FERNANDO R. HERNANDEZ JOSE

SENIOR QUALITY ASSURANCE & COMPLIANCE CONSULTANT | QMS STRATEGY & RISK MANAGEMENT

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PROFESSIONAL SUMMARY

Biomedical Engineer and Senior Quality Assurance & Compliance Consultant with 9 years of experience across highly regulated medical device, biotechnology, and pharmaceutical industries. Comprehensive expertise in quality management systems (QMS), regulatory compliance, and risk management across the full product lifecycle, from design and development through commercialization, post-market surveillance, and continuous improvement. Proven ability to assess QMS effectiveness, identify systemic compliance gaps, lead cross-functional remediation initiatives, and translate complex regulatory and technical requirements into practical, risk-based solutions. Specialized experience in Software as a Medical Device (SaMD), software lifecycle processes, cybersecurity risk assessments, design quality, and software quality assurance.

CORE COMPETENCIES

QMS Strategy & Regulatory Compliance
QMS Strategy & Optimization • Regulatory Compliance Assessments • Regulatory Gap Analysis • Quality System Remediation • Quality Risk Management • Internal & Supplier Auditing • Quality Metrics & Management Review • Cross-Functional Quality Leadership • Continuous Improvement

Regulatory Standards & Frameworks
ISO 13485:2016 • ISO 14971:2019 • ISO/IEC 42001:2023 • 21 CFR Part 820 (QMSR) • 21 CFR Parts 210 & 211 • IEC 62304 • GxP/cGMP • ALCOA+ Data Integrity

Product Lifecycle & Quality Engineering
Design Controls • Design History Files (DHF) • SaMD • Software Quality Assurance • Software Lifecycle Compliance • Design Verification & Validation • Supplier Quality Management • Post-Market Surveillance • PSUR • Complaint Investigations • MDR Reporting • CAPA • Root Cause Analysis • Change Control

Risk Management & Emerging Technologies
FMEA / DFMEA / PFMEA / CTFMEA • Cybersecurity Risk Assessments • CVSS Scoring • Threat Modeling • Software Architecture Concepts • Risk-Based Decision-Making • AI-Enabled Productivity Tools

PROFESSIONAL EXPERIENCE

Design Quality Engineer **Oct 2025 – Nov 2026**
Zimmer Biomet | Warsaw, IN (Remote)

- Led quality deliverables supporting the successful transfer of SaMD operations and design authority during a site closure, ensuring continuity of design controls, regulatory compliance, and stakeholder alignment.
- Led a comprehensive assessment of local design procedures against global QMS requirements, identifying 10 compliance gaps across seven procedures and driving remediation of 95% of identified deficiencies to strengthen regulatory alignment.
- Led remediation of 40 cybersecurity FMEA risk lines, identifying risk management gaps and driving cross-functional implementation of enhanced risk controls, updated harm severity criteria, and CVSS-based vulnerability assessments.
- Supported cybersecurity and software risk activities with exposure to threat-modeling analysis and software architecture, collaborating with technical stakeholders to understand system risks, vulnerabilities, and appropriate control measures.
- Served as the primary Quality Assurance representative for a product Periodic Safety Update Report (PSUR), contributing risk assessment and benefit-risk analysis through review of complaint trends and sales/exposure data.
- Supported a controlled process-improvement project for destruction of protected health information (PHI), applying patient-data handling and compliance considerations to improve secure and documented data disposition.
- Partnered cross-functionally with Software Development, Regulatory Affairs, Document Control, and complaint-trending teams on design authority transfer, design reviews/approvals, validation periodic reviews, and post-market quality activities.
- Applied Microsoft Copilot to streamline selected research, analysis, drafting, and administrative workflows while maintaining appropriate quality oversight and review.

