

M. VIJAYA KUMAR

Senior Instrumentation & Automation Engineer

API Pharma | PLC / SCADA / DCS | Calibration & Maintenance

📍 Hyderabad, India

📞 +91 9010800328

✉ vijaymallepu74@gmail.com

🌐 Open to Relocation

PROFESSIONAL SUMMARY

Senior Instrumentation & Automation Engineer with 14+ years of progressive experience across pharmaceutical manufacturing — API (Oncology, General API), Injectables, OSD — and Power Plants. Core strengths lie in comprehensive field instrumentation maintenance, calibration management, PLC/SCADA/DCS operations, and ensuring uninterrupted GMP-compliant production. Proven expertise in preventive & breakdown maintenance of process equipment (Reactors, ANFD, RCVD, Centrifuges, FBD, Autoclaves, Filling Lines), calibration of 200+ instruments, and full compliance with cGMP, 21 CFR Part 11, GAMP 5, and Data Integrity (ALCOA+) standards. Track record of zero critical downtime events and successful regulatory audit support at Dr. Reddy's Laboratories.

KEY ACHIEVEMENTS

~20–30% Downtime Reduced	Designed and executed proactive PM schedules and predictive maintenance routines for PLC/SCADA-controlled process equipment, cutting unplanned downtime by 20–30%.
Zero Critical Downtime Events	Maintained uninterrupted 24/7 DCS/SCADA and field instrument availability across multiple pharma plants — zero critical production-loss events during 5-year tenure at DRL.
200+ Instruments Calibration Managed	Established and managed calibration schedules for over 200 field instruments (flow, pressure, level, temperature, pH, conductivity) across API and injectable manufacturing.
Multiple Regulatory Audits Cleared	Supported USFDA, EU GMP, WHO GMP, and internal QA audits — zero critical instrumentation/automation observations; maintained audit-ready documentation at all times.
CSV & Interlock Validation Completed	Executed IQ/OQ/PQ protocols and validated process safety interlocks for critical equipment in compliance with 21 CFR Part 11 and GAMP 5 requirements.

CORE COMPETENCIES

Field Instrumentation Maintenance	Calibration Management	Preventive & Breakdown Maintenance
PLC: Siemens S7-300/400/1200	Allen Bradley RSLogix / Studio 5000	SCADA: WinCC & Wonderware
DCS Architecture & Operations	Flow, Pressure, Level, Temp Instruments	Control Valves, Positioners
VFD Installation & Troubleshooting	cGMP & GAMP 5 Compliance	21 CFR Part 11 & ALCOA+
CSV — IQ / OQ / PQ Lifecycle	Audit Trail & Data Integrity	Interlock & Safety Validation

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RCA, CAPA & Deviation
Management

I/O Marshalling & Module Config

Loop Checking & Loop Tuning

Instrument Commissioning

Calibration SOPs & Documentation

Cross-functional Team
Coordination

PROFESSIONAL EXPERIENCE

Senior Instrumentation Engineer | Dr. Reddy's Laboratories Ltd. — API Division (Oncology)

Aug 2020 – May 2025 | Hyderabad

Scope: Multi-reactor API synthesis plant — Siemens S7-400 PLC, WinCC SCADA, DCS, 21 CFR Part 11 regulated environment

- ▶ Planned and executed preventive maintenance (PM) schedules for PLC, SCADA, DCS panels, field instruments, and process control loops across API manufacturing.
- ▶ Managed calibration of 200+ field instruments including pressure transmitters, differential pressure (DP) flow elements, temperature (RTD/thermocouple), level (radar/DP), pH, and conductivity analyzers.
- ▶ Performed breakdown maintenance and first-response troubleshooting on control valves, positioners, VFDs, solenoid valves, and process actuators to minimise production downtime.
- ▶ Conducted loop checking, loop tuning, and signal integrity verification for new and modified instrument loops during shutdowns and commissioning activities.
- ▶ Maintained calibration records, PM logs, and instrument history cards in compliance with cGMP documentation standards and audit trail requirements.
- ▶ Handled instrumentation, maintenance, and troubleshooting of breach isolators (Relay & PLC based), including pressure control, interlocks, VHP systems, and compliance with cGMP, ALCOA+, and 21 CFR Part 11 standards.
- ▶ Executed I/O marshalling, module configuration, and PLC/SCADA backup & restoration procedures during system upgrades and change management activities.
- ▶ Validated all process safety interlocks (pressure, temperature, level, flow, and solvent containment) per IQ/OQ/PQ protocols and 21 CFR Part 11 requirements.
- ▶ Supported Computerized System Validation (CSV) lifecycle documentation including URS, FRS, traceability matrices, and validation summary reports.
- ▶ Led Root Cause Analysis (RCA) and CAPA for recurring instrument failures, eliminating repeat breakdowns through systemic corrective actions.
- ▶ Coordinated with QA, Production, and Engineering teams — successfully supported USFDA, EU GMP, and WHO GMP regulatory audits with zero critical observations.

Key Achievement: Reduced unplanned downtime by ~20–30% through structured PM program and predictive maintenance routines.

