RESUME

NAME – Kothapelli Thirupathi Reddy

MOBILE NUMBER – 7702217377

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EXECUTIVE SUMMARY

Industry Experience –

- Expertise in preparation and execution of control system(software), IT infrastructure validation documents like GxP, QP, Risk Assessment, GAP assessment, SRS /URS, IQ, OQ, PQ, RTM / VSR, SRC.
- Adept Knowledge in computer system validation (CSV non -configurable, configurable, and customized software).
  Data integrity policies (ALCOA+ principles), Software development life cycle (SDLC, V-model) from requirementgathering to till release of the application in production environment for end user.
- Adept knowledge on 21CFR part11 and EudraLex Annexure 11 clauses.
- Adept knowledge in Risk assessment approach by failure mode and effect analysis (FMEA), Fish bone diagrams.
- Handled and executed equipment qualification and software validation activities.
- Single point of contact for internal and external regulatory audits for CSV related activities.
- Lead as training coordinator and trainer for the end user for existing and new software modules.
- Preparation and revision of SOPs for the quality department as per planners.
- Experience in Handling of QMS tools for Incidents, deviation and change management system.
- Adept knowledge in CAPA handling and implementation.
- Experience in independent handling, decision Making and providing solution to wide range of difficult challenges from project initiation phase, testing and deployment in production environment.
- Co-ordination with IT team for server installation and qualification activities.
- Complete knowledge of instruments like laboratory equipment's and software's

Technical Skills

- SAP S/4 HANA
- IT Compliance
- Caliber LIMS (Version 4.0.0)
- 21 CFR PART 11
- GAMP 5
- Validation
- QMS
- SDLC
- Test Management

Education

Degree/Board	University/Board	Year	Percentage
MSc (Organic Chemistry)	Osmania University	2008-2010	70%
BSc (MPC)	Kakatiya university	2004-2007	71%
MPC	Board of intermediate	2002-2004	77.50%
SSC	Secondary school of education	2001-2002	82.00%

professional Experience – 11+ years of experience in pharmaceutical domain in which **8 years** of experience in Quality Systems and Computer System Validations.

Organization	From	To	Experience	Role
Anthea pharma	25th OCT-2023	Present	01 year	Assistant Manager
Aurobindo pharma	10th Aug 2018	16th Oct 2023	04 years 09 months	Sr.Executive
Dr. Reddy's laboratories	1st Jun 2015	16th Oct 2018	03 years	Team Member
Mylan laboratories	27th May 2014	23rd May 2015	11 months	Officer
Natco pharma	1st Jun 2012	20th Aug 2014	02 years 02 months	Assistant-Quality

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Company: Anthea pharma
Industry: Pharma life sciences
Role: QA CSV
Location: Hyderabad

Project Details: Computer system validation of laboratory software's and QMS software, SCADA/IPC, PLC Connected software's

Role and Responsibilities:

- Preparing and reviewing the Change Lifecycle Documents such as Impact Analysis & Test Strategy Document and System Lifecycle Documents such as URS, FRS, DS, FRA, TMX and others.
- Reviewing and validating computer systems in compliance with 21 CFR part 11 and GxP FDA regulations. Working Knowledge of GLP, GCP, GMP, GAMPV guidelines especially in the areas of computer or related systems.
- Authored and reviewed Design Specification and Functional Specification as per needs of client sites.
- Preparing and reviewing of validation protocols IQ/OQ/PQ documentation, SOPs, risk assessment, periodic review report.
- Creating validation strategies & reports to define all actions, deliverables, responsibilities and procedures to meet the validation and compliance requirements.
- Reviewing Change controls, Deviations, Investigation and CAPA along with maintaining data integrity.
- Checking the Functions like Security Policy, Access Control, Authority Checks, Audit Trail, Print Report, Alarms, Interlocks, Data Integrity, Data Backup & Restore (PLC, SCADA, HMI), I/O's, Communication Loss and Power Failure based on 21 CFR part 11, GAMP5 and cGMP Guidelines.

