Annetta Odeh-Quirion

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Accomplished and results-oriented professional with extensive experience in quality assurance and control within highly regulated industries. Demonstrated success in conducting root cause analysis, corrective and preventive action, and failure mode and effects analysis. Instrumental in evaluating operational, manufacturing, and supplier performance. Adept at formulating technical reports to support decision-making. Proficient in steering quality management audits. ***Proven expertise in:***

- Team Leadership & Coaching
- Operational Planning & Analysis
- Process Optimization
- Root Cause Analysis
- Quality Assurance & Control
- Audit & Compliance Testing
- Stakeholder Communication
- Regulatory Reporting

EDUCATION

Bachelor of Science in Biosystems Engineering
University of Arizona

Master of Business Administration
University of Maryland University College

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 – April 2025 (Contract)

Responsible for the remediation of Pfizer's medical device and combination product complaints, with expertise in malfunction analysis, adverse event evaluation, assessment, and reportability determination.

Key Contributions:

- Reduced complaint backlog from over 7,000 in October 2024 to under 4,500 by April 2025 through diligent investigation, prioritization, and resolution support.
- Played a key role in backlog reduction efforts, enabling the client to meet a critical KPI of maintaining less than 5% of complaints open for over 60 days.
- Conducted reviews and audits of global complaint records to ensure compliance with FDA QSRs and ISO 13485:2016 standards and procedures.
- Evaluated complaint records, identify non-conformances, and provide remedial actions.
- Communicated detailed non-conformances within complaint reports to key stakeholders to support informed decision-making.
- Collaborated with project leadership to identify issues and implement corrective strategies, enhancing overall team efficiency and performance.
- Performed thorough inspections and audits of complaint files within the client's database system to ensure accuracy, completeness, and regulatory compliance.
- Understand and support business strategy and collaborate with business teams and other business groups as necessary to design and implement appropriate controls to manage potential compliance risks.
- Proficient using Veeva and Argus software system.

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RQM+ – Monroeville, PA
Project Engineer/Consultant, Feb 2021 – Feb 2024 (Contract)

Responsible for the ongoing review and auditing of Olympus's global complaint records to ensure compliance to FDA QSRs and ISO 13485:2016 standards/procedures. Responsible for complaint record evaluation, providing remedial action, and training personnel on the complaint handling process. Periodically, update and maintain customer feedback and complaint databases to ensure alignment with quality management system and regulatory standards. Communicate detailed non-conformances within complaint reports with key stakeholders for informed decision-making.

Key Contributions:

- 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.
- Support the compliance training program to educate employees, including new hires, on legal and ethical standards and to ensure a comprehensive understanding. Assist in identifying compliance training needs, develop and deliver training to employees to ensure awareness, understanding, and compliance with policies/procedures and regulations. for alignment of global Quality Management System.
- Developed process for verification and remediation of MDR complaint records.
- Developed complaint verification checklists to provide clear and concise requirements for review and approval of affected complaint records.
- Ensured timeliness of MDR reporting by facilitating expedited review and processing of high-risk complaints for recalled product line in the USA.
- Ensure customer notifications are completed according to the timelines established in the Global Field Action Plan; ensure compliance with global regulations and/or laws.
- Reduced the number of complaints associated with SAP bridging errors.
- Conducted trend analysis on major non-conformance findings from FDA to provide applicable stakeholders with actionable issues to address.
- Reviews device labeling and advertising materials for compliance with submissions and applicable regulations; analyzes and recommends appropriate changes.
- Responsible for ensuring complaints are entered in database systems accurately, assigning appropriate adverse event codes for investigation determination, and following up on additional requests from investigators.
- Managed the initial complaint handling process for third-party distributors from receipt of repair to initiation of the complaint in database system.
- Created complaint trackers to monitor all repairs conducted by third party distributors in client's regions in Europe.
- Build partnership with business teams and provide guidance on questions related to compliance program, process, and requirements.
- Develop a consultative and collaborative relationship with internal cross-functional teams as well as external vendors.
- Provided team leadership, coaching, training and guidance on the review and processing of complaints at the initiation, evaluation, investigation, and closure phases.
- Proficient using EtQ Reliance, Trackwise, Agile, SAP CRM, Datasweep, Salesforce, Endowise, Avaya and Power BI.

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

Independently led cross-functional teams for the monitoring of all non-conformances and post-market surveillance activities. Enforced end-to-end controls for compliance with ACell, FDA QSR, Health Canada, and ISO 13485:2016 standards/procedures. Updated and maintained non-conformance, CAPA, complaint, and MDR database for future reference. Formulated and communicated detailed non-conformance, CAPA, vigilance, and MDR reports with key stakeholders for informed decision-making. Discussed impeding issues and corrective strategies with executive and senior leadership, engineering and regulatory affairs in weekly risk management meetings.

