Annetta Odeh-Quirion

annettaodehquirion@gmail.com • 443-962-1626 • www.aqconsults.com

Accomplished and results-oriented Quality Assurance professional with extensive experience in quality assurance and control within highly regulated industries, including Class III medical devices. Proven success in conducting gap assessments, leading remediation projects, and driving risk management initiatives in alignment with ISO 13485 and FDA QSR/QMSR frameworks. Demonstrated expertise in root cause analysis (RCA), CAPA, and failure mode and effects analysis (FMEA). Adept at evaluating operational, manufacturing, and supplier performance to support executive decision-making.

CORE COMPETENCIES & TECHNICAL TOOLS

Document Control & eQMS

- Electronic Document Management (EDMS / eQMS)
- Document Lifecycle Management (Authoring, Review, Approval, Change Control, Archiving)
- Technical Document Rewriting & Regulatory Formatting
- SOP, WI, Form & Template Standardization
- Metadata, Version Control & Audit Trails
- Inspection-Ready Documentation

Quality Systems & Compliance

- FDA QSR / QMSR Transition
- ISO 13485:2016
- Change Control & Configuration Management
- CAPA, NCR, Complaint & Risk Documentation
- Global Regulatory Compliance

Systems & Digital Tools

- Veeva Vault
- TrackWise
- EtQ Reliance
- Grand Avenue
- SAP CRM
- Agile PLM
- Argus
- Power BI
- Salesforce

(System implementation, remediation, and workflow optimization experience)

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)

PROFESSIONAL EXPERIENCE

Black Diamond Network – Phoenix, AZ
Project Engineer/Consultant, Oct 2024 – Currently (Contract)

- 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 – 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.

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:

- 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.
- 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.
- 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*