Dae Cain

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SUMMARY

Manufacturing engineering leader with 12 years supporting regulated electromechanical and medical technology products, including more than four years developing engineering teams. Leads engineers and technicians through **new product introduction**, sustaining production, validation, reliability testing, repair, rework, and production support. Combines hands on expertise in PCB and PCBA assemblies, electronics, robotic subsystems, **manufacturing test equipment**, data acquisition, sensors, motors, controllers, pneumatics, wiring, harnesses, and **electromechanical fixtures**. Applies ISO 13485, ISO 14971, 21 CFR 820, **good manufacturing practices**, SPC, Minitab, SAP ERP, Jira, ETQ, documentation control, and structured troubleshooting. Coordinates R&D, Quality, Manufacturing, Service, Supplier Quality, and program stakeholders while improving readiness, audit evidence, serviceability, and production reliability.

EXPERIENCE

Manufacturing Engineering Manager, Systems and Test

March 2022 - Present

Helix MedTech Systems *Santa Clara, CA*

Leads eight engineers and technicians supporting robotic capital equipment, electronics, system test, and electromechanical fixtures across new product introduction and sustaining production. Owns technical prioritization, validation, documentation quality, production readiness, and cross functional risk resolution in a regulated environment.

- Led workload reviews and **cross training** for eight engineers and technicians, distributing critical fixture knowledge.
- Directed PCBA and harness **validation** using controlled protocols, risk based decisions, and production readiness gates.
- Reviewed schematics, **PCB layouts**, MPIs, and **rework instructions**, strengthening audit readiness under ISO 13485 controls.
- Partnered with R&D, Quality, Service, and **Supplier Quality**, resolving **capital equipment** risks before production release.
- Qualified replacement electronics and fixture hardware, preserving safety, reliability, serviceability, and functional requirements.

Senior Manufacturing Engineer, Electronics and Fixtures

July 2018 - February 2022

Arcwell Surgical Technologies *Milpitas, CA*

Owned manufacturing engineering for electromechanical test stations used with regulated surgical equipment. Combined fixture design, test development, validation, SAP records, repair support, and technical mentoring across production and service operations.

- Designed automated fixtures with **data acquisition**, pneumatics, and service friendly interfaces for production **repair**.
- Executed process validations and reliability studies using Minitab, SPC reviews, and controlled quality procedures.
- Resolved board and harness failures through electrical measurements, test logs, and repeatable **rework** methods.
- Managed SAP **work standards**, **standard costs**, material changes, and controlled manufacturing records.
- Mentored engineers and technicians on **troubleshooting** discipline, fixture safety, validation evidence, and technical documentation.

Manufacturing Engineer

September 2014 - June 2018

Northstar Diagnostic Devices *San Mateo, CA*

Supported **new product introduction** and sustaining manufacturing for regulated diagnostic equipment containing PCBAs, sensors, motors, **power supplies**, harnesses, and mechanical assemblies. Prepared controlled processes, test methods, validation records, and corrective actions for production release.

- Transferred diagnostic equipment into **production** with PCBAs, sensors, motors, **harnesses**, and mechanical assemblies.
- Developed **test procedures** and fixtures that converted engineering requirements into repeatable production checks.
- Investigated nonconformances using root cause methods, electrical measurements, equipment records, and process data.
- Prepared MPIs, work instructions, validation records, and engineering change documentation for **Quality** review.
- Coordinated supplier and engineering responses to component availability, workmanship, and test equipment issues.

Manufacturing Engineer I

September 2012 - August 2014

Vector Biomedical Instruments *Redwood City, CA*

Supported production engineering for benchtop electromechanical medical instruments and associated test equipment under senior engineering guidance. Built test setups, maintained production documentation, analyzed process data, and coordinated practical issue resolution with technicians, Quality, and design engineers.

- Built cable, sensor, controller, and **PCBA** test setups from **schematics** and approved procedures.
- Updated work instructions and equipment records after engineering changes, keeping production documentation current.
- Collected process data for **SPC** analysis and used **Minitab** to identify recurring variation.
- Supported fixture maintenance, design improvements, and component substitutions through documented verification activities.
- Coordinated issue follow up with technicians, Quality, and design engineers during regulated production.

PROJECTS

Robotic Capital Equipment Readiness 2024

A late fixture change threatened production timing. Coordinated validation, documentation, serviceability reviews, and stakeholder decisions, creating a controlled readiness path for robotic equipment.

Electronics Obsolescence Recovery 2021

An obsolete component challenged long term support. Compared qualified alternatives, verified electrical performance, updated records, and protected reliability across sustaining production.

LEADERSHIP & AWARDS

- Recognized by engineering and operations leaders for building shared ownership across fixture and test support.
- Received team recognition for practical resolution of electronics obsolescence and production reliability issues.

EDUCATION

Master of Science in Mechatronics Engineering 2012

San José State University GPA: 4.0 *San José, CA*

Coursework: *Systems engineering, robotics, electronics, controls*

Bachelor of Science in Electrical Engineering 2010

California State University, Sacramento GPA: 4.0 *Sacramento, CA*

Coursework: *Circuit analysis, electronics, control systems, engineering design*

CERTIFICATIONS

- ASQ Certified Quality Engineer 2021
- ISO 13485 Quality Systems Training 2021

TECHNICAL SKILLS

- **Quality Systems:** ISO 13485, ISO 14971, 21 CFR 820
- **Regulatory Standards:** QSIT, FDA guidelines, 21 CFR Parts 210 and 211
- **Enterprise Systems:** SAP ERP, standard costs, work standards
- **Project Tools:** Jira, Agile, Microsoft Office
- **Quality Platforms:** ETQ, Box, Maximo
- **Electronics Engineering:** PCB, PCBA, schematics
- **Electrical Documentation:** Wiring diagrams, PCB layouts, test procedures
- **Electromechanical Systems:** Sensors, motors, controllers
- **Fixture and Test Engineering:** Manufacturing test equipment, fixture automation, data acquisition
- **Manufacturing Quality:** SPC, Minitab, statistical procedures
- **Production Processes:** GMP, validation, repair and rework
- **Systems Hardware:** Power supplies, cabling, pneumatic systems

SKILLS

- Manufacturing Engineering
- Systems Engineering
- People Leadership
- New Product Introduction
- Sustaining Engineering
- PCB and PCBA
- Electromechanical Systems
- Robotic Systems
- Test Equipment
- Fixture Design
- Validation
- Reliability Testing
- Repair and Rework
- Statistical Process Control
- SAP ERP

PROFESSIONAL AFFILIATIONS

- ASQ member, applying quality engineering practices in regulated manufacturing environments.
- Medical device engineering community participant, sharing practical methods for validation, documentation, and production support.

LANGUAGES

- English (Native)
- Spanish (Intermediate)

ADDITIONAL INFORMATION

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

REFERENCES

AVAILABLE ON REQUEST