MyQACoach.com

Diane G. Kulisek

Quality Assurance Leader

QA Superpowers: Quality Management System Implementation and Repair, Corrective and Preventive Action, Performance Metrics

Summary

Quality Assurance leader with proven track record of improved performance for start-up, turn around, small, medium, large and huge organizations, across multiple industries, markets and technologies. Collaborative leadership style, cross-functional team approach. Emphasizes long term strategic vision with near term focus upon tangible deliverables. Entrepreneurial, innovative and versatile. Leverages current best practices and lessons learned from external environment to optimize internal results. Big picture strategist and detail-oriented tactician. Open and frequent communicator. Hands-on, front line, problem-solver.

Notable Achievements:

Implemented new or repaired damaged Quality Management Systems for numerous small and mid-sized organizations, in all states of business maturity from start-up to acquisition, within 3 to 6 months each, since 2002, to adequately achieve ISO 9001, ISO 13485 or AS 9100 certifications, CE Mark registrations and Medical Device Manufacturer licenses, as well as to support FDA premarket submissions.

Implemented enterprise automated tracking system (EtQ) to initiate, monitor, electronically approve and close Corrective and Preventive Actions (CAPA), NonConformance (NC) reports, Material Review Board dispositions (NCs/MRBs), and internal/customer/regulatory/supplier audit Observations (OBS) in less than six months, on time and within budget, at Advanced Sterilization Products (ASP).

Formed a cross-functional council for quality system standardization and aligned the Franchise (local operating company) with 37 Medical Device & Diagnostics (MD&D) industry Sector (division) and Enterprise (corporate) Quality System standards as required to successfully pass a Johnson & Johnson corporate compliance verification assessment within less than 3 months from project initiation, at ASP.

Created and maintained key performance metrics, trend analysis, Pareto analysis and action plans for local dashboards used in Management Reviews and to populate corporate scorecards (Johnson & Johnson Supply Chain Scorecard or 'JJSC' Scorecard), at ASP.

Improved training system compliance and audit readiness, updated and revalidated the computer-based learning system (CLS; ComplianceWire), formed a cross-functional training council, and collaborated with Human Resources to initiate version control of job descriptions for creation of task-based training curricula, at ASP.

Remediated and mitigated residual risks for 24 legacy CAPAs associated with a 2009 FDA 483 and 2010 FDA Warning Letter. Created, implemented and assessed effectiveness of the two-phase project plan, documented the project completion reports and successfully passed three annual third party assessments (performed on behalf of the FDA) with no observations against the CAPA remediation effort; at ASP.

Formed and led a cross-functional team, comprised of managers and engineers from QA and from R&D, to eliminate aging customer complaint investigations for 6 product families and 67 specific product components or subassemblies, on contract to ASP.

Facilitated new product development quality and manufacturing engineering management collaboration for verification and validation (V&V) of a newly-automated biomedical device manufacturing process, generated a statistically valid acceptance sampling plan, reviewed IQ-OQ-PQ protocols and reports and made recommendations for approval or rejection throughout the effort, on contract to ASP.

Work History:

10/2015 – Present MyQACoach.com; Virtual w/ HQ in Simi Valley, CA

Founder, President, Quality Assurance Leader

Founded MyQACoach.com, a CA S Corporation, providing concierge quality assurance, regulatory science and organizational excellence (QA, RS, OE) coaching services by subscription. Provides leadership for an outstanding team of senior subject matter experts (SME's). Currently building Affiliate relationships with automated Solution Providers, specializing in the needs of start-ups, small organizations and mid-sized turn-around organizations. A customized resource library is included with each subscription and is built during coaching sessions as needs arise for each client. Additional complimentary quality assurance resources are also provided to newsletter subscribers and registered company followers. The MyQACoach.com Team brings, collectively, close to 300 (parallel-processed) years of case studies, templates, training materials and other resources to help fulfill client needs and objectives. Please visit www.myqacoach.com for additional information.

04/2015 – 10/2015 SynCardia; Tucson, AZ

CAPA Engineer *(W2 Consultant)*

Implantable total artificial heart manufacturer; provided failure investigation and Corrective and Preventive Action (CAPA) system support; drafted update to the client CAPA process; established CAPA lifecycle-based performance metrics; developed return on investment staffing analysis to support projected company growth for the quality assurance organization in collaboration with financial personnel; assisted with corrective action related regulatory correspondence.