Quality Assurance Consultant **Feb 2023 – Sep 2025**
Regeneron | Tarrytown, NY (Remote)

- Reviewed investigations, deviations, batch records, CoAs/CoCs, retain examinations, lot genealogy, and trend investigations for compliance within a cGxP-regulated environment.
- Conducted quality-system gap assessments, identifying 25 documentation and process deficiencies and recommending remediation actions aligned with updated QMS requirements to harmonize all documents.
- Supported migration from a legacy QMS platform to Veeva Vault, including document hierarchy mapping, metadata verification, version-control integrity, and process alignment.
- Authored and implemented work instructions and job aids supporting complaint investigations and updated QMS procedures.
- Built and executed data queries to identify, analyze, and trend manufacturing quality events.
- Reviewed quality investigations and deviations involving drug-device combination products, including patient-operated injection devices and healthcare professional-administered vial-and-syringe therapies.

Quality Engineer **Sep 2022 – Feb 2023**

Encision Inc. | Boulder, CO

- Spearheaded a QMS modernization initiative, performing gap assessments, revising SOPs, and supporting migration to an upgraded eQMS to improve usability and audit readiness.
- Managed design history files and product-lifecycle documentation for laparoscopic surgical instruments using Veeva Vault.
- Supported supplier-quality activities including qualification, audits, SCARs, and IQ/OQ/PQ validation.
- Investigated CAPAs, NCMRs, supplier corrective actions, and product failures; authored Periodic Safety Update Reports (PSURs) supporting post-market requirements.

Post-Market Surveillance Consultant **Mar 2022 – Sep 2022**

ZOLL LifeVest | Pittsburgh, PA (Remote)

- Investigated and processed high-volume complaints (20 daily) involving a wearable cardioverter defibrillator used by patients at risk of sudden cardiac death.
- Assessed adverse events for FDA reportability and submitted Medical Device Reports (MDRs) within required timelines.
- Contributed to a 75% reduction of existing complaint backlog while maintaining investigation quality and compliance.

Quality Engineer II **Sep 2021 – Feb 2022**

Bio-Rad Laboratories | Hercules, CA (Remote)

- Reviewed CAPA records for quality and compliance and approved completed CAPAs for closure.
- Updated and maintained product risk-management documentation, including DFMEAs, hazard analyses, and risk tables.
- Standardized and consolidated legacy risk files to improve consistency, traceability, and regulatory readiness.
- Remediated technical documentation to support FDA, EU MDR, and IVDR compliance.

Post-Market Surveillance Specialist **Sep 2020 – Sep 2021**

ACIST Medical Systems | Eden Prairie, MN (Remote)

- Evaluated product complaints and adverse events for reportability to global regulatory authorities and supported responses to agency requests for additional information.
- Managed complaint-lifecycle activities to support complete documentation, timely investigation, and compliant closure.

Quality Assurance Engineer **Jan 2018 – May 2020**

Cook Medical | Bloomington, IN

- Investigated product complaints and performed root-cause analyses using 5 Whys, Fishbone diagrams, flowcharting, and other structured problem-solving methods.
- Developed an end-to-end complaint investigation process encompassing device retrieval, failure analysis, CAPA, PFMEA-based risk assessment, and effectiveness verification.
- Supported Quality System Remediation initiatives involving DHFs, SOPs, manufacturing procedures, work instructions, and document change controls.
- Developed FMEAs and supported supplier-quality activities, including SCAR investigations and compliance with engineering and manufacturing specifications.
- Trained employees on complaint-investigation and technical-writing procedures.

EDUCATION

Marquette University | Milwaukee, WI **May 2017**

Bachelor of Science, Biomedical Engineering – Bioelectronics

SYSTEMS, TOOLS & LANGUAGES

eQMS / Enterprise Systems: Veeva Vault, TrackWise, ETQ Reliance, Salesforce, Windchill (PLM), SAP, LIMS, LiveLink (OpenText), IQMS, ProcessCompliance

Analytics / Productivity: Microsoft Excel, Power BI, Microsoft 365, Microsoft Copilot, Azure DevOps, Data Querying & Analysis

Languages: English (Fluent) | Spanish (Fluent)

PROFESSIONAL TRAINING & CERTIFICATIONS

ISO 13485:2016 Internal Auditor Training Program – Certificate of Completion • PathWise – Technical Writing & Documenting Investigations (2018) • PathWise – Investigations & CAPA (2018)