**Mahesh KumaR. A**

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**objective**

Leverage my skills and inherent abilities to contribute my productive best to the organization and willingness to work as a key player in challenging and creative environment.

**Professional Summary**

* Around **9** Years of extensive experience in Life Science Industries and comprehensive understanding approach in Software Testing for Clinical Trials (IVR,IWRS and ePRO) in Validation Analysis and Quality Review activities.
* Sound knowledge of Computer System Validation [CSV] , 21 CFR Part 11 standards and Familiarity with FDA requirements for computerized systems.
* Involved in delivery of around 50 Studies of various clients in the Life Sciences Domain.
* Solid understanding of clinical drug development process.
* Exposure to People Management, System Change Requests , Project Estimations for testing and Resource Allocation.
* Experience in interacting with internal and External clients at different stages of Testing.
* Executed various Test cases via Interactive Voice Response (IVR), Web (IWR) and ePRO.
* Worked for studies of various Pharma Clients like Novartis Pharmaceuticals, Allergan,Inc., Merck Serono, Pfizer, Idenix, Astellas Pharma, Eisai, Hospira, Eli lilly and Samsung,Johnson and Johnson etc.
* Excellent organization, interpersonal and communication skills in both written and verbal .
* Strong customer service ethic with ability to establish and maintain effective working relationships with co-workers, managers and clients.
* Good problem solving, analytical skills and Team management skills.
* Performing the UAT and Responsible for the CAT plan Execution and Supervision of the testing and summarizing the CAT results.
* Involved in Test Planning of Report Unit Test and Proficiency in Preparing Traceability Matrices.
* Expertise in Writing Test Strategy, Test Plans (Test Cases) & Test Executions like System Proficiency in Test Analysis, Bug Detection, defect isolation and Report generation skills.
* Communicate and co-ordinate with other project support staff within and across the global team unit to identify and consolidate support processes and business improvement activities as required in validation phase.
* Demonstrated ability to deliver quality results within appropriate timeline metrics.
* Manage and Lead study design meetings with the internal project team and client.
* Liaise with clients and establish working relationships to independently support assigned client studies.
* Responsible for design and live study support activities including client contact.
* Maintaining project plans and timelines. Ensures timely communication of timeline deviations and/or deliverables to all appropriate parties.

**Professional Experience**

* Currently employed with **PAREXEL International** as **Project Quality & Test Specialist** in RTSM Client Services from Jul 2018 – Present.
* Previously worked as **Associate Project Manager** for **PAREXEL International** in RTSM Client Services from May 2016 – Jun 2018.
* Previously worked as **Team Lead**- CDM for **Theorem Clinical Research India Private Ltd(Acquired by Chiltern International Ltd.).** Bangalore from May 2015 to April 2016.
* Worked as **Sr.Test engineer** - Validation for **Cenduit (India) Pvt. Ltd.** Bangalore from March 2010 to May 2015.

**EducationAL Qualifications**

* Post-Graduation (**MCA**) from MUFFAKHAM JAH COLLEGE OF ENGINEERING AND TECHNOLOGY, HYDERABAD.
* Graduation (**BCA**) from SRI SAINATH Degree College, HYDERABAD.

**Technical Skills**

|  |  |
| --- | --- |
| Operating System | Windows XP, Windows 2K, and Windows NT. |
| Tools | Quality Center 9.2 |
| Data Base | SQL Server |
| GUI | Visual Basic 6.0 |

**THERAPEUTIC AREA EXPERTISE:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Indication | Phase | # Patients | # Sites | Countries | Services Involved |
| Oncology studies | III | N/A | N/A | N/A | Validation |
| Suicidal Behavior | III | N/A | N/A | N/A | UAT Testing(ePRO) |
| Cancer | III | N/A | N/A | N/A | Validation |
| Vaginal Bleeding | III | N/A | N/A | N/A | UAT Testing(ePRO) |

**AWARDS & ACHIEVEMENTS**

* Appreciation from client at Chiltern International for completing UAT on time for the sunrise depot changes to 11 studies simultaneously.
* Member of Winner of the Star Team of the Quarter Award at Cenduit in Jul 2011.
* Member of Winner of the Star Team of the Quarter Award at Cenduit in Oct 2013

**PROJECT DETAILS**

**PAREXEL International, India pvt Ltd.**

**Project Name :** ClinPhone RTSM

Client : Novartis, Astrazeneca, Boehringer Ingelheim, Bayer,

Sandoz/Menarini, Ucb,MorphoSys etc.