06/2005 – 10/2015 CAPAtrak; Simi Valley, CA (formerly CAPAtrak, LLC)

Quality Assurance Leader and Consultant

Provided W2 and 1099 contract management consulting and project leadership for biomedical, biopharmaceutical, filtration, consumer, government, electronic and aerospace industries; partial list of clients and projects:

- ***Arbios*** (hepatic filtration device manufacturer): performed and documented biocompatibility assessments and gamma irradiation sterilization validation; secured FDA approval for initiation of clinical trials;
- ***Defense Contract Management Agency*** (DCMA; U.S. Government): Provided agency-wide feedback to streamline lean agency operations report for presentation to the Senate Budget Committee;
- ***ImplantDirect*** (dental implant manufacturer): Secured Medical Device Manufacturing Facility license; negotiated with FDA to secure approval of an unprecedented multi-device 510k submission; developed electronic, web-hosted, customer feedback form; achieved ISO-9001 and ISO-13485 quality management system certifications; resolved equipment manufacturer process capability issue on behalf of client;
- ***Johnson & Johnson*** (Johnson & Johnson Comércio e Distribuição Ltd., São Paulo, Brazil via Ethicon; suture manufacturer): provided web-hosted training on quality performance metrics, scorecards and dashboards;
- ***Medtronic Minimed*** (insulin pump manufacturer): provided CAPA training for Executive Board members; tailored to include client's own Quality Management System CAPA procedures;

05/2014 – 02/2015 Bruin Biometrics LLC; Los Angeles, CA

Director, Quality Assurance and Performance Improvement

Quality Systems leader for start-up/think-tank developer of diagnostic, sensor-based, medical devices. Achievements included: completion of company-wide internal ISO 13485:2003/EN ISO 13485:2012, 21 CFR 820, CMDR and MDD QMS audits; development and implementation of MS Excel-based CRM preliminary to acquisition of a SQL-based enterprise CRM software solution; implementation of hardcopy document controls, while also preparing existing e-copy documents, including quality records, for migration to an enterprise QMS software solution; performance of on-site QMS pre-commercialization audit of critical OEM for first product to market; development of Quality Agreements for two 3PL distributors in Europe; successful completion of first SGS surveillance assessment for CMDCAS certification, including Technical File compilation for CE Mark; provision of direct support for parallel submission of 510(k) application to FDA in collaboration with Director of Clinical & Regulatory Affairs, including DMR and DHF compilations/updates.

11/2013 – 05/2014 Zila, Inc., a Tolmar Company; Batesville, Arkansas (W2 Consultant through Real Staffing)

Director, Quality Assurance (transitional)

Provided strategic and tactical quality assurance and regulatory affairs leadership for developer, manufacturer and distributor of classic legacy and innovative medical devices for use by the dental healthcare industry to prevent and treat gum disease and oral cancer. Evaluated and qualified one major external manufacturer in Missouri, including on-site assessment and crafting of a formal Quality Agreement. Collaborated with engineering director to update validation templates and qualify new manufacturing processes for acquired and out-sourced product subassemblies. Zila's technology was divested by parent company, Tolmar, in February 2014. Decommissioning of the 4-facility operation in Batesville, AR was the subsequent focus of QA effort. Preparation and shipment of records and product retains to the new owners was a critical element of that activity. QA operations in Arkansas ended 4/5/14. Remaining transitional oversight was done from offices in Fort Collins, CO and in Southern California.

01/2010 – 10/2013 Advanced Sterilization Products (ASP), a Johnson & Johnson Company; Irvine, CA

Quality Systems Manager (Regular Hire 03/2011 – 10/2013)

Managed the overall Quality Management System, Quality Manual, Corrective and Preventive Action (CAPA) system (via EtQ), Training (via ComplianceWire), Audits and Good Documentation Practices (GDP) compliance; ASP developed, manufactured and serviced Class II, FDA-regulated, clinical sterilization equipment and related consumable products.

Project Manager, Quality Compliance and Engineering (W2 Contractor, Oxford; 01/2010 - 03/2011)

Remediated 20+ legacy CAPAs; eliminated aging customer complaint investigations; facilitated new product development quality and manufacturing engineering management collaboration for a major new process verification and validation (V&V) project.

