating Compliance Risk Profiling (CRP) to identify risk category of an application\deployment against the applicable risk domains like GxP, Information Security \ Data Privacy, SOX, 21 CFR Part 11, DMZ etc
- Provide guidance and consultancy to Project team explaining them the QA expectations throughout the project lifecycle
- Consulting Project Stakeholders in preparation of Tailoring form which determines the necessary documentation applicable to projects
- Review project specific documents which includes Project Plan, Requirement Specification, Traceability Matrix, Design Document, Test Plan, Test Scripts, Test Summary report, Support Plan, Deployment Plan
- Providing regular updates to stakeholders on applications documentation status to stakeholders on regular basis
- Review executed test scripts to ensure acceptable level of testing evidences, correct documentation and complete execution
- Monitor the deviations at regular intervals and proceed towards their closure

Employer: Mahindra Special Services Group (Jun - Nov 2011)
Client: Mahindra & Mahindra (Various Sectors/BUs, Corp Offices & Data Centers), Group Companies
Location: Mumbai, India (Travelling across India for client offices including Corp Offices, Data Centers, various BUs)
Role: Information Security Analyst
Project: ISMS Implementation & Audit – OP Suraksha

- Implementing Information Security Management System (ISMS) based on ISO 27001 standards.
- Conducting ISMS internal audits across the country for all establishments of M & M certified under scope of ISO 27001:2005 certifications
- ISO 27001:2005 Pre-certification Audits & assistance during third party certification audits (was part of STQC recertification audits)
- End User, DR and HOD Training on Information Security and its best practices.
- Setting up of the Information Security Organization structure

Employer: Wipro Technology Services *erstwhile Citi Technology Services* (Jan 2008 to Jun 2011)
Client: Citigroup
Location: Mumbai, India
Role: Quality Analyst
Project: Quality Control Unit

Quality Control Unit (QCU) was responsible for **Quality Control (QC)** and **Quality Assurance (QA) review/RCSA testing**. Below is the details:

QC support was to verify whether all the PRD and CTNGY server builds are compliant across CITI Technology Infrastructure Services. These servers build across business occurs in accordance with Change management, Incident management, Configuration management, Release management. QCU team channelized the flow of servers into PRD or CTNGY post verification by ensuring the following:

- BMC patrol Database Monitoring tool
- Schema Alert
- Ensure LMS (Login Management System) connectivity.
- EOL, EOCS (End of Citi Support) & EOVS (End of Vendor Support)
- Security Event Management System (SEMS)
- IPLocks Scan and Communicating the IPLocks report and coordinate with DBA team, Application Management team and ISA team if any vulnerability found

Quality Assurance (QA) review/RCSA testing for CIBIS/CITS DB NAM/EMEA (Quarterly), Bi-Sys group (Semi-annual), Entitlement Review for Wintel and UNIX Servers (Semi-annual)

- RCSA exercise of IT related controls for various business units under the CITIGROUP umbrella. Major responsibilities involve auditing and analysis of data provided by different business units and mapping them to a RCSA matrix.
- Ensure that EMEA/NAM application technology processes are in accordance with internal policies and standards, and that regulatory expectations for control, monitoring and reporting of risk are satisfied.
- Work closely with the Controls Officers to improve the consistency, effectiveness and efficiency of the risk management function in the region. Assist in taking steps to reduce risk to an acceptable level.
- Assistance in the definition of and oversight over regional Risk Control and-Self Assessment (RCSA) activities ensuring that an effective Control Foundation is defined, implemented and executed timely within appropriate quality levels and weaknesses are identified and corrective actions are planned and tracked through to completion.
- Following up with business unit managers regarding control compliance and deciding if a control should be passed or failed based on evidence provided.
- Generate weekly UNIX/WINTEL RCSA Scorecards to keep track of tool exceptions and ensure that they get resolved by their respective owners.

Tools/Platforms experience (till date): Trackwise (QTS, CITI), Documentum (PCOM, PDOCS), Veeva/CRM/SFA (PforceRx), CMDB, Gnosis, MSB, SharePoint, Box, JIRA, Confluence, IPRM (Archer), HP ALM, Tableau, Microsoft Surface Hub, SmartGlasses (VR/AR), Tableau, IPLocks, Mobile, iRep, MS Office, Visio