

TARHAN KAYIHAN

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QUALITY LEADERSHIP

Medical Device | Biotech | Startup Growth | Quality Systems Development | New Product Introduction

Quality and regulatory leader with 18 years' experience driving growth, launching products, developing strategies, and establishing quality systems from start-up to large medical device companies. Proven success leading quality teams and cross-functional projects. Extensive knowledge of global regulations, ISO13485, 21CFR803, 21CFR820 (QSR), MDR.

PROFESSIONAL EXPERIENCE

R2 TECHNOLOGIES, San Ramon, CA

2021-present

Director of Quality Assurance and Regulatory Affairs

Launched products, led growth initiatives, and supported regulatory submissions for class 2 aesthetics device manufacturer.

- Developed quality and regulatory strategies with a focus on domestic and international markets, business development, customer retention, and revenue growth.
- Communicated company's quality programs/vision to internal and external stakeholders.
- Led quality and regulatory activities to launch two projects, domestically and internationally.
- Expanded QMS to support international requirements, leading to ISO13485 and MDSAP certification.
- Coordinated quality program for conformance with phase appropriate GMPs.
- Established and supported compliant Marketing focus for social media program.
- Presented quality and regulatory budgets that included resource planning, submissions, and licenses.
- Developed and optimized processes and procedures meeting global regulatory standards, as well as having implemented training, development, and career advancement programs.
- Participated in selection, management, and oversight of quality contract service providers, including CMOs.
- Strengthened supplier management program with detailed quality agreements, NDAs, and reclassifications for greater flexibility of the cross-functional teams (Operations, R&D, Purchasing).
- Expanded quality processes, such as complaints, QC, document control to enable lean activities and process improvements, suitable for a start-up environment but with room for growth.
- Served as the primary liaison and subject matter expert (SME) to the organization on US and International agencies for all areas relating to quality control and quality assurance.
- Led, hired, developed, and mentored team members to ensure a cohesive, dedicated, and productive group.
- Created custom quality tool to support full QMS gap assessment (MDSAP, ISO13485, QSR, ISO9001).
- Identified regulatory pathways for cosmetic and non-medical product lines for domestic and international markets.

SMITH&NEPHEW (CETERIX ORTHOPAEDICS), Fremont, CA

2018-2021

Quality and Regulatory Director

Developed QMS and led growth initiatives for class 2 orthopaedics device manufacturer.

- Introduced mature quality systems concepts (supplier quality, root cause analysis, continuous improvement, data analysis, safety), leading to acquisition of start-up by an established leader in medical device manufacturing.
- Coordinated local integration activities, including expanding QMS, incorporating ISO13485, restructuring NC/CAPA and complaints, implementing software systems.
- Supported regulatory submissions and managed communication with multiple regulatory agencies.
- Provided cross-functional teams with regulatory guidance for site projects, including NPI and Marketing.
- Supported post-acquisition changes, leading site to 5X production increase within 8 months.
- Increased inspection throughput 3X through improvement projects.
- Improved cross-functional communication with tier-based metrics reporting and data sharing.
- Introduced supplier quality processes to a start-up, including supplier monitoring and audit management.
- Supported class 3 ENT site as interim Quality Director.
- Developed multi-site Quality best practices and information/resource sharing.
- Led team of 15 in Quality Engineering, Quality Control/Inspection, and Document Control, providing opportunities for cross-training, growth, development, and promotion.
- Prepared and managed budget for QA/RA activities at multiple sites, covering projects, headcount, equipment.

VORTEX BIOSCIENCES, Menlo Park, CA 2016-2017

Director of Quality and Regulatory

Led quality and regulatory activities for instrument development at a biotechnology (IVD RUO) start-up.

- Introduced quality systems, testing, and procedures with plan for strategic growth (RUO to Class II).
- Managed suppliers (CM and development partners) for design transfer to production.
- Created and submitted regulatory files for FDA and CE Marking (EU).
- Created risk management file and assembled DHF.
- Managed independent safety and software testing to comply with IEC60601, ISO62304, IEC62366, MDD, LVD/EMC.
- Developed programs for training, calibration, service/maintenance, testing, decontamination.
- Introduced Practical Process Improvement (PPI, 8-step kaizen) problem solving techniques to organization.

THERMOFISHER SCIENTIFIC, Pleasanton and South San Francisco, CA

2015

Quality Assurance Consultant

Developed and implemented regulated controls for leading biotechnology company.

- Introduced ISO13485 and QSR requirements to new regulated production line and processes.
- Led quality improvement projects (PPI, kaizen) and prepared/managed external audits at multiple sites.
- Conducted gap assessments across multiple sites to identify quality/regulatory improvements.
- Developed CAPA Dashboard and site review board to address late corrective actions, leading to 80% improvement in CAPA timeliness.

PREVIOUS PROFESSIONAL EXPERIENCE

ALIVECOR, San Francisco, CA

2014-2015

Head of Quality Assurance

Developed and implemented quality systems and production line for a class 2 mobile medical device/software start-up.

STRYKER ORTHOPAEDICS, Alameda, CA

2012-2014

Manager Quality Systems

Managed, developed, and improved quality systems for a class 2 medical device company (instruments).

CONCEPTUS, Mountain View, CA

2008-2012

Senior Regulatory Quality Engineer

Managed regulatory and quality assurance improvements for a class 3 medical device company (women's health).

NORTH COAST MEDICAL, Morgan Hill, CA

2004-2007

Operations Quality Manager (2005-2007)

Regulatory Compliance Administrator (2004-2005)

Managed quality, regulatory compliance, and manufacturing for a class 1&2 medical device manufacturer/distributor.

PACIFIC GAS & ELECTRIC (PG&E), San Jose, CA

2003-2004

New Business Representative / Project Manager

Managed new business accounts in a contract position for a public utility firm.

SOLECTRON, Milpitas, CA

2000-2001

Process Quality Assurance Engineer

Supported production for a contract manufacturer of printed circuit board assemblies (PCBAs).

PLASTIKON INDUSTRIES, Hayward, CA

1999- 2000

Manufacturing Engineer

Created and improved processes in secondary operations for a plastic injection molding contract manufacturer.

EDUCATION

B.S. in Industrial Engineering