Instrumentation Executive | Hetero Laboratories — Injectables & OSD

Dec 2019 – Aug 2020 | Hyderabad

Scope: Sterile injectable filling lines, vial inspection, tablet coating, and OSD packaging automation

- ▶ Maintained PLC-controlled sterile filling, vial wash, depyrogenation tunnel, and packaging line instrumentation.
- ▶ Managed periodic calibration of critical instruments in classified clean rooms, — temperature, humidity, differential pressure, and flow meters.
- ▶ Ensured continuous GMP-compliant batch production by rapid breakdown response and root cause elimination.
- ▶ Supported cleaning validation instrumentation checks and environmental monitoring system maintenance.

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Instrumentation Engineer | Dr. Reddy's Laboratories Ltd. — API Division

Apr 2016 – Nov 2019 | Hyderabad

Scope: API synthesis and intermediate manufacturing — PLC/SCADA/DCS maintenance and calibration

- ▶ Carried out preventive and corrective maintenance of Reactors, ANFD, RCVD, Centrifuges, Vacuum Systems, and associated instrumentation.
- ▶ Maintained calibration program for all field instruments ensuring traceability to NABL-accredited standards and compliance with cGMP SOPs.
- ▶ Performed loop checking, instrument loop diagrams (ILD) review, and commissioning support for new project installations.
- ▶ Supported DCS/SCADA availability, change control adherence, and documentation of all maintenance activities in instrument history cards.
- ▶ Diagnosed and resolved PLC-based interlock faults, signal failures, and HMI communication issues to restore normal production rapidly.

Instrumentation Engineer | Nadhi Bio Products Pvt. Ltd.

Oct 2013 – Mar 2016 | Kalukuntla

- ▶ Performed calibration, preventive maintenance, and troubleshooting of field instruments in fermentation and downstream processing areas.
- ▶ Installed and commissioned flow meters, level transmitters, pressure gauges, control valves, and temperature sensors.
- ▶ Maintained instrument calibration records and PM schedules in line with plant SOPs and GMP guidelines.

Instrumentation Engineer | S.N.S Starch Ltd.

Sep 2011 – Oct 2013 | Yerravalli

- ▶ Provided instrumentation maintenance support for boilers, turbines, and balance of plant (BOP) systems.
- ▶ Carried out calibration and condition monitoring of process instruments ensuring plant operational reliability.
- ▶ Executed routine preventive maintenance of pressure, flow, level, and temperature measurement systems.

COMPLIANCE & VALIDATION EXPERTISE

cGMP / GMP	Operated under cGMP discipline throughout career — change control, deviation management, CAPA, and GMP documentation practices in API, Injectables, and OSD plants.
21 CFR Part 11	Configured and maintained audit trails, electronic records, backup/restore validation, and user access controls for SCADA/DCS systems in FDA-regulated facilities.
GAMP 5	Applied risk-based GAMP 5 approach for CSV categorisation (Category 3, 4, 5 systems) in API and sterile manufacturing environments.
Data Integrity (ALCOA+)	Ensured ALCOA+ compliance across SCADA/DCS historians, calibration records, and maintenance logs — supported data integrity assessments.
Interlock Validation	Executed IQ/OQ/PQ for process safety interlocks on reactors, dryers, centrifuges, and filling lines including loop verification and functional safety checks.

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Regulatory Audits

Active support in USFDA, EU GMP, WHO GMP, and corporate QA audits — maintained audit-ready instrumentation/automation documentation and responded to audit observations.

EQUIPMENT & INSTRUMENTATION HANDLED

Pharma Process Equipment

- ▶ Reactors — Glass-lined & SS, Multi-purpose
- ▶ Agitated Nutsche Filter Dryers (ANFD)
- ▶ Rotary Cone Vacuum Dryers (RCVD)
- ▶ Centrifuges — Peeler & Inverting Filter
- ▶ Autoclaves & Steam Sterilizers
- ▶ Sterile Filling Lines & Vial Inspection
- ▶ Tablet Coating & Packaging Lines

Instruments & Automation Systems

- ▶ Pressure, DP, Level (Radar / Guided Wave / DP)
- ▶ Temperature — RTD, Thermocouple, Transmitters
- ▶ Flow — Coriolis, Magnetic, Vortex, DP Flow
- ▶ pH, Conductivity & TOC Analyzers
- ▶ Control Valves & HART/FF Positioners
- ▶ VFDs (Variable Frequency Drives)
- ▶ Siemens S7-300/400/1200 PLC
- ▶ Allen Bradley ControlLogix / CompactLogix

EDUCATION & CERTIFICATION

Education

Diploma in Applied Electronics & Instrumentation Engineering

K.D.R. Govt. Polytechnic College, Wanaparthy | 2011

Certification

Industrial Automation — Siemens & Allen Bradley PLC + SCADA

Laya Automations, Kukatpally | 2018

ADDITIONAL INFORMATION

Languages: English, Hindi, Telugu | **Date of Birth:** 09 August 1991 | **Location:** Hyderabad, Telangana — Open to Relocation