Annetta Odeh-Quirion

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Accomplished and results-oriented Quality Assurance and Quality Systems professional with 15+ years of experience supporting Class II and III medical device manufacturers in highly regulated environments. Proven expertise leading quality system remediation, audit readiness, supplier quality, complaint handling, CAPA, post-market surveillance, and risk management initiatives aligned with FDA QSR/QMSR, ISO 13485, MDR, and MDD requirements.

Experienced in supporting both large global organizations and small emerging medical device companies by building scalable, practical, audit-ready quality systems. Adept at managing cross-functional quality operations, driving process improvements, and supporting electronic QMS platforms including Grand Avenue, TrackWise, EtQ, and Veeva Vault. Comfortable operating in lean and fast-paced environments requiring hands-on ownership across multiple quality functions.

EDUCATION

Bachelor of Science in Biosystems Engineering
University of Arizona

Master of Business Administration
University of Maryland Global Campus

ISO 13485:2016 Certified Lead Auditor (Certificate No: 115743)
ASQ Certified Quality Auditor (Certificate No: 72323)

TECHNICAL & QUALITY SYSTEMS

Veeva Vault—TrackWise—EtQ Reliance—SAP CRM—Grand Avenue—Salesforce—Power BI

CORE COMPETENCIES

Quality Operations

- Quality Systems Oversight
- Inspection Readiness
- Supplier Quality Management
- eQMS Administration Support
- Workflow Configuration Support
- Manufacturing Process & Validation Review

Audit Execution & Compliance

- Lead Auditor (ISO 13485:2016 Certified)
- Internal & External Audit Programs
- Manage Nonconformance Identification
- Risk-Based Audit Evaluation
- Regulatory Compliance (FDA QSR / QMSR)
- Backroom Support During Audits

PROFESSIONAL EXPERIENCE

AQ Consults – Baltimore, MD
Founder / Quality Systems Consultant, 2025 – Present

- Provide independent consulting support to medical device manufacturers requiring quality system remediation, audit readiness, CAPA management, supplier quality oversight, and complaint handling support.
- Support small and mid-sized organizations with scalable quality system development aligned with FDA QSR/QMSR and ISO 13485 requirements.
- Advise clients on quality operations, risk management activities, document control, inspection readiness, and post-market quality processes.
- Support electronic quality system workflows and process harmonization activities across document control and supplier quality functions.

Black Diamond Network – Phoenix, AZ
Quality Systems & Remediation Consultant, Oct 2024 – Jun 2026

- Led QMS and document control remediation for Class II & III medical device manufacturers responding to FDA observations.
- Authored, revised, and standardized SOPs, work instructions, and controlled forms to align with FDA QMSR and ISO 13485 requirements.
- Managed controlled documents within validated electronic quality systems, ensuring version control, traceability, and inspection readiness.
- Partnered with IT and Quality Systems teams to ensure compliant document workflows, access controls, and electronic approvals.
- Conducted audits of controlled documents and records to verify data integrity, formatting consistency, and regulatory alignment.

Key Contributions – West Pharmaceutical Services:

- Authored a new Work Instruction defining the end-to-end sample transfer, chain-of-custody, measurement ownership, and batch record inclusion process to support a manufacturing transition to a contract partner.
- Led a gap analysis against governing quality procedures, identifying and resolving compliance gaps prior to document release.
- Designed chain-of-custody controls between production and quality teams across separate facilities, including a controlled transfer log, signature-based receipt verification, and backup coverage protocols.
- Established sign-off requirements ensuring batch record compliance while limiting external partner access to internal quality systems.
- Supported change control impact assessments for a testing strategy transition, updating manufacturing process, test method, and training documentation.

Key Contributions – Avertix Medical Inc.:

- Led remediation of FDA Inspection Observations, delivering 10 FDA-ready Verification of Effectiveness (VoE) reports with 100% observation coverage, supporting inspection closure readiness.

- Directed QMSR document harmonization across 50+ controlled documents, prioritizing document control, change control, and management review procedures to meet FDA QMSR and ISO 13485 requirements.
- Executed and documented a QMSR gap analysis (Jan 2026), using risk-based prioritization to drive procedural updates and reduce regulatory exposure.
- Established audit-ready document control workflows, ensuring traceability from FDA observation → CAPA → VoE with complete, defensible records.
- Partnered with Quality, Regulatory, and IT stakeholders to manage controlled document updates, approvals, and implementation within the electronic QMS.
- Developed executive KPIs and management review inputs demonstrating QMS effectiveness and top-management oversight.
- Supported Grand Avenue quality system workflows including supplier quality processes, approved supplier list (ASL) management, document routing, and controlled document implementation activities.