Key Contributions:

- Reduced average closure time for complaints by 17% as well as CAPA and NC by 40%.
- Participated in the ISO 13485 recertification as well as Health Canada and MDD certification; achieved zero nonconformance findings in the Complaint, CAPA, and NC processes.
- Conducted trend, root cause, and FMEA analysis on major non-conformances, CAPAs, and complaints.
- Responsible for the review and approval of all medical device product investigation reports for single and combination product complaints.
- Responsible for drafting and filing all MDRs, supplemental MDRs, Field Actions and Recalls (Monthly Reports, Effectiveness Checks).
- 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.
- Worked within the internal and external audit team, ensuring preparedness for regulatory body audit.
- Assisted with developing and maintaining positive relationships with device reviewers through oral and written communications regarding pre-submission strategy/regulatory pathway development, testing requirements, clarification and follow-up of submissions under review.
- Responsible for creating and maintaining product technical files for the CE marking directive. Serve as the subject matter expert in ensuring the clinical quality assurance of multiple trials across several Phase 1 programs and a Phase 3 asset.
- Provided the quarterly updates/revision for Audit Schedule, tracking of Observations for Audit CAPAs.
- Responsible for updating risk management files (Hazard Analysis (HA), User FMEA), Instructions for Use (IFU), labeling and advertising materials for compliance with submissions and applicable regulations.

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

Aligned existing operational framework with BD, FDA, ISO, and other international regulatory requirements. Assessed the effectiveness of the quality management system and accordingly provided recommendations. Directed geographically disbursed teams for continuous compliance assurance. Resolved product quality concerns of health care workers, consumers, and other professionals. Ensured accountability, transparency, and consistency within existing operations by driving internal audits. Reviewed complaint narrative, root cause analysis and investigation of adverse events. Presented complaints, adverse events, and other reports to key stakeholders for data-driven decision-making.

Key Contributions:

- Improved performance of complaint management system by steering corrective action.
- Enhanced multi-skilled competency of complaint specialists via inspirational leadership and training.
- Recognized for slashing average closure time for complaints by 10%.

- Coached and trained new quality systems specialists.

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

Analyzed and recommended both biologics and tissue membranes for physician's use in treating and correcting varying degrees of wound healing. Kept abreast with biological products, such as allografts, xenografts, and placenta membranes. Steered comparative analysis on proposed and existing products for maximum benefits. Delivered technology reports to physicians for seamless operations.

Key Contributions:

- Convinced and enabled DPM to switch to less expensive, competitor biological products.
- Recommendation of a competitor mesh enabled the reduction in wound bed size of two diabetic foot ulcer cases receiving treatment with little success with prior wound management.

Roche – Tucson, AZ
Quality Engineer, 2010 to 2013

Strengthened quality management system using scientific methods, such as 5S and Lean Six Sigma to improve product manufacturing life cycle. Managed suppliers with a focus on achieving desired quality levels. Benchmarked and completed approval activities in coordination with existing and new suppliers in line with ISO 9001, ISO 13485, and FDA standards. Defined procedures for supplier quality management systems to meet organizational needs. Conducted audits and reviewed supplier performance, providing corrective strategies. Mediated between customers and outside suppliers for prompt and accurate communication exchange.

Key Contributions:

- Streamlined and optimized the supplier qualification process.
- Credited for re-categorizing 5,000+ suppliers in three months for annual internal audit.
- Drove and executed corrective actions that minimized instrument damage during transportation and shipping which eliminated customer complaints.
- Supported the compliance training program to educate employees, including new hires, on legal and ethical standards and to ensure a comprehensive understanding. Assist in identifying compliance training needs, develop and deliver training to employees to ensure awareness, understanding, and compliance with policies/procedures and regulations.
- Support compliance operations and initiatives as required including incident reporting, auditing/monitoring, training, and investigations.
- Develop qualification surveys for vendors/suppliers.
- Risk Assessments of vendor to identify level of risk for frequency of audits.
- Documenting/maintaining GVP vendor records for approved suppliers within QMS.
- Review and approval of supplier/vendor deviations (ensuring right Root Cause and CAPA)
- Develop a consultative and collaborative relationship with internal cross-functional teams as well as external vendors.
- Drove corrective action and continuous improvement initiatives to enhance supplier performance.
- Supported implementation of electronic batch record and document control system on the instrument manufacturing floor.

*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*