10/2008 – 8/2009 Moore Industries-International, Inc.; North Hills, CA

Director, Quality Assurance

Achieved UL Safety Product Certifications and ISO 9001 Quality Management System (QMS) Certification, created intranet application for key performance metrics and implemented companywide touchscreen access for metrics and controlled documents (standard operating procedures, work instructions, forms and templates), maintained product reliability database, developed and implemented inspector certification program for operations personnel, implemented electrical assembly visual standards, ensured compliance with applicable RoHS and REACH requirements. Moore developed and manufactured electronic process control devices for temperature and pressure monitoring systems in the petroleum drilling, petroleum refining, sugar and flour milling, chemical processing, nuclear power generation, natural gas processing, hydraulic power generation, and mining industries.

08/2007 – 03/2008 Triumph Actuation Systems; Valencia, CA

Acting Director, Quality Assurance / Quality Manager (W2 Contractor)

Created strategic quality plan, trained entire workforce and achieved facility post-relocation ISO 9001, AS9100 and AS9102 (first article) re-certifications; established key performance metrics; interfaced with key customer representatives (Boeing and Goodyear) and government source inspectors (DCMA) on quality-related matters; converted manual (hardcopy) quality system documents to electronic files with process maps, improved version control and companywide accessibility. This Triumph facility manufactured, tested and serviced hydraulic actuators for use in commercial and military aircraft landing gear and ejection seat systems.

08/2004 – 06/2005 Spectrum Laboratories; Rancho Dominguez, CA

Vice President Quality Assurance/Regulatory Affairs

Achieved ISO 9001 and ISO 13485 re-certification after facility relocation; interfaced with key customer representatives for on-site and desktop audits; successfully submitted 510k and obtained premarket approval for class II device (syringe filter); maintained medical device manufacturing facility license; performed product and process qualifications, validations (IQ-OQ-PQ) and re-validations, including cleanroom controls, water endotoxinicity / pyrogenicity, work surface

bioburden assessments, biocompatibility assessments, and gamma irradiation for device sterilization. Performed process capability assessments for Critical-to-Quality (CTQ) and Critical-to-Safety (CTS) design characteristics. Spectrum developed and manufactured hollow fiber filters for use in biomedical and biopharmaceutical applications.

07/2002 – 08/2004 PTI Advanced Filtration, Inc.; Oxnard, CA

Director, Quality Assurance

Implemented Quality Management System and achieved initial triennial ISO 9001 certification; implemented paperless document control and record management system; reduced warranty costs, customer complaints and nonconformance reports; reduced product audit expenses by ~80% (~$200K/year) by aligning with Marketing claims; improved company financial posture from 5 prior consecutive years of unprofitability to 2 consecutive years of profitability as part of 3-person new top management team; PTI-AFI developed and manufactured pleated modular, spiral wound and flat sheet hydraulic and pneumatic filters for applications in the biomedical, biopharmaceutical, dairy, wine, food, automotive paint, major appliance paint, and semiconductor industries.

Most Significant Earlier Work:

07/1980 – 10/1984 and 06/1995 – 06/1999 Gillette Company; Westlake Village and Santa Monica, CA

Manager, Quality Engineering – Stationery Products Group; 1995 – 1999
Senior Quality Engineer – Jafra Cosmetics Division; 1982 – 1984
Quality Engineer – Gillette PaperMate; 1980 – 1982

09/1986 – 05/1995 Rocketdyne Division of Rockwell Aerospace; Canoga Park, CA

Associate Product Manager, Quality Assurance, Avionics & Controls – Space Shuttle Main Engines (SSME); 1992 - 1995
Project Manager, Quality Assurance – Space Shuttle Main Engines (SSME); 1988 – 1992
Manager, Quality Performance Reporting & Corrective Action; 1987 - 1988
Manager, Supplier Control; 1986 - 1987

Education and Certifications:

M.S. Engineering, *Civil, Industrial and Applied Mechanical Engineering Management*; California State University, Northridge (1992)

Graduate Certificate, *Program Management*; West Coast University (1990)

B.A. Biology, *Environmental*; California State University, Northridge (1979)

Lean Six Sigma Green Belt; Six Sigma Systems, Inc. (2000)

ASQ CMQ/OE; American Society for Quality Certified Manager of Quality/Organizational Excellence (1995; maintained current)

ASQ CQE; American Society for Quality Certified Quality Engineer (1982; maintained current)