

Giovanni Sandoval

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SUMMARY

Senior Quality Engineer with five years supporting regulated medical product design, manufacturing quality, **post market surveillance**, and lifecycle activities. Leads complaint investigations, **failure analysis**, post market risk assessment, CAPA, change control, SCAR review, and ISO aligned quality system work. Partners with R&D, laboratories, manufacturing, engineering, and supplier teams during product development, sustaining changes, and issue resolution. Uses evidence from complaints, returned products, production records, studies, and risk files to guide practical decisions involving patient risk, product performance, cost, and schedule. Facilitates review boards, **instrument qualification** work, audit preparation, and inspection readiness with clear written and verbal communication. Brings thoughtful judgment to ambiguous problems and can contribute immediate value across quality, engineering, and **regulated manufacturing** operations.

EXPERIENCE

Senior Quality Engineer, Infusion Product Quality

January 2025 - Present

Helix Medical Systems

Deerfield, Illinois

Owns quality engineering support for infusion related disposable products, connecting post market signals, design history, manufacturing evidence, and risk files with lifecycle decisions. Leads investigations, review boards, quality deliverables, and audit readiness across **R&D**, laboratories, engineering, and operations.

- Led **post market risk assessments** for complaint clusters using severity, occurrence, and failure evidence.
- Directed returned product **failure analysis** with laboratory partners, producing defensible conclusions and follow up actions.
- Represented Quality on CAPA and **change control** boards, closing evidence gaps before approval.
- Defined **quality** deliverables for product improvements, coordinating verification evidence, risk updates, and implementation readiness.
- Prepared qualification records and quality system evidence, resolving readiness gaps before **internal audits** and inspections.

Quality Engineer II, Design Quality

July 2023 - December 2024

Vantage BioDevices

Northbrook, Illinois

Supported **design quality** for regulated fluid delivery components from development through release. Facilitated cross functional investigations, laboratory quality activities, CAPA progression, supplier corrective action review, and interpretation of ISO aligned requirements.

- Reviewed design changes, verification plans, risk documents, and manufacturing impacts before component release.
- Evaluated complaint and **SCAR** trends, identifying recurring failure modes for deeper technical investigation.
- Facilitated root cause investigations with **R&D**, manufacturing, supplier **quality**, and laboratory partners.
- Oversaw **instrument qualification** packages, confirming protocols, acceptance criteria, deviations, and final reports met expectations.
- Advanced **CAPA** records from problem definition through effectiveness planning with complete evidence traceability.

Quality Engineer, Regulated Manufacturing

October 2021 - June 2023

Prairie Clinical Products

Schaumburg, Illinois

Executed quality engineering activities for **regulated manufacturing** processes supporting disposable **therapeutic products**. Investigated nonconformances, assessed changes, reviewed environmental and safety considerations, analyzed trends, and prepared objective evidence for audits.

- Investigated nonconformances using production records, test results, samples, and engineering input.
- Supported **change control** assessments by identifying affected specifications, validation records, risks, and deliverables.
- Reviewed environmental, safety, and regulatory factors with manufacturing partners during equipment changes.
- Analyzed recurring **quality** events, presenting trend summaries that guided focused corrective actions.
- Verified audit records, retrieved objective evidence, and closed documentation gaps within quality system timelines.

PROJECTS

Post Market Complaint Trend Review 📅 2025

Built a structured review approach for complaint clusters, returned product findings, risk evidence, and action decisions across infusion related products.

Instrument Qualification Evidence Program 📅 2024

Coordinated laboratory qualification records, protocols, acceptance criteria, deviations, and final reports for regulated product studies.

LEADERSHIP & AWARDS

- ASQ Certified Quality Improvement Associate recognition, 2022
- Selected as Quality representative for complaint, CAPA, and change control review boards
- Recognized by technical partners for clear investigation conclusions and practical risk recommendations

EDUCATION

Bachelor of Science in Biomedical Engineering

2021

University of Illinois Chicago GPA: 3.5

Chicago, Illinois

Coursework: Biomedical systems, materials science, quality engineering, human factors

CERTIFICATIONS

- ASQ Certified Quality Improvement Associate 📅 2022
- ISO 9001 Quality Management Systems Training 📅 2023

TECHNICAL SKILLS

- **Quality Systems:** CAPA, Change Control, Complaint Management
- **Risk Management:** Post Market Risk Assessment, Risk Files, FMEA
- **Investigation Methods:** Failure Analysis, Root Cause Analysis, Trend Analysis
- **Regulatory Standards:** ISO Requirements, Quality Procedures, Regulatory Compliance
- **Product Development:** NPD, SPO Development, Design Quality
- **Laboratory Quality:** Laboratory Studies, Instrument Qualification, Acceptance Criteria
- **Audit Preparation:** Internal Audits, External Inspections, Objective Evidence
- **Manufacturing Quality:** Regulated Manufacturing, Nonconformance Review, Product Release
- **Technical Documentation:** Investigation Records, Verification Plans, Qualification Records
- **Cross Functional Review:** Complaint Review Boards, CAPA Review Boards, Change Control Boards
- **Compliance Areas:** Environmental Compliance, Safety Compliance, Quality Compliance

SKILLS

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|---------------------------|------------------|----------------------|----------------------------|
| • Quality Systems | • CAPA | • SPO Development | • Instrument Qualification |
| • Complaint Investigation | • Change Control | • ISO Requirements | • Audit Readiness |
| • Failure Analysis | • SCAR | • Risk Management | • Root Cause Analysis |
| • Post Market Risk | • NPD Support | • Laboratory Studies | |

PROFESSIONAL AFFILIATIONS

- American Society for Quality, quality improvement community member
- Biomedical engineering professional community participant
- Cross functional quality review board contributor

LANGUAGES

- English (Native)
- Spanish (Proficient)

ADDITIONAL INFORMATION

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

REFERENCES

AVAILABLE ON REQUEST