Satish Akarapu

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**Professional Summary**

* **7.3 Years** of experience in **Computer System Validation and Build and Release Deployment.**
* Over **3+ Years** of experience in **Computer System Validation** in **Regulated Life Sciences- Pharmaceutical**.
* Involved in validation activities for the **Drug discovery, Pre-Clinical, Clinical, Quality Management** regulatory products like TrackWise Digital, DocuSign.
* Hands on experience on **GLP, GCP** and **GAMP 5** guidelines and Good Documentation Practices.
* Having **3+ Years** of experience in **Application Build and Release ,Hosting Deployment to QA, stage and Production Environments.**
* Proficient generating and reviewing Computer System Validation (CSV) deliverables according to **21 CFR Part 11** and FDA regulations for the Pharmaceutical industries that includes **IQ/OQ/PQ**, **SOPs**, **Risk Assessment** and **Validation Summary Report**.
* Experience in reviewing User Requirement Specifications (URS) and Functional Requirement Specifications (FRS), Design Specifications (DS)/ Configuration Specification (CS).
* Prepared Trace Matrices, Validation Summary Reports and Deviation Reports for various system implementations.
* Experience in creating and reviewing of **Change Control, CAPA, Quality Events** and **Audits** using Quality Management System (QMS).
* Good understanding & implementation knowledge of Good Testing Practices (GTP).
* Experience in performing GUI, System & Integration, Regression, Performance & UAT (User Acceptance Testing) testing.
* Hands on experience in tools like **Installshield ,Ant GIT Hub**.
* Hands on experience in **Wildfly,Jboss** Application servers and Oracle Database

**Skills**

**Validation and Quality Compliance:** GxP assessment,Change Control, CAPA,SDLC (V-Model), Validation Plan, Installation Qualification, Operational Qualification, Performance Qualification, Requirement Traceability Matrix, Validation Summary Report.

**Electronic Signature Solution:** DocuSign

**Software configuration Management Tools:**VSS(Visual Sourcsafe),GITHub,Jenkins,Installshield

**Database:** Oracle, MySQL**.**

**Operating systems -** Windows 10,Windows server 2016 and Ubuntu**.**

**Application Servers:** Tomcat, Wildfly, Jboss**.**

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| **Education** | **B.Tech (Computer Science and Engineering) from JNTUniversity (Hyderabad) - 2012.** |

**Professional Experience**

**Organization : Xybion Corporation Apr 2017 to till date**.

**Client :** Covance, FDA,

HSRL (Histo-Scientific Research Laboratories), Zoetis, Level Biotechnology.

**Projects : Pristima® and SEND Savante®**

**Role :** Senior Build Engineer

**Projects Descriptions:** The objective of these projects was to validate **Pristima® and SEND Savante®** (Standard Exchange of Non-Clinical Data) Products as per the client requirements and operational qualification scripts and making build’s installed for QA,Stage and Production Environments.

**Responsibilities:**

* Developed Validation Plan (VP) to define the validation strategy for Pristima and Savante.
* Actively participated and Involved in Computer System GxP Assessment and GxP Computer System Risk Assessment for Pristima and Savante.
* Reviewed Vendors documentation and updated the User Requirements, Functional Specifications and Configuration Specifications.
* Conducted System level and Functional level Risk Assessment Sessions with the team to identify Potential Hazards and gaps.
* Drafted Installation Qualification (IQ) per Design Speciation (DS) and executed in Validation and Production environment.
* Reviewed Operational Qualification (OQ) and Performance Qualification (PQ) for Pristima and Savante.
* Developed and maintained Requirements Traceability Matrix (RTM) to keep track of relationship between User Requirements with Performance Qualification (PQ) and Functional Specifications with Operational Qualification (OQ).
* Authored, reviewed and routed Performance Qualification Summary Report (PQSR) and Validation Summary Reports (VSR).
* Worked on build and Release creation and Deployment in QC lab Environment ,Crystal RAS 2016 server installation.
* Deploy code to QA, Stage and Production Environments.
* Having experience in setting up Hosting environment ,Oracle 12c Database installation and support for client during deployment failure.
* Worked on application issues and server issues and having experience in build tools like ANT, worked on issue tracking tools like Census.
* Involved in First Level Unit Testing, Troubleshooting.

**Organization : Royal Cyber Private Limited - MARCH 2015 to Apr 2017.**

**Projects :** Cybershop and Ecatalyst

**Role** : Software Engineer

**Responsibilities:**

* Worked on build and Release Promotion and Deployment for war files and exploded files format.
* Worked on taking build and Release promotion to onsite. Worked on Oracle Database server and Oracle Database Client installations
* Worked on Hybris suite installation, Deploy code to QA, Stage and Production Environments.
* Worked on application issues and server issues and having experience in build tools like ANT. worked on issue tracking tools like JIRA.
* Involved in First Level Unit Testing, Troubleshooting, restarting the Applications during the failures.
* Worked on Jenkins for build automation and ANT Tool for build.
* Worked on Tomcat server for deploying the applications.
* Coordinate with the team at onsite for a smooth deployment, any change management or production issues.
* Provided support to the developers and QC staff for technical issues which might come across. Worked on Root cause analysis for post-production issues after the deployment
* Worked with VM ware and Citrix applications and resolved the client issues during deployment.

**Organization : Polaris -** **DECEMBER 2013 to FEB 2015.**

**Project : National Bank of Abu Dhabi**

**Role** : Software Engineer

**Responsibilities:**

* Worked on Deploying the build to SIT environment and Promoted to Onsite.
* Worked on application issues and server issues. Maintaning Release tracker.
* Involved in First Level Unit Testing. Provided support to the frontend developers for technical issues which might come across.
* Coordinate with the team at onsite for a smooth deployment, any change management or production issues. Involved in Creating New environment setup For Developer Testing.