**Chaitanya**

Contact: 973-524-6366

Email:chaitanyatest18@gmail.com

**Summary**

7 years of Qualified Software Test Engineer with experience in proving quality and reliability of Class III medical devices, IPG mobile applications, Continuous Glucose and Blood Glucose monitor software through the application of standard Software Quality Assurance, Software V&V practices.

* Specialized in software V&V, system design, requirement analysis, quality assurance, and software testing, medical device testing, system, and equipment validation.
* Experienced in developing software test protocols in a regulated environment in accordance with internal operating procedures and external standards and regulations.
* Experience in formulation of Test Plan, Test Cases and Test Scripts for functional, system, integration and regression testing based on the designed document and user requirement specification document for the functional, security and performance testing.
* Expert testing skills for various levels of testing that include White box, System, Integration, Functional, End- to -End, Regression and UAT.
* Experienced in FDA regulated environment, testing embedded software and systems.
* Hands on experience of requirements and test management tools such as DOORS, Rationale, HP ALM, HP Quality Centre, Defect tracking tools such as JIRA.
* Experienced with testing methodologies, SDLC and software testing life cycle, Agile Methodologies, Test driven development and Software V & V life cycle.
* Experienced in planning and execution of Validation Master Plan, requirements gathering.
* Experienced in creating, reviewing, and executing test protocols Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ).
* Hands on experience on performing Risk Assessment.
* Good Knowledge in Data Integrity.
* Good Knowledge with all the phases of Validation Life Cycle.
* Strong understanding of FDA, ISO 9001, IEC 62304, 21 CFR part 11, GXP.
* Performed investigation of Corrective/Preventive Actions (CAPA) to determine the root cause using fishbone diagram, 5 Whys.
* Experienced with cross-functional teams to implement the mitigation and updated risk assessment documents to document the risk associated with the CAPA.
* Experienced with Robot Framework, and Linux Environment.
* Experienced in Agile and waterfall methodologies.
* Experienced in testing devices using MTP cable, UART to USB cable, oscilloscopes, multimeters, function generators, thermometers, temperature chamber and Load resistors.

**Technical Skills:**

* Software Testing :  **Automation and Manual Testing**
* Automated Tools :  **Squish, Ranorex.**
* Framework :  **Robot Framework**
* Command prompt tool : **PTU Tool**
* Test Management Tool :  **Jira, Rally**
* Operating Systems : **Windows, Linux**
* Application Management Tool **: HP ALM**
* PLM : **TCU, Windchill**
* Code review : **Gerrit**
* Repository management : **GIT, Bitbucket,**
* Requirement management Tool : **DOORS**
* SDLC : **Agile, V&V**
* Statistical Analysis Tool : **Mini tab**
* CI/CD **: Jenkins**

**PROFESIONAL EXPERIENCE:**

***Abbott Diabetes care, Alameda, CA January 2021 to till date.***

***Software Verification Engineer***

**Responsibilities:**

* Performed software validation and verification (V&V) for Abbott Diabetes care medical devices.
* Worked with SME to complete validation deliverables, including risk assessment, verification plans, protocol development and execution.
* Used HPQC quality center for the testing, tracking, and reporting test defects.
* Involved in software verification test case design, development and testing of few modules.
* Responsible for troubleshooting technical issues to root cause and providing technical solutions.
* Efficient usage of Bluetooth protocol analyzer for BLE communications and EVM boards for near field communications.
* Performed black box testing, white box testing, and automation testing.
* Interface with software developers in areas of creating software test work products including test cases, test plans, test procedures and test reports.
* Work with engineering development team on Bluetooth, and near field communication system to bring up and design validation.
* Documented, tracked, and escalated issues as appropriate using HPQC**,** worked with core team to validate and resolve them.
* Responsible for troubleshooting technical issues to root cause and providing technical solutions.
* Developed the protocols with module based on workflows by using PTU Gen tool.
* Write test plans, execute testing, and create test reports during software development.

***Abbott Laboratories, Plano, TX April 2020 to December 2020***

***Systems Test Engineer***

**Responsibilities:**

* Performed software testing, verification, and validation efforts for existing medical devices.
* Performed exploratory testing and Characterization to find out the bugs in initial stages.
* Worked on testing medical device like Implantable pulse generator.
* Responsible for creating Clinical Feature based verification workflows based on Functional requirements.
* Created requirement traceability matrix to ensure validation covers all functional requirements.
* Developed the Test Scripts with module based on workflows by using Ranorex.
* Interface with software developers in areas of creating software test work products including test cases, test plans, test procedures and test reports.
* Involved Automated Script Reviews in Bitbucket
* Write test plans, execute testing, and create test reports during software development.
* Work with engineering development team on amplitude, pulse width, and frequency system bring up and design validation.
* Documented, tracked, and escalated issues as appropriate, using **JIRA.** worked with developers to validate and resolve them.
* Responsible for troubleshooting technical issues to root cause and providing technical solutions.
* Performed manual and automated testing on IPG’S using iOS mobile application via wireless communication.
* Tested iOS application software on various mobile devices, including iPhones, iPods, and iPads.
* Automate test cases, test suites for Regression Testing via Ranorex.

