NIKHIL TURKE

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Manual Testing | Functional Testing | Regression Testing | SQL | JIRA | Life Cycle Documents | Agile Methodology | GAMP 5 | FDA Regulation | GMP | ICH Q7 | GDP | Data Integrity | ALCOA Principle | V Model | 21 CFR Part 11 | EU Annexure 11 | EDMS |Validation Plan | GxP Assessment | User Requirement | FRS | Design Specification | Excel Sheet Validation | Computerized Software Validation | SCADA | CDAS | Server Qualification | Equipment Qualification | PLC Validation | HVAC Validation | EMS | Quality Risk Management | Mitigation Plan | Testing Life Cycle | Test Scripts | Testing Strategy | User Management | Data Backup Restore | Data Protection Control | RTM | CAPA | Compliances Against Deviations | Change Control Management | Periodic Review | GAP Assessment | UAT | Validation Summary Report | System Release Report | Validation Documentation Status | Defect Management | Retirement Report

--- **OBJECTIVE** ---

Detail-oriented, enthusiast, motivated individuals with over 7.9 years of experience in Software Validation, Verification and Testing along with Requirement Analysis intend to build a career in a challenging environment with commitment and dedication which will allow me to explore self and help to grow the organization. To work devotedly for the organization with great pride in the profession where my knowledge transitioned, and talents are encouraged.

--- **PROFESSIONAL SNAPSHOT** ---

- A very skilled IT professional having proven experience in **Computerized Software Validation in API Plant, Oral facility & Injectable/Sterile Unit (pharma Industry) Software Systems along with Software Testing over more than 6 years and Rest of in Technical Field.**

- Well acquainted with **Software Development Life Cycle, Software Testing Life Cycle, Agile Methodology, Life Cycle Documents, Quality Risk Management, Deviation Management, Change Control Procedure, Electronic Document Management System (EDMS), System Release Report, Validation Documentation, Traceability Matrix.**

- Expertise in **Periodic Review, GAP Assessment, Functional Testing, Risk Assessment, Test Script, Design Specification, RTM, SCADA, CDAS, Server Qualification, Equipment Qualification etc.**

- Have hands on **CSV Validation, HVAC Validation, PLC Validation, Excel Sheet Validation, Microsoft SQL Server, User Management, Data Backup Restore, Data Protection Controls & policy update activity, etc.**

- Have knowledge of **GAMP 5 guideline, GMP, GDP, Data Integrity, ALCOA Principle, ICH Q7, FDA Regulation, 21 CFR PART 11, EU ANNEX 11, V model, GAMP Categories, Validation Strategy, etc,**

- Good knowledge of Retesting**, Regression Testing, Manual Testing, Bug/ Defect Life Cycle, Defect Tracking And Reporting in Jira Tool, Testing Strategy with Test Scripts**

- Proficient in **Requirement Analysis, Life Cycle Documents** like **GxP Assessment, 21 CFR PART 11 Assessment, URS, FRS, Functional Risk Assessment, EDC Assessment Checklist, DCS, Validation Project Plan, IQ, OQ, PQ Test Scripts, RTM, VSR, SRC, System Retirement Report, Change Verification Checklist, EMS Qualification, AHU Qualification, Mitigation Plan, CR Handling, etc.**

- Experience to work independently or as Team player with Good Communication and Presentation skills.

- Ability to understand and adapt to New Technologies and Environment.

- Able to Deliver projects within tightest deadlines while maintaining the quality.

- Efficient to work in different roles and responsibilities. Responsible for Co-ordinating with client & handling site also Monitoring & reporting status of testing & validation compliance activity.

- Training and coordinating with team regarding aspects of GAMP5, GAMP Categories, User Managements, Data Backup & Restoration, IT Policy, SOP's compliance procedure, etc.