Company: Aurobindo pharma
Industry: Pharma life sciences
Project: Implementation of laboratory software's and LIMS migration
Role: CSV (Sr . Executive)
Location: Hyderabad

Project Details:

- **QC Systems**: Empower (Waters, Agilent, Shimadzu), Standalone Systems (Empower, Lab solutions, UV probe, Spectrum ES, DSC, IC Magicnet, Mastersizer-2000,TOC,LBPC and Tiamo etc), Newtronic (IC DAS), Thermo(smart VU application) for stability chambers.

- Infrastructure Qualifications and caliber LIMS migration

Job roles and responsibilities:

- Involved in qualification/validation activities and to develop qualification documentation for software and computerized systems used in GXP environments as per GAMP 5 and internal procedures.
- Reviewed and provided compliance approvals for CSV deliverables (URS, FRS, DS, CS, TM, IQ, OQ, PQ and IQ/OQ/PQ test reports, VSR, USR, VP, CAPA).
- Authoring, Review, Execution and Approval of Validation Protocols, Validation Scripts, Validation Summary Reports.
- Take part in SOP Preparation and ensuring all procedures and tools accurately support GxP related requirements.

Company: Dr. Reddy's Lab, Hyderabad. (TS)
Industry: Pharma life sciences
Project: SAP S/4 HANA, Labware LIMS
Role: Associate
Location: Hyderabad

Project Details:

- QC software validations and verification of CDS Data transfer from Empower to Caliber LIMS through API, SAP S/4 HANA implementation

Job roles and responsibilities

- To perform the computer system validation of all the process and equipment's as per 21 CFR Part 210,211 and EudraLex Annexure 11.

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- Maintaining User Administration Activities to All GxP Computerized Systems like (User Creations, Deletions, Privileges Modifications, Password Reset and User Unlocks as Per User Request), Schedule Backups and Software Inventory List for Computerized Systems.
- Preparation of Validation & Qualification Documents to Computerized Systems Like (GxP Assessment, Vendor Assessment, System Validation Plan (VP), FRS, Functional Risk Assessment (FRA), IQ, IQ Report, OQ, OQ Report, PQ, PQ Report 21 CFR part11 Compliance, Requirements Traceability Matrix (RTM), Validation Summary Report (VSR) and Periodic Review (PR) & Audit readiness.

Name of an Organization: Mylan laboratories, Hyderabad

Job roles and responsibilities:

- Responsible for the protocol preparations (IQ,OQ,PQ) and execution and compilation
- preparation of calibration planner, master list of instruments yearly as standard operatingprocedure and execute the calibration activities every week as per planner and update calibration schedule.
- Participate actively in GDP, self-inspection and implementation related to Maintenance and the documentation changes as per periodic requirements.
- Prepare, implement and conduct training related activities of Quality Department.
- Handled QMS tools for Incidents, deviation and change management system.

Name of an Organization: Natco pharma, Hyderabad

Job roles and responsibilities:

- Worked in a quality team and responsible for operate & maintain lab equipment's/instruments as per procedures.
- Planning and monitoring of day-to-day GLP activities in the lab.
- Ensuring calibration and qualification of standalone instruments on timely basis.
- Ensuring GDP & GLP compliance in the lab.
- Responsible for preparation, review and training of SOP's and guidelines.
- Handle Deviation Identified during Qualification Activity (if any)
- Participate in investigation during failure of Qualification Activity (if any)
- Handling Change Control Activity

Skills & Certifications –

- Trained on agile-scrum methodology
- SAP Certified Application Associate - SAP S/4HANA Asset Management (Verify: https://www.credly.com/go/S65FJBkM)
- Completed Caliber LIMS (version 4.0.0) Training & Certifications from caliber LIMS
- Completed risk analysis, Evaluation & Assessment training

PERSONAL DETAILS:

Name	: K.Thirupathi Reddy
Date of Birth	: 01/07/1987
Sex	: Male
Marital Status	: Married
Permanent Address	: plot no-114, Shankar green homes, ameenpur, hyd.

DECLARATION:

I hereby declare that all the information furnished by me is true with best of my knowledge.

Date:

Place: Hyderabad (K. Thirupathi Reddy)

Thanking you.