Role : Associate Project Manager

Software’s used : VB.net & SQL Server

Team Size : 9

Duration : May 2016 – Till date

**Job Profile , Roles & Responsibilities:**

The **ClinPhone RTSM** system provides access to a set of project management tools designed to allow the client’s own project team greater control over their RTSM study during the clinical trial operational phase.

The Perceptive Informatics technology platform, framework, and product suite offered in combination with our technology services – all provided from a single point of access (mytrials.com). An RTSM only MyTrials study can benefit from improved user provisioning tools which provide the client with direct control.

**As a Project Quality & Test Specialist, my responsibilities are:**

* Execute the UAT scripts including any data setup as required.
* Assist in the preparation of UAT scripts and other documentation with supervision from the experienced resources.
* Document work to agreed standards and procedures.
* Ensures delivery of RTSM UAT Services and / or products to clients, within expected timelines and budget, with quality.
* Provides timely notification to all appropriate parties regarding deliverable status and any deviations from timelines and/or deliverables.
* Ensures adequate and timey responses to all internal and/or client inquiries and communication.
* Develop the UAT scripts and other UAT documentation as required within the process.
* Provide UAT coverage on project related duties during the RTSM study build and live phase of the project.
* Occasionally may act as a secondary client contact and manage client relationship as required during the UAT of the study during build or live phase.
* Communicates with the Project Manager and other internal members regarding the UAT status of the project.
* Help the project team to identify, control and track the risks in relation to the study requirements at any time, during the build and live phase of the project.
* Where required, provide support in triaging of UAT issues and liaising with the other project teams for resolution of issues.
* Solicits input from team members asking for help when needed and values the expertise of colleagues.

As a Associate Project Manager my roles and responsibilities are:

* Serves as project lead for assigned client studies with guidance and direction from line manager or mentor as required.
* Liaises with clients and establishes working relationships to independently support assigned client studies.
* Maintains project plans and timelines. Ensures timely communication of timeline deviations and/or deliverables to all appropriate parties.
* Identifies and documents study-specific potential issues; timely escalation of critical problems to line manager or mentor. Works with line manager or mentor, project teams, clients, and investigators to resolve open issues. May identify inefficiencies with current processes and recommend improvements.
* Drafts, reviews, and maintains accurate study-specific documentation. Ensures appropriate input from all stakeholders.
* Takes work direction from line manager or mentor when necessary to ensure appropriate delegation and negotiation skills to obtain maximum productivity and team involvement.
* May facilitate client training as required.
* May be required to travel to cover client or internal meetings.
* May attend face to face client meetings and investigator meetings as necessary.
* Responsible for successful completion of project deliverables including, but not limited to, client signatures, user documentation.
* Ensure compliance with SOPs and other relevant regulatory body directives
* Able to translate often complex technical and/or requirement descriptions into language that can be understood by clients to aid in their decision making and understanding of project functionality.
* Manage and lead study design with the Internal Project Team and Client and prepare required documentation associated with this process, with input from internal stakeholders as necessary.
* Where required, create and configure projects within the appropriate toolset
* Drive consistency within projects, products and within clients.
* Promote efficiency, quality and consistency in requirements design process
* Ensure that all project requirements have been stated unambiguously; and that inconsistencies, omissions, and errors have been detected and corrected.
* Help the project team to identify, control, and track requirements and changes to requirements at any time as the project proceeds.
* Manage and lead study design and configuration for change requests to a live study with the Internal Project Team and Client and prepares required documentation associated with this process, with input from internal stakeholders as necessary.
* Responsible for resolving study issues in a timely, proactive and effective manner.
* Responsible for live study support activities.
* Propose solutions or efficiencies on live study issues.

**Theorem Clinical Research India Private Ltd.**

**Project Name :** 191622-101/105/111/112/103//137/133

Client : Allergan.

Vendors : CRF Health and Perceptive Informatics

Role : Test Director

Software’s used : VB.net & SQL Server

Team Size : 8

Duration : June 2015 – April 2016

**Description**

The **TrialManager** is an online internet-based application used by investigators, monitors, study personnel, the Helpdesk and Data Management to monitor and manage the study. In addition, the TrialManager enables study personnel to follow overall compliance and recruitment statistics. Ithas a connection to the study database, in which patient reported study data is stored.

