

Steven Mueller

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SUMMARY

Equipment Engineer with four years supporting automated manufacturing and test assets in regulated **medical device** and life sciences operations. Hands on work covers electromechanical systems, robotics, PLC controls, pneumatics, sensors, instrumentation, calibration, custom fixtures, and **automated test systems**. Structured troubleshooting restores production safely while protecting product quality, data integrity, personnel, and validated status. Experience includes equipment specification, FAT and SAT, commissioning, qualification, change control, preventive maintenance, and lifecycle documentation. Uses OEE, Availability, Performance, Quality, MTBF, MTTR, cycle time, yield, **first pass results**, CMMS history, FMEA, 5 Whys, **fault tree analysis**, fishbone analysis, and data trending to drive lasting improvements. Collaborative work with Manufacturing, Quality, Validation, EHS, Facilities, IT and OT, technicians, and suppliers supports compliant equipment performance.

EXPERIENCE

Equipment Engineer II January 2025 - Present
NovaMed Automation *San Jose, CA*

Owns lifecycle support for robotic assembly and automated test cells, guiding design reviews, qualification, maintenance, modifications, release, supplier response, and reliability improvement within GMP operations.

- Led robotic cell qualification using **validation protocols**, protecting release timing and **validated status**.
- Diagnosed PLC, pneumatic, sensor, fixture, and **software interface** faults through schematics and event histories.
- Built OEE reviews separating downtime, micro stops, slow cycles, false failures, and equipment defects.
- Used CMMS history, MTBF, MTTR, and **spare parts** usage to revise **preventive maintenance** tasks.
- Authored change records, risk assessments, **work instructions**, calibration requirements, and validation reports under GMP practices.
- Led supplier and technician recovery using FMEA, 5 Whys, trending, and post change monitoring.

Equipment Engineer July 2023 - December 2024
Arcadia Life Sciences Manufacturing *Sunnyvale, CA*

Sustained electromechanical **manufacturing equipment**, automated testers, instrumentation, and custom fixtures for regulated disposable device production, connecting asset reliability with yield and safe operations.

- Investigated **cycle time** losses, **jams**, intermittent faults, and reduced rates against confirmed operating baselines.
- Partnered with Quality and Process Engineering on defects, rework, **calibration drift**, and first pass yield.
- Prepared **engineering drawings**, technical specifications, maintenance strategies, spare parts plans, and equipment records.
- Supported FAT and SAT, installation, commissioning, and qualification, closing issues before production release.
- Trained operators and technicians on safe recovery, compliant operation, and escalation during equipment events.
- Coordinated Facilities and **IT and OT** support for asset installations, interfaces, and production readiness.

Associate Equipment Engineer October 2022 - June 2023
Precision BioSystems Operations *Santa Clara, CA*

Supported automated assembly, inspection, and **test equipment** in GMP operations, documenting failures, qualification work, maintenance history, and configuration changes for reliable production.

- Supported automated equipment using **robotics**, controls, pneumatics, sensors, instrumentation, and calibration.
- Created CMMS work orders capturing failure modes, repair actions, parts usage, and verification details.
- Applied fishbone analysis and **5 Whys** to separate mechanical, electrical, process, and measurement causes.
- Reviewed CAD drawings, schematics, wiring diagrams, and validation documents before maintenance work.
- Supported deviation and nonconformance investigations with downtime data, **calibration** records, and technical observations.
- Executed **qualification** and **change control** for fixture and sensor updates, escalating discrepancies before release.

PROJECTS

Automated Test Cell Reliability Program 📅 2025
Improved equipment readiness through OEE review, CMMS history, repeat failure analysis, preventive maintenance updates, and verified corrective actions.

Regulated Equipment Qualification Portfolio 📅 2024
Supported FAT and SAT, commissioning, qualification, controlled documentation, calibration planning, and production release for new manufacturing assets.

LEADERSHIP & AWARDS

- Received Certified Maintenance and Reliability Technician recognition in 2024 after demonstrating applied reliability practice.

- Earned team recognition for dependable production recovery and clear equipment investigations during regulated manufacturing escalations.
- Selected to coordinate supplier and technician troubleshooting for recurring robotic and automated test failures.

EDUCATION

Bachelor's Degree in Mechatronics Engineering
San José State University GPA: 3.7
Coursework: Controls engineering, robotics, manufacturing systems, instrumentation

2022
San Jose, CA

CERTIFICATIONS

- Certified Maintenance and Reliability Technician 📅 2024
- GMP and Equipment Qualification Certificate 📅 2023

TECHNICAL SKILLS

- **Reliability Metrics:** OEE, Availability, Performance, Quality
- **Reliability Analysis:** MTBF, MTTR, downtime trending
- **Root Cause Methods:** FMEA, 5 Whys, fishbone analysis
- **Equipment Controls:** PLC controls, robotics, software interfaces
- **Electromechanical Systems:** Motors, sensors, instrumentation
- **Pneumatic Systems:** Pneumatics, valves, actuators
- **Test Engineering:** Automated test systems, custom fixtures, false failure analysis
- **Qualification Practices:** FAT, SAT, commissioning, equipment qualification
- **Quality Systems:** GMP, design controls, deviations
- **Documentation Systems:** CMMS, work instructions, controlled documentation
- **Engineering Drawings:** CAD drawings, schematics, wiring diagrams
- **Maintenance Planning:** Preventive maintenance, spare parts, calibration

SKILLS

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|-------------------------|--------------------------|---------------------------|-----------------------|
| • Equipment Engineering | • Pneumatics | • Equipment Qualification | • FMEA |
| • Medical Devices | • Sensors | • Change Control | • Root Cause Analysis |
| • Robotics | • Calibration | • OEE | • CAD Drawings |
| • PLC Controls | • Automated Test Systems | • CMMS | |

PROFESSIONAL AFFILIATIONS

- Professional participation in regulated manufacturing, equipment reliability, and medical device engineering communities.
- Ongoing collaboration with Manufacturing, Quality, Validation, EHS, Facilities, IT and OT, technicians, and suppliers.

LANGUAGES

- English (Native)
- German (Intermediate)

ADDITIONAL INFORMATION

Work Status : Authorized to work in United States. No sponsorship required.

REFERENCES

AVAILABLE ON REQUEST