***Baxter Healthcare, Greater Chicago area, IL February 2019 to March 2020***

***Software Test Engineer***

**Responsibilities:**

* Designed test sets, produced, and tested rack and test equipment.
* Performed complex testing and trouble analysis.
* Ensured environmental testing including shock and vibration, thermal cycling.
* Assembled chassis equipment and components.
* Followed and developed test procedures, documented testing, and modifications.
* Executed tests from a test plan.
* Maintained and updated results and logs database.
* Recorded, tracked, and verified defects.
* Prepared test reports and developed automated data reduction techniques.
* Analyzed root cause and resolved customer product design issues.
* Involved in Integration testing, debugging automation scripts and fixing bugs.
* Developed the Test Scripts based on feature-based workflows by using (Robot Framework) in Linux Environment using PyCharm.
* Carry out on regression testing every time when changes are made to the code to fix defects.
* Created Test Cases and running them in HP Quality Center/ HP ALM for applications used for testing.
* Worked closely with the software development team in reviewing specifications, writing test procedures, plans, entering product issues, and collecting completed test data/documentation for archiving.

***Medtronics, St Paul, MN February 2018- January 2019***

***Software Test Engineer***

**Responsibilities:**

* Responsible for the development, execution, and reporting of software product test plans and detailed software test procedure.
* Modifying and executing software test plans to ensure that the device meets product and system requirements, analyzing and writing test designs and procedures, and establishing traceability to requirements and risk mitigations.
* Participated in reviewing, modifying and execution of protocols (test cases) that comply with FDA 21 part 11 standards - IQ, OQ & PQ.
* Developed the Test Scripts based on feature-based workflows by using (Robot Framework) in Linux Environment using PyCharm.
* Designed and developed software verification/validation test protocols and procedures from software requirement specifications and detailed design descriptions.
* Organized and executed test protocols and test procedures/scripts.
* Shared technical knowledge with others on the team.
* Collected and analyzed test results from SV&V activities.
* Created Test Cases and running them in HP Quality Center/ HP ALM for applications used for testing.
* Worked closely with the software development team in reviewing specifications, writing test procedures, plans, entering product issues, and collecting completed test data/documentation for archiving.
* Used software tools in support of NPD and Sustaining SV&V activities.
* Involved in module Unit Testing, Integration testing, debugging code and fixing bugs.

***Cardinal Health, Cleveland, Ohio July 2017 – January 2018***

***Software Test Engineer***

**Responsibilities:**

* Responsible for the development, execution, and reporting of software product test plans and detailed software test procedure.
* Developed verification and validation test protocols for a specified medical device.
* Modifying and executing software test plans to ensure that the device meets product and system requirements, analyzing and writing test designs and procedures, and establishing traceability to requirements and risk mitigations.
* Designed and developed software verification/validation test protocols and procedures from software requirement specifications and detailed design descriptions.
* Organized and executed test protocols and test procedures/scripts.
* Shared technical knowledge with others on the team.
* Collected and analyzed test results from SV&V activities.
* Created Test Cases and running them in HP Quality Center/ HP ALM for applications used for testing.
* Worked closely with the software development team in reviewing specifications, writing test procedures, plans, entering product issues, and collecting completed test data/documentation for archiving.
* Used software tools in support of NPD and Sustaining SV&V activities.
* Involved in module Unit Testing, Integration testing, debugging code and fixing bugs.

***BioTek, Hyderabad, TS***

***Software Test Engineer August 2013 – August 2015***

**Responsibilities:**

* Performed Manual Testing on functionality of the application.
* Created Test Scenarios, Test Cases & Test Data for the application
* Executed test cases and generated test summary reports.
* Administered testing activities which includes Functional, Retesting, Regression, System and Acceptance Testing
* Raised & reproduced bugs for Developer Team.
* Involved in understanding the requirements and business of the application.

**Education:**

* Master’s in Engineering Management, Trine University, Indiana, United States(2017)
* Bachelor’s in Electronics and Communication Engineering, JTNUK(2013)