TOTAL EXPERIENCE: 7.9 Yrs

INSTRUMENTATION AND CONTROL SOLUTION, INDORE   Exp: 1 Yr 9 Months (From Mar 2023 to till date)

Designation : Executive (Validation Consultant/ Validation Engineer)
Department : Validation Engineering Services /It Csv
Project/Role : API Facility, Oral Formulation SCADA, DAS Software Systems, Periodic Review, GAP Assessment, Change Control Management, Handling Of Deviation, Backup Restoration, SQL, User management Activity, CSV Validation, Excel Sheet Validation, Electronic Document Management, Quality Risk Management, CAPA compliance, etc.
Client : LUPIN Limited (Pharma Industry)

VST ELECTRONIC AND SECURITY PVT. LTD. PUNE   Exp: 3 Yr 5 Months (From Oct 2019 to till Mar 2023)

Designation : Executive (Validation Consultant/ Validation Engineer)
Department : Validation Services
Project/Role : Sterile/Injectable Unit, OSD Formulation, IPC/SCADA, HMI, PLC,CDAS Software Systems, EDMS, EMS Software, HVAC Validation, PLC Validation, CSV Validation, Equipment Qualification, Equipment Decommissioning, System Release Report, Addendum, Impact Assessment, Justification for ETD, etc.
Client : EMCURE Pharma, GENNOVA Biopharma, LUPIN Limited, CIPLA Limited (Pharma Industry)

PRANAL UTILITY SERVICES PVT. LTD. NAGPUR   Exp: 1 Yr 3 Months (From Apr 2018 to till July 2019)

Designation : Technician cum Engineer
Department : Engineering (HVAC/EMS/Utility) Dept.
Project/Role : HVAC Operation Shift Incharge, EMS Software System operator, Preventive Maintenance, Involvement in Validation Activity, CFM checking, ACPH Testing, Filter Integrity Test, PAO Testing with vendors, Prepare PM checklist, Logbook Management, Equipment Qualification, Periodic Qualification & Document Review, Substation & Synchronized Panel Monitoring, DG Maintenance, Cooling Tower, Chiller, Air Compressor, Utility monitoring & Maintenance, Daily Status Reports, Weekly Status Reports. etc.
Client : LUPIN Limited, Nagpur (Pharma Industry)

NAGARJUNA AGRO CHEMICALS PVT. LTD. WARDHA   Exp: 1 Yr 4 Months (From Nov 2016 to till Apr 2018)

Designation : Junior Technical Engineer
Department : Quality & Testing Dept.
Project/Role : PCB Testing, Component Mounting, Soldering, Assembling , Monitoring Operation, Maintenance & Shaker Assembling according to program, Final Quality Checking, Product Quality Inspection, Product Release Report, Document Review, Site Acceptance Testing, etc.

IT PROFICIENCY & SKILLS

Software (Manual)Testing
Microsoft SQL Database Testing
System Integration Testing (SIT)
Software Testing Life & Software Development Life Cycle
Sprint Backlog
Test Terminology (Exploratory Testing, Adhoc Testing, Monkey Testing
Test Plan, Test scenario, Test Cases Prepare & Execute
Smoke Testing, Functional Testing, Regression Testing, End to End testing, Sanity Testing
Agile Methodology & Ceremony, Scrum Meeting
Defect Analysis
Defect Report in JIRA TOOL
Defect Life Cycle Management

EDUCATION DETAILS

Completed Bachelor Of Engineering From RTMNU, Nagpur University
Electrical (Electronics And Power) Engineering
2016

PERSONAL DETAILS

- Father Name : Digambar S. Turke
- Date of Birth : 17/12/1993
- Languages known : English, Hindi, Marathi
- Nationality : Indian
- Marital Status : Unmarried
- Permanent Address : At. Atmurdi Tq. Ralegaon Dist. Yavatmal - 445402

DECLARATION

I hereby declare that the information stated herein above is true and correct.

Place :
Date :

Nikhil Turke
(Signature)