Key Contributions – Pfizer Inc.:

- Reduced complaint backlog from over 7,000 in October 2024 to under 4,500 by April 2025 through diligent investigation and resolution support.
- Enabled the client to meet a critical KPI of maintaining less than 5% of complaints open for over 60 days.
- Led gap assessment and remediation activities to close deficiencies in complaint handling processes per ISO 13485 and FDA QSR.
- Conducted reviews and audits of global complaint records to ensure compliance with FDA QSRs and ISO 13485:2016 standards

RQM+ – Monroeville, PA

Project Engineer/Consultant, Feb 2021 – Feb 2024 (Contract)

- Supported global medical device clients with electronic document remediation and harmonization across complaint, CAPA, and risk documentation.
- Performed technical rewriting and restructuring of controlled quality documents to improve clarity, consistency, and regulatory defensibility.
- Ensured complaint and MDR documentation accuracy within TrackWise and other eQMS platforms.
- Developed standardized document templates and trackers to support global compliance and inspection readiness.
- Collaborated with cross-functional stakeholders, including IT, Regulatory Affairs, and Quality Systems, to resolve documentation gaps.

Key Contributions – Olympus, Inc.:

- Developed standardized processes for the verification and remediation of MDR complaint records.
- Ensured timeliness of MDR reporting by facilitating expedited review and processing of high-risk complaints for recalled product lines.
- Conducted trend analysis on major non-conformance findings from the FDA to provide stakeholders with actionable issues.
- Developed and delivered training to employees to ensure awareness and compliance with policies/procedures and regulations.

- Created complaint trackers to monitor all repairs conducted by third-party distributors in European regions.

ACell, Inc. [Acquire by Integra Inc.] – Columbia, MD
Program Manager/Engineer (Complaint/CAPA), Jan 2017 to Jan 2021

- Owned and maintained controlled quality documentation supporting CAPA, complaints, risk management, and post-market surveillance.
- Led document change control activities, ensuring compliant review, approval, and release within electronic systems.
- Created and maintained technical files, risk management files, IFUs, labeling, and procedures in alignment with EU and FDA requirements.
- Supported system and process improvements impacting document control, traceability, and audit readiness.
- Independently led cross-functional teams for the monitoring of all non-conformances and post-market surveillance activities for Class II and III medical devices.
- Enforced end-to-end controls for compliance with FDA QSR, Health Canada, ISO 13485, and ISO 14971 standards.

Key Contributions:

- Reduced average closure time for complaints by 17% and CAPA/NC by 40%.
- Directed risk management and remediation initiatives resulting in zero audit findings during ISO 13485, MDD, and Health Canada recertifications.
- Conducted compliance policy and procedure assessment, and support development and implementation of new or updated policies, procedures, or systems to address new risk areas or to improve operations and/or internal controls.
- Responsible for creating and maintaining product technical files for the CE marking directive.
- Updated risk management files (Hazard Analysis, User FMEA), Instructions for Use (IFU), and labeling materials for regulatory compliance.

Becton Dickinson – Sparks, MD
Senior Quality Systems Specialist, Apr 2016 to Jan 2017

- Managed controlled documentation for complaint handling, CAPA, and risk management within regulated quality systems.
- Improved document control effectiveness by strengthening corrective actions, training, and standardized workflows.
- Trained quality staff on risk-based documentation practices and ISO 13485 compliance.

Key Contributions:

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- Improved performance of complaint management system by steering corrective action.
- Trained quality specialists on risk-based decision-making and ISO compliance.

National Capital Foot & Ankle Center – Potomac, MD
Biomedical Biologics Consultant, Oct 2015 to Apr 2016

- Analyzed and recommended biologics and tissue membranes for wound healing treatments.
- Enabled a reduction in wound bed size for diabetic foot ulcer cases by recommending superior competitor biological products.

Roche – Tucson, AZ
Quality Engineer, 2010 to 2013

- Strengthened QMS using 5S and Lean Six Sigma to improve product manufacturing life cycles.
- Credited for the re-categorization and gap analysis of over 5,000 suppliers in three months for a TUV audit.
- Drove corrective actions that minimized instrument damage during shipping, eliminating customer complaints.

*Additional experience as **Manufacturing/Quality Engineer** at B/E Aerospace Inc., as **Design Engineer** at Kennedy/Jenks Consultants Inc., as **R&D Intern** at SEBRA, as **Research Assistant** at University of Arizona*