

Cruz Pierce

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SUMMARY

Staff Quality Engineer with 9 years and 3 months supporting medical device **new product development**, manufacturing, and lifecycle quality. Leads design control, risk management, verification and validation, process validation, **equipment qualification**, **manufacturing transfer**, engineering changes, NCR investigations, CAPA, and failure analysis for complex regulated products. Applies DFMEA, PFMEA, AFMEA, GSPR, MDR, GMP, QMS, SPC, DOE, DMAIC, **Gauge R&R**, ANOVA, sample size methods, Minitab, CAD drawings, GD&T, and ASME Y14.5 to guide evidence based decisions. Partners with R&D, Operations, manufacturing, sterility, biocompatibility, packaging, and regulatory stakeholders. Mentors engineers, improves quality systems, and communicates business risk clearly. Brings practical judgment, steady growth, and collaborative leadership to programs requiring reliable products, compliant processes, and disciplined execution.

EXPERIENCE

Staff Quality Engineer, New Product Development

January 2024 - Present

Summit Vascular Technologies

San Diego, CA

Leads Quality Engineering for catheter based devices across design inputs, verification, validation, transfer, and lifecycle controls. Guides risk documentation, testing, manufacturing readiness, NCR resolution, and cross functional delivery while mentoring quality engineers and aligning technical priorities.

- Led catheter **design control** from design inputs through validation, strengthening transfer readiness and lifecycle traceability.
- Built DFMEA, PFMEA, AFMEA, GSPR, and traceability evidence for complex design reviews and regulatory readiness.
- Approved verification protocols, validation plans, equipment qualifications, **engineering changes**, and **catheter test methods**.
- Applied Minitab DOE, **Gauge R&R**, ANOVA, and SPC for acceptance and capability decisions.
- Directed NCR investigations and CAPA actions for significant compliance and process capability risks.
- Mentored quality engineers while coordinating **R&D**, **Operations**, sterility, biocompatibility, packaging, and manufacturing priorities.

Senior Quality Engineer, Medical Devices

July 2021 - December 2023

Asteron Medical Devices

Oceanside, CA

Owned quality deliverables for new and sustaining devices, connecting design control, risk controls, statistical evidence, validation, transfer, and audit readiness. Developed technical judgment through complex investigations, coached junior engineers, and aligned stakeholders around milestone risks and compliant release decisions.

- Owned verification, risk controls, validation, and transfer evidence for new and sustaining **medical devices**.
- Reviewed SolidWorks drawings, **GD&T**, tolerance stacks, and **ASME Y14.5** callouts before tooling release.
- Designed DOE, ANOVA, SPC, and capability studies supporting fact based acceptance decisions.
- Led **process validation** and equipment qualification reviews covering protocols, deviations, reports, and controlled specifications.
- Facilitated nonconformance investigations using structured **problem solving**, **risk assessment**, and CAPA methods.
- Coached junior engineers on design control, V&V, QMS documentation, audit readiness, and milestone risks.

Quality Engineer II, Interventional Devices

July 2019 - June 2021

Northshore Interventional Labs

Irvine, CA

Supported lifecycle quality for minimally invasive devices from prototype work through transfer. Combined test planning, statistical acceptance analysis, supplier evidence coordination, engineering change review, QMS investigation, and Lean improvement with close partnership across R&D and Operations.

- Supported lifecycle quality for minimally invasive devices through prototype, verification, validation, and transfer.
- Developed dimensional test protocols using sample size rationale and statistical acceptance analysis.
- Coordinated **sterility**, **biocompatibility**, and packaging evidence for design reviews and release decisions.
- Reviewed **engineering changes** for traceability, risk controls, validation, and procedural impacts.
- Investigated nonconformances through **failure analysis** and **root cause** methods within QMS requirements.
- Partnered with **R&D** and Operations on Lean improvements for legacy products and process controls.

Quality Engineer, Regulated Manufacturing

July 2017 - June 2019

Canyon Biomedical Manufacturing

Temecula, CA

Executed regulated manufacturing quality activities across inspection controls, process monitoring, NCR review, validation records, audit evidence, and measurement system studies. Built practical capability in variation analysis, drawing interpretation, CAPA, GMP, SOP compliance, and Lean improvement.

- Executed inspection controls, process monitoring, **NCR** review, and validation documentation for regulated production.
- Created **SPC** charts and capability studies that identified production variation requiring **engineering** review.
- Supported **Gauge R&R** studies before production inspection methods received approval for routine use.

- Reviewed drawings and specifications using GD&T concepts for inspection planning and manufacturing control.
- Prepared audit evidence and controlled records supporting **ISO 9001**, SOP, GMP, and **CAPA** requirements.
- Contributed to root cause investigations and Lean improvements across regulated manufacturing processes.

PROJECTS

Catheter Transfer Readiness Program 📅 2024

Good transfer work starts before production asks for a handoff. Built connected evidence across risk controls, verification, validation, equipment qualification, manufacturing specifications, and lifecycle quality for catheter device readiness.

Statistical Process Capability Initiative 📅 2022

Averages can hide a process problem. Applied Minitab, SPC, DOE, ANOVA, Gauge R&R, and capability analysis to strengthen acceptance decisions and focus engineering attention on meaningful variation.

LEADERSHIP & AWARDS

- ASQ Certified Quality Engineer recognition, earned in 2020 for advanced quality engineering practice.
- Lean Six Sigma Green Belt recognition, earned in 2019 for disciplined process improvement methods.
- Staff level technical leadership, mentoring quality engineers across medical device development and manufacturing programs.

EDUCATION

Bachelor's Degree in Biomedical Engineering

2017

California State University, Long Beach GPA: 3.5

Long Beach, CA

Coursework: Biomedical device design, statistics, materials science, biomechanics

CERTIFICATIONS

- ASQ Certified Quality Engineer 📅 2020
- Lean Six Sigma Green Belt 📅 2019

TECHNICAL SKILLS

- **Quality Systems:** QMS, GMP, CAPA, SOPs
- **Design Controls:** Design Control, V&V, Design Trace Matrix
- **Risk Management:** DFMEA, PFMEA, AFMEA
- **Statistical Methods:** SPC, DOE, ANOVA
- **Measurement Analysis:** Gauge R&R, Sample Size, Capability Analysis
- **Quality Software:** Minitab, R, Statistical Software
- **CAD And Tolerancing:** SolidWorks, AutoCAD, Tolerance Stack Analysis
- **Engineering Standards:** GD&T, ASME Y14.5, ISO 9001
- **Medical Device Compliance:** MDR, GSPR, GMP
- **Validation Activities:** Process Validation, Equipment Qualification, Packaging Testing
- **Testing Disciplines:** Sterility Testing, Biocompatibility Testing, Catheter Test Methods
- **Improvement Methods:** Six Sigma, DMAIC, Lean Manufacturing

SKILLS

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|-----------------------|------------------------|-------------------------|-------------------|
| • Quality Engineering | • Risk Management | • Stakeholder Influence | • Communication |
| • Medical Devices | • Statistical Analysis | • Mentoring | • Negotiation |
| • Design Control | • Root Cause Analysis | • People Leadership | • Problem Solving |
| • Process Validation | • Project Management | • Auditing | |

PROFESSIONAL AFFILIATIONS

- ASQ member, supporting professional quality engineering practice and continuous learning.
- Lean Six Sigma professional community participant, sharing process improvement methods across regulated operations.

LANGUAGES

- English (Native)
- Spanish (Intermediate)

ADDITIONAL INFORMATION

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

REFERENCES

AVAILABLE ON REQUEST