# Archana Kadam

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**15 plus** of total experience in IT including Sr. Business Analyst, Project Quality Manager, Quality Assurance, Regulatory compliance Professional, Technical Assurance Analyst, Software Testing of various web applications and windows applications.

- Involved in Software Development Life Cycle (SDLC), business process modelling, quality management systems.
- Involved and worked as a Sr. Business Analyst, Quality Manager and Quality Assurance/Regulatory Compliance professional, QA Lead.
- Involved in Agile projects with Backlog grooming, User story development, refinement, and prioritization.
- Experience in preparing/reviewing documents like Quality/Compliance Plan, User requirement/User Stories, BRD, Functional Specifications, Test Plan, System test Protocol, System test report, Requirement traceability Matrix, Quality/Compliance Summary report.
- Experience in incident management, root cause analysis and incident resolution.
- Involved in Scrum ceremonies including Program Increment (PI) planning, daily stand-ups, Sprint Planning, Sprint review, Sprint Retrospective.
- Ability to prioritize tasks well and work on multiple applications concurrently.
- Ability to work well in fast paced, team dynamic environment.
- Possess excellent communication and organization skills with the ability to adapt to a new environment.

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## MANAGEMENT SKILLS

- Client Senior Management interfacing & issue resolution.
- Strong analytical and excellent communication skills, stakeholder management, problem-solving abilities, documentation skills, individual contributor, and a good collaborator.
- Onsite-offshore team coordination.

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## TECHNICAL SKILLS

### FUNCTIONAL
- Business Analyst
- Quality Management System/Quality Assurance
- Regulatory Compliance
- User Acceptance Testing
- Clinical Trial Specialist
- Trial Master File (TMF) Analyst
- Test Planning & Approach
- Defect Management
- Requirement Traceability Matrix (RTM)
- Technical Assurance Analyst

### TECHNOLOGY
- MS Office
- JIRA, Confluence
- Salesforce
- SAFe Agile framework
- Veeva
- HP ALM/Quality Center, PROTON, CoreDox DIARY,
- ETL/Informatica
- Microsoft SQL Server
- Web Methods/Web Logic
- HTML
- CSV

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## PROFESSIONAL EXPERIENCE

**Client: Johnson & Johnson, Raritan, NJ**                                             **Oct 2022 – Present**
**Quality and Compliance: Pharma (Innovative Medicine), Hospital Medical Devices (MedTech), Corporate Business Technology (Corporate)**
**Position: Sr. Business Analyst / Validation Lead/ IT Quality & Compliance/ Software Quality Assurance (SQA)**
**Roles and Responsibilities:**
**In the role of Sr. Business Analyst:**
•Worked closely with product owners, Scrum Master, business representatives, scrum teams
•Assisted product owner with Backlog grooming, User story development and prioritization
•Experience with agile toolsets, including Atlassian JIRA, Confluence
•Owned Planning and scheduling sprints
•Elicited and analyzed Business requirements
•Conducted technical and business refinement sessions with stakeholders, scrum team to create User story acceptance criteria and to articulate product vision to scrum teams to refine stories
•Performed testing and validation of the project
•Ensured successful project delivery on time and within budget
**In the role of Validation Lead/ IT Quality & Compliance/ Software Quality Assurance (SQA):**
•Enabled and helped teams to control and build in quality during the software development lifecycle for GxP/non-GxP applications. Supplied coaching and guidance on best quality practices and trained new quality assurance staff
•Ensured that the delivered software, the related deliverables, and applied processes do meet and follow defined J&J Quality standards/ policies/procedures.
•Prepared Compliance Plan/Report, reviewed/approved documentation like SIT, UAT, RTM. Focused on initiative-taking quality assurance activities, risk-based verification, data driven governance, metrics and continuous process improvements based on data and trend analysis

•Worked as an asset owner to manage assets in Asset management tool
**Environment:**
SAFe Agile framework, Scrum Agile MSOffice, ETL, Bitbucket, SonarQube, Salesforce, Physician Engagement Database Tool, Cardiovascular Solutions Group, Informatica Scheduler, API, SQL, Reporting Tools, Jira, Jira X-Ray, Confluence, QMS (Quality policy, Procedures, Manual, Work instruction, Records/Forms), ISO 9001

**Client: Novartis, East Hanover NJ**                                                                                **Jun 2017 – Oct 2022**
**Quality and Compliance: Commercial IT, Enterprise Resource Planning (ERP) IT, Corporate & Business Services (CBS) IT**
**Position: Project Quality Manager/ Validation Lead/ IT Quality & compliance**
**Roles and Responsibilities:**
•Worked on Quality management activities within an IT Project and supported the project team for GxP/non-GxP applications.
•Ability in the Quality Assurance processes and Computerized Systems Validation (CSV) principles
•Developed a Qualification Plan / Validation Plan, which defines all actions, deliverables, responsibilities, and procedures to satisfy the user/customer quality and/or validation requirements
•Supported in the preparation of risk assessments, contributed to project tollgates
•Ensured that the standard quality management procedures followed, executed with supplying Qualification Report / Validation Report
**Environment:**
MSOffice, Oracle 11g, ETL, Veeva, Salesforce, Reporting Tools, Agile framework, PROTON, Jira, DIARY, QMS (Quality policy, Procedures, Manual, Work instruction, Records/Forms), SOX, ISO 9001, ISO 27001, 21 CFR Part 11

