Cesar Shaw

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SUMMARY

Staff level supplier and manufacturing engineer with 10 years supporting regulated **medical devices**, robotic systems, mechatronic assemblies, and plastic components. Leads **supplier process development** from design transfer through tooling, characterization, production validation, scale up, and sustaining production. Partners across R&D, Manufacturing Engineering, Quality, Purchasing, Supply Chain, Marketing, and Finance to turn design requirements into capable, controlled manufacturing processes. Applies GD&T, DFM/A, SPC, capability analysis, FMEAs, **root cause analysis**, CAPA, Six Sigma, Lean, risk management, and inspection strategy across supplier programs. Uses **21 CFR Part 820** and ISO 13485 requirements to guide validation evidence, supplier controls, and change decisions. Mentors engineers, resolves process issues with data, and supports reliable product performance, quality, cost, and production growth.

EXPERIENCE

Staff Supplier Engineer

January 2023 - Present

NovaMotion Medical Systems

Fremont, CA

Leads **supplier engineering** for plastic components and precision **sub assemblies** in robotic medical devices. Owns technical delivery from design transfer through validated production, supports scale up, guides engineers, and aligns supplier decisions with quality, cost, risk, and production goals.

- Led plastic component validation using **GD&T** and SPC, supporting reliable robotic device production.
- Directed tooling characterization and inspections, resolving process window constraints before program milestones.
- Drove supplier CAPA investigations using FMEAs, capability studies, and corrective action evidence.
- Applied **DFM/A** reviews to balance product performance, manufacturing stability, quality, and component cost.
- Mentored engineers on **Six Sigma**, Lean, **ISO 13485**, and supplier technical governance.

Senior Supplier Quality Engineer

April 2020 - December 2022

Redwood Surgical Technologies

Sunnyvale, CA

Managed **supplier qualification** and improvement for molded plastics, machined components, and electromechanical surgical assemblies. Coordinated validation, **supplier selection**, design clarification, audit support, and sustaining controls across regulated production programs.

- Qualified molded plastic suppliers through capability reviews, tooling assessment, and production readiness evidence.
- Planned process validations using risk analysis, **SPC**, drawings, GD&T, and measurement evidence.
- Resolved recurring supplier nonconformances through **root cause analysis** and **CAPA** effectiveness reviews.
- Clarified design requirements with engineering before specifications entered supplier production controls.
- Supported ISO 13485 audits, **21 CFR Part 820** controls, and manufacturing change reviews.

Manufacturing Engineer

June 2018 - March 2020

Pacific Mechatronics Health

San Mateo, CA

Developed electromechanical and plastic sub assembly processes for minimally invasive medical equipment. Supported prototype transition, controlled production, validation planning, supplier manufacturability, risk controls, and cross functional process changes.

- Developed plastic sub assembly processes, moving prototype methods into controlled medical production.
- Created characterization protocols covering critical parameters, equipment settings, **inspections**, and repeatability.
- Applied drawings and **GD&T** to fixture decisions, inspection plans, and supplier manufacturability reviews.
- Prioritized quality controls through FMEAs, **capability analysis**, SPC, and **risk management**.
- Coordinated process changes with Quality, **R&D**, Purchasing, and **Supply Chain** teams.

Supplier Manufacturing Engineer

October 2016 - May 2018

BayTech Medical Components

Hayward, CA

Supported suppliers producing injection molded **plastics** and mechanical components for regulated medical device assemblies. Reviewed drawings, tooling, inspections, validation evidence, corrective actions, Lean improvements, and compliance documentation.

- Reviewed drawings, **GD&T**, **tooling** concepts, and inspection plans before supplier qualification release.
- Executed process studies using statistical methods, measurement data, and documented acceptance criteria.
- Investigated supplier defects with structured root cause methods and verified corrective action effectiveness.
- Applied **Lean** and Six Sigma tools to improve process stability and inspection discipline.
- Maintained **supplier qualification**, manufacturing change, ISO 13485, and **21 CFR Part 820** records.

PROJECTS

Robotic Plastic Component Scale Up **2024**

A narrow process window threatened production timing. Led supplier characterization, capability analysis, tooling review, and inspection planning that supported validated scale up for robotic medical device components.

Electromechanical Assembly Validation **2019**

A prototype assembly needed repeatable production controls. Built characterization protocols, reviewed tolerances, aligned supplier evidence, and supported controlled manufacturing for minimally invasive medical equipment.

LEADERSHIP & AWARDS

- Six Sigma Green Belt recognition, 2019
- Staff level supplier engineering appointment, 2023
- Technical Mentor, Medical Device Supplier Engineering Peer Forum, 2023 to Present

EDUCATION

Bachelor's Degree in Mechanical Engineering 2016

San Jose State University GPA: 3.5 *San Jose, CA*

Coursework: *Engineering design, manufacturing processes, statistics, quality systems*

CERTIFICATIONS

- Six Sigma Green Belt 2019
- ISO 13485 Quality Systems Training 2020

TECHNICAL SKILLS

- **Quality Standards:** 21 CFR Part 820, ISO 13485, supplier controls
- **Statistical Methods:** SPC, capability analysis, measurement systems
- **Risk Tools:** FMEA, risk management, control plans
- **Manufacturing Methods:** Lean, Six Sigma, process characterization
- **Design Engineering:** GD&T, DFM/A, engineering drawings
- **Supplier Management:** Qualification, selection, improvement
- **Plastics Manufacturing:** Injection molding, tooling, plastic components
- **Validation Activities:** Process validation, production validation, scale up
- **Quality Investigation:** Root cause analysis, CAPA, corrective actions
- **Inspection Systems:** Dimensional inspection, inspection plans, measurement evidence
- **Medical Robotics:** Robotic devices, mechatronics, electromechanical assemblies

SKILLS

- Supplier engineering
- Manufacturing engineering
- Medical devices
- Robotics
- Mechatronics
- Plastics
- Process development
- Production validation
- GD&T
- DFM/A
- SPC
- Capability analysis
- Root cause analysis
- Supplier qualification
- Risk management

PROFESSIONAL AFFILIATIONS

- Medical Device Supplier Engineering Peer Forum
- Technical Mentor, supplier engineering peer community

LANGUAGES

- English (Native)
- Spanish (Proficient)

ADDITIONAL INFORMATION

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

REFERENCES

AVAILABLE ON REQUEST