The CRF Health platform is called TrialMax, on which the TrialSlate software is configured. CRF HealthTrialSlate standard screens are pre-defined parts of all projects. These screens typically include generic functionality such as patient setup, patient discontinuation and data sending.

The vendor (Perceptive Informatics) is a provider of automated randomization and logistics management via Interactive Voice Response (IVR) and Interactive Web Response (IWR) technologies using their ClinPhone® RTSM(Randomization and Trial Supply Management) solution.

**Job Profile , Roles & Responsibilities:**

* Responsible for the CAT plan Execution and Supervision of the testing and summarizing the CAT results.
* Performing UAT for ePRO and IVR System.
* Liaise directly with internal clients in UAT phase and provide regular updates at regular intervals.
* Involved in Requirement analysis, Setting the targets to meet the timeslines, assigning the studies to team members and coordinate with team and Providing guidance to team where required to complete the UAT effectively.
* Participate in regular Vendor and client meetings,teleconferences and Webx meetings.
* Provide support to the Test Manager on study related duties during Post UAT activities.
* Performing the UAT and setting the test data as and when requested on internal basis.
* Involved in preparation of Test cases and traceability matrix.
* Actively perform Pre and Post Reviews to identify potential issues in writing and testing phases.
* Setting up the test environment.
* Involved in UAT testing,system testing, compatibility testing, regression testing.
* Involved in complete defect life cycle.
* Sending Weekly Status Reports to manager.
* Involved in GUI, Functional and Regression Testing.
* Preparing the CAT Summary Report. Communicate and co-ordinate with other project support staff within and across the global team unit to identify and consolidate support processes and business improvement activities as required in validation phase.

Liaision with global and internal teams on study related issues.

**Cenduit India Services (P) Ltd.**

**Project Name : C.I.R.T**(Cenduit Interactive Response Technology)

Client : Novartis, Astellas,Eisai,Merck Serono,Idenix,Hospira,Eli lilly,Samsung etc.

Role : Software Testing

Software’s used : VB.net & SQL Server

Team Size : 10

Duration : March 2010 – May 2015

**Description**

The system is a customized IRT software application. The system is designed to automate data trials through the utilization of Interactive Voice Response (IVR) Technology, Interactive Web Response (IWR) Technology& Interactive Fax Response (IFR) Technology.

C.I.R.T will provide absolute control of clinical trials. Whether trials are developing a vaccine or a biotech product, or running an early-phase or late-phase study, C.I.R.T will design a smart process and a smart system tailored to the needs of clinical trial. The unique combination of clinical operations and clinical supplies expertise and our study-specific approach to project management will help you ensure seamless patient enrollment, randomization, Post-Randomization Visits, Subject Status Change (Active, Unbinding, Discontinuation, Treatment Complete), Second Randomization (Re-Randomization), Shipment Confirmation, Order Shipment, Data Transfers and drug supply management and patient safety management.

**Job Profile , Roles & Responsibilities:**

* Involved in Requirement analysis.
* Participate in regular client meetings and teleconferences.
* Participate in study meetings, kick off meetings along with the Project Manager, Test Manager, Requirements Analyst and other project teams.
* Provide support to the Test Manager on study related duties during Post validation activities.
* Liaise directly with internal clients in validation phase and provide regular updates at regular intervals.
* Performing the UAT dry runs and setting the test data as and when requested on internal basis.
* Involved in preparation of Test cases and traceability matrix.
* Actively perform Pre and Post Reviews to identify potential issues in writing and testing phases.
* Involved in preparation of Test data.
* Setting up the test environment.
* Involved in functional testing, integration testing, system testing, compatibility testing, regression testing.
* Involved in complete defect life cycle.
* Sending Weekly Status Reports to manager.
* Involved in GUI, Functional and Regression Testing.
* Preparing the SRT Summary Report.
* Develops and maintains good communications and working relationships with teams and external clients.
* Develop and oversee maintenance of internal databases and project plans.
* Communicate and co-ordinate with other project support staff within and across the global team unit to identify and consolidate support processes and business improvement activities as required in validation phase.
* Liaision with global and internal teams on study related issues.

**Strengths**

* Interpersonal and Communication Skills.
* Positive Approach, Attitude & Good Time Management.
* Confident and Committed.