**Client: Johnson & Johnson, Raritan NJ**                                                                         **Apr 2015 – Jun 2017**
**Position: Sr. Clinical Trial Specialist/ TMF Analyst/Sr. Business Analyst**
**Roles and Responsibilities:**
•Assisted in the development and monitoring of metrics for the overall TMF completeness process for real-time data and visibility into the state of the TMF.
•Collaborated with Global Trial Managers, Local Trial Managers and Functional Area representatives regarding Binder Review.
•Used the V-TMF reporting tool to monitor TMF completeness and supported the user community in the use of the reporting tool.
•Involved and interacted with CTMS team to align on Study/Country/Site build as well as general support.
•Collaborated with various teams in supporting the management of TMF documents and maintaining inspection readiness and submission readiness within the V- TMF system.
•Worked with Lead TMF Analyst and TMF Compliance Specialist to locate and identify areas yielding highest efficiency.
•Involved in study lock/unlock.
•Supported Audits/Inspections.
•Collaborated with users to identify and manage study expected document lists (EDL).
•Provided system demonstrations to TMF Content Owners as needed.
•Involved in supporting TMF business user questions.
• Involved in UAT testing and interacted with validation team, IT team.
**Environment**: MSOffice, Oracle 11g, Java 1.6, CTMS, Veeva(V-TMF), Reporting Tools

**Client: Merck, Rahway NJ**                                                                                             **Sept 2014 – Apr 2015**
**Position: Technical Assurance Analyst (Validation/Compliance)**
**Roles and Responsibilities:**
•Provided guidance regarding the nature and extent of validation scope and activities.
•Coordinated risk assessments.
•Created system specific Quality Assurance Plans (QAPs) and Quality Assurance Summary Reports (QASRs).
•Reviewed all the project deliverables including the Development and UAT test results for completeness, correct results, and adequacy of documentation and ensured all incidents (test defects) disposition prior to the moving of the system to production.
•Reviewed Change Requests for completeness and correctness.
•Determined the impact of changes to the validation status of the system.
•Provided review of key validation SDLC documents as identified in the QAP to ensure adherence to standards, including the enforcement of quality gates.
**Environment**: Oracle 11g, Oracle SQL Developer V3.2.20.09, Unix HP-UX 11.31, Java 1.6, Web logic, HPALM 11.5, MSOffice

**Client: Johnson & Johnson, Piscataway NJ**                                                                     **Aug 2013 – Sept 2014**
**Position: Sr. Business Analyst/QA Lead / UAT Coordinator**
**Roles and Responsibilities:**
• Attended requirement gathering sessions. Daily status calls and meetings.
• Extensively worked with users to get the clear understanding on the requirements and daily meetings.
• Prepared and reviewed User requirement specification, Functional specifications, Business rules documents
• Prepared and reviewed System Test protocol, Test Scenario Preparation, Test Cases, Test Execution,
   System test report, Requirement Traceability Matrix
• Worked with compliance team, web Methods team during Validation testing for 21 CFR Part 11 requirements.
• Experience in documenting Defects and interacted with developers and tech leads to resolve issues and
   root cause analysis.
• Handled Onsite/Offshore work module

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• Experience in Software Verification, Validation Testing Methodology
• Performed Smoke, Integration, Dry Run testing, Functionality, Regression, System Tests, UAT testing and
  End to End testing,
• Wrote SQL queries to retrieve data
• Verified application in Dev, QA, UAT environments.
**Environment**: Informatica MDM 9.0, Power Center 9.0, Oracle 11g, Oracle SQL Developer V3.2.20.09, webMethods 8.2, Unix HP-UX 11.31, Java 1.6, Web logic, HPQC 10.0

**Client: Marsh & McLennan, Hoboken NJ**                                                          May 2013 – Aug 2013
**Position: QA Lead**
**Environment**: Quality Center 10.0, Internet Explorer, MSOffice, Windows XP, Windows 7, SQL Developer, MS SQL, Informatica

**Client: Standard & Poor's, NYC, NY**                                                          Sept 2012 – Apr 2013
**Position: Sr. Business Analyst/QA lead**
**Environment**: Quality Center 10.0, Internet Explorer, MSOffice, Windows XP, Windows 7, SQL, Mobile Devices, PEGA test framework

**Client: Toy's Rus, Wayne, NJ.**                                                          Jun 2012 – Aug 2012
**Position: Sr. Business Analyst/QA lead**
**Environment**: Quality Center 10.0, POS, KIOSK, Internet Explorer, MSOffice, Windows XP, SQL

**Client: AT &T, Middletown, NJ**                                                          Oct 2010 - Jun 2012
**Position: Software QA Analyst**
**Environment**: Quality Center10.0, JIRA, TRAC, XML, HTML, Java Scripts, CSS, Android Devices, iPhone, Blackberry, MSOffice, Windows XP

**Client: IPSOS Loyalty, Parsippany, NJ.**                                                          Apr 2007– Dec 2007
**Position: QA Analyst**
**Environment**: Quick Test Pro 8.2, Quality Center 9.0, Load Runner 6.5, MS SQL Server 2000, VB 6.0, Windows XP, MS Office

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**EDUCATION & TRAINING**

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- Bachelor of Science (Computers), Mumbai, India
- SAFe Agile framework, Scrum Master, Technical Writing, SOP Writing, SOX, AUDIT
- Quality Management Systems (Quality Policy, Procedures, Manual, Work instruction, Records/Forms), ISO 9001, ISO 27001, ISO 13485, ISO 14001, GDPR, HIPPA