

Zayden Martinez

☎ (407) 555-7318 ✉ zayden.martinez@example.com 💼 linkedin.com/example/zaydenmartinez 📍 Orlando, FL 32801

SUMMARY

Senior Quality Engineer with five years supporting regulated **medical device manufacturing**, inspection, testing, packaging, labeling, and **finished goods** control. Leads Non Conformance investigations from containment through disposition and closure, using production evidence, risk assessment, and documented root cause analysis. Directs CAPA work, corrective and preventive actions, effectiveness monitoring, complaint evaluation, change control, and product and **process risk management**. Applies GMP, FDA, ISO, MDSAP, MDD, and MDR expectations across active operations and **quality systems**. Builds quality metrics, measurement systems, audit evidence, and management review inputs that help teams identify defects and prevent recurrence. Partners with manufacturing and operations leaders across multiple facilities, translating quality data into practical action while protecting compliance, reliability, and product safety.

EXPERIENCE

Senior Quality Engineer, Medical Device Manufacturing

July 2025 - Present

Meridian Surgical Systems

Orlando, FL

Leads daily quality engineering across assembly, inspection, functional testing, packaging, labeling, and finished goods release. Owns investigations, CAPA, risk decisions, audits, metrics, and quality systems support across two operational areas.

- Leads assembly, inspection, testing, **packaging**, labeling, and finished goods quality support across active production lines.
- Owns **Non Conformance** investigations through containment, disposition, closure, and documented product risk decisions.
- Directs CAPA root cause investigations, **corrective actions**, preventive actions, and **effectiveness monitoring** for quality systems.
- Applies GMP, FDA, ISO, MDSAP, MDD, and MDR requirements during changes, complaints, and risk reviews.
- Reviews **quality metrics** and reliability trends, then establishes measurements that bracket defects and guide prevention.
- Coaches manufacturing partners on audits, quality control tools, Six Sigma methods, and **Value Improvement** initiatives.

Quality Engineer II, Regulated Manufacturing

January 2024 - June 2025

HarborPoint Medical Manufacturing

Kissimmee, FL

Provided quality engineering coverage for regulated manufacturing operations, with ownership of inspection records, packaging controls, labeling documentation, Non Conformance records, CAPA support, audits, change control, and management review reporting.

- Evaluated **inspection**, testing, packaging, **labeling**, and production records before finished goods disposition decisions.
- Managed component and process Non Conformance records through containment, evidence review, **risk assessment**, and closure.
- Facilitated CAPA investigations, documented root causes, and tracked effectiveness evidence against acceptance criteria.
- Performed internal quality system audits against **GMP** and ISO procedures, then verified remediation evidence.
- Evaluated process changes through formal **change control** and product and **process risk management** reviews.
- Built recurring quality metric summaries covering defects, complaints, reliability trends, and management review needs.

Quality Engineer, Orthopedic Devices

June 2022 - December 2023

Nova Ortho Devices

Melbourne, FL

Supported manufacturing quality for orthopedic device components, applying GMP, ISO procedures, risk management, CAPA controls, quality control methods, and Six Sigma techniques across production and finished goods activities.

- Reviewed in process **inspection**, testing, production records, and **finished goods** controls for orthopedic components.
- Investigated production Non Conformances with process history, inspection data, and structured root cause tools.
- Maintained **CAPA** action records and verification evidence within documented quality system workflows.
- Applied GMP and **ISO** procedures during floor support, audit preparation, and documentation correction activities.
- Reviewed hazards, controls, and manufacturing changes within product and **process risk management** activities.
- Used quality control and **Six Sigma** methods to reduce recurring defects without weakening validated controls.

Quality Engineering Intern, Medical Device Operations

October 2021 - May 2022

Coastal Biomedical Products

Daytona Beach, FL

Supported senior quality engineers with regulated manufacturing records, Non Conformance evidence, CAPA tracking, audit preparation, risk assessment, change documentation, and defect analysis during supervised medical device operations work.

- Organized inspection, testing, and production records used for routine product acceptance decisions.
- Prepared **Non Conformance** evidence packages by tracing affected material, findings, and manufacturing history.
- Maintained CAPA trackers and assembled verification evidence for corrective action effectiveness reviews.
- Compared controlled procedures with manufacturing records during internal audit preparation and documentation review.
- Applied GMP, **FDA**, and ISO concepts to supervised assignments involving **risk assessment** and defect control.
- Analyzed **inspection** data with basic quality control and **Six Sigma** tools for internship completion work.

PROJECTS

Multi Site Quality Metrics System 2025

Created recurring quality and reliability reporting across operational areas. Connected defect categories, complaint signals, and management review inputs so teams could focus investigations on meaningful patterns.

Medical Device CAPA Effectiveness Review 2024

Structured CAPA evidence reviews around root cause, corrective action, preventive action, acceptance criteria, and effectiveness monitoring. The approach gave reviewers a clearer path from issue discovery to closure.

LEADERSHIP & AWARDS

- Six Sigma Green Belt recognition, 2024
- Selected by quality leadership to coach manufacturing partners on audit readiness and quality control methods, 2025
- Recognized for dependable cross site support during Value Improvement initiatives, 2025

EDUCATION

Bachelor of Science in Biomedical Engineering

2022

University of Central Florida GPA: 3.7

Orlando, FL

Coursework: Biomedical instrumentation, biomechanics, statistics, quality systems

CERTIFICATIONS

- Six Sigma Green Belt 2024
- Good Manufacturing Practice Training 2023

TECHNICAL SKILLS

- Regulatory Standards: FDA, ISO, MDSAP
- Medical Device Regulations: MDD, MDR, GMP
- Quality Systems: Quality Systems, EES, management review
- Corrective Action: CAPA, root cause analysis, effectiveness monitoring
- Risk Management: Product risk, process risk, risk mitigation
- Manufacturing Quality: Inspection, testing, finished goods control
- Packaging Controls: Packaging, labeling, release control
- Quality Methods: Six Sigma, quality control, process excellence
- Audit Practices: Internal audits, compliance audits, objective evidence
- Data and Metrics: Quality metrics, reliability metrics, measurement systems
- Operational Controls: Non Conformance, containment, disposition
- Process Governance: Change control, complaint evaluation, escalation

SKILLS

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|-----------------------|-----------------------|-------------------|----------------------------|
| • Quality engineering | • Change control | • GMP | • Complaint evaluation |
| • CAPA | • Root cause analysis | • FDA compliance | • Process improvement |
| • Risk management | • Quality audits | • ISO compliance | • Manufacturing operations |
| • Non Conformance | • Six Sigma | • Quality metrics | |

PROFESSIONAL AFFILIATIONS

- Association for the Advancement of Medical Instrumentation member
- American Society for Quality member

LANGUAGES

- English (Native)
- Spanish (Intermediate)

ADDITIONAL INFORMATION

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

REFERENCES

AVAILABLE ON REQUEST