|  |
| --- |
| **HARISHA D B** |
| **Email:** [harishbalakrishnadore@gmail.com](mailto:harishbalakrishnadore@gmail.com)  **Mobile: +918050148167** |

**Objective**

To work for an organization which provides ample opportunities and utilize my skills to which I can add value as an employee and work towards each other’s growth.

|  |
| --- |
| **Professional Experience: 7+ years in LifeScience Domain** |
| Currently working as **Software Implementation Consultant** at **ArisGlobal** Pvt Ltd. |

**Professional Summary**

* Well versed experience in Testing of clinical EDC products like TrialOne, TrialMaster, Promasys
* Experience on Testing and validation of Clinical, Safety, Medical affairs, VetSafety products
* Strong knowledge and work experience on HP Quality Center, Test Management Tool
* Good experience in identification of test scenarios
* Well versed in writing test cases IQ, OQ and UAT for various scenarios, execution and defect tracking.
* Experience in Developing and reviewing User Requirement Specifications, Functional Requirements Specification
* Experience in System Validation, Agile Methodologies, worked in sprint testing team, scrum.
* Carrying out Black Box testing, Regression testing and User Acceptance Testing, Adhoc Testing, Integration Testing.
* Good knowledge of test case design techniques, analyzed Test results and generated Reports to track the defects and assign fixes using HP Quality Center
* Expert in strategic planning, delivering Status Reports, Summary Report and ready to work in strict timelines
* Ability to prioritize along critical path to meet the Project deadlines and Deliverables
* Implementation and Validation process, knowledge on change management process.
* Product Knowledge on LifeSphere Medical Information, Adverse Events and Product Complaint, drug safety applications LifeSphere Reporter, LifeSphere Veterinary Safety, ARISg, LifeSphere Safety Multi Vigilance, LifeSphere Signal and Risk management application hosted on AWS cloud.
* Data Migration of the products from Oracle to PostgreSQL 15.2 version, Setup the Infrastructure, request the RDS, Data Migration tool, replication instance and its end points and verifying its configuration as it requested
* Worked with guidelines of 21 CFR part 11 regulatory
* Experience in working with JIRA v8.13.5 tool, AWS, Jenkins, DevOps CI/CD pipelines, GIT, GITHub.
* Experience in AWS hosted Linux based systems Multi-tenants LifeSpere Products upgrade, Deployment, Integrations and configurations.
* Worked on Tomcat server application deployments.
* Work experience in E2B R3 Tag verification for safety products.

# Responsibilities at ArisGlobal:

# March 2020-present

* Planning Multi-tenant application hosted on AWS cloud linux systems upgrade, deployments, integrations and its configuration, required downtime for the region.
* Co-ordinating with Team members to complete the work as planned within Downtime.
* Set up the infrastructure for new customer application, host them on the cloud and complete the deployment and its related configuration in Sandbox, validation and Production environments
* Attaching the on-premise customer into the Multi-tenant platform
* Handled Data Migration: Migration of the products from Oracle to PostgreSQL 15.2 version, Setup the Infrastructure, RDS, Data Migration tool, replication instance and its end points and verifying its configuration as it requested
* Coordinating with product team to have the planning on data migration scripts and its execution
* Authoring test cases and Execution in HP ALM
* Analysis of test results, defect tracking
* Internal review of test cases, Configuration specific changes documents.
* Configuration, Implementing and upgrading LifeSphere Medical Information and LifeSphere Reporter applications in windows and linux environments.
* Analyze the incidents reported from customer and provide the proper resolution.
* Managed Services to the Live projects.
* Creating RFC, verification and validation through IQ, OQ and CSCV changes as per the customer request
* Co-ordinate with customer and Quality team
* Knowledge on reported AEs, Medical information and processing the Request and Response in the LifeSphere Medical Information application.
* Receive information on AE's, perform initial checks, send them for safety system.
* Handling Multi-tenant AWS platform linux based systems for LifeSphere applications like LifeSphere Medical Affairs, LifeSpere Reporter, LifeSphere Veterinary Safety
* Handling Multi-tenant application upgrades and deployment, Implementation and Configurations
* Working with Jenkins and GitHub with DevOps CI/CD pipelines

# Responsibilities at iEllipse 2016-2020

# Project: ClinConsent

* ClinConsent is an eConsent tool that transform the informed Consent Process and removes the risk of mishandled Consent documents and subsequent issues in regulatory inspections.
* Performing Adhoc, Regression and functional testing and Authored functionality test cases
* Reviewed test cases on JIRA
* Executing test cases on Web app and on iPad product application
* Organized and attended meetings to discuss the status of the project.
* Tracking and reporting of defects
* Participate in status review meetings, schedule discussions, and standup meeting

# Project: Trial Master and Trial One Client: OmniComm Systems, Florida

This EDC software allows clinical trial Sponsors and investigative sites to easily and securely collect, validate, transmit and analyze clinical study data including patient histories, patient dosing, adverse events and other clinical trial related information.

* Creating test cases and loading them to HP ALM Quality Centre tool
* Identifying Test Scenarios to execute test cases
* Execution of test cases
* Logging and reporting defects
* Assist other team members and monitor their work
* Provide daily and weekly status report to Trial Verification Manager
* Testing archives generated by the Integration deployment team
* Maintain the Test Execution Reports, Pass/Fail Criteria and communicate the Progress and issues within the team
* Reviewing test results and recommending changes
* Drafting/reviewing test summary results
* Participated in status review meetings, schedule discussions, defect reporting
* Responsible for coding all medical history, events, drugs, indications and laboratory tests using MedDRA and WHO-DD

# Project: Promasys

# Client: CHDR, Netherlands

Promasys is an integrated clinical data management and EDC system that brings industry standard quality and efficiency to data collection and data management in your clinical trials. The responsibilities are as follows:

* Review of Validation Protocols IQ/OQ/PQ documentation
* Performing Regression Testing, System Testing & Functional testing
* Identifying test scenarios to execute test cases
* Writing test cases for the identified scenarios
* Uploading test cases to Spira Team, test management tool
* Executing test cases on Web app and on iPad product application
* Logging and reporting defects
* Assist other team members and monitor their work
* Tracking and reporting of defects
* Reviewing test results and recommending changes
* Drafting/reviewing test summary results
* Participated in status review meetings, schedule discussions, defect reporting
* Provide the daily Status Report, Summary Reports to Project manager

# Project: CluePoints

**Client: CluePoints, Belgium**

CluePoints is a Risk-Based Monitoring and Central Statistical Monitoring solution. It employs unique statistical algorithms to determine the quality, accuracy, and integrity of clinical trial data both during and after study conduct. The responsibilities are as follows:

* Performing Functional Testing & Performance Testing as per the requirements
* Logging and reporting defects to development team
* Assisting team members
* Tracking and reporting of defects
* Drafting/reviewing test summary results
* Participated in status review meetings, schedule discussions, defect reporting
* Provide the Daily Status Report, Summary Reports to Team lead and Project manager

**Responsibilities at Wipro Limited: 2015-2016**

* Identifying Test Scenarios to execute test cases
* Execution of test cases
* Logging and reporting defects
* Provide daily and weekly status report to Trial Verification Manager
* Testing archives generated by the Integration deployment team
* Participated in status review meetings, schedule discussions, defect reporting

**Qualification**

Bachelor of Engineering in Electronics and Communication Engineering

July 2015 Government Engineering College, Kushalnagara (VTU)

**Personal skills**

* Keen to learn new things
* Good team player
* Optimistic
* Good Leadership qualities

**Personal profile**

Father Name : Late. Balakrishna D B

Mother Name : Late. Dakshayini

Date of Birth : 05-Nov-1993

Nationality : Indian

Location : Mysore

Languages Known : English, Kannada and Hindi

DECLARATION: I hereby declare that the information furnished above is true to the best of my knowledge and belief.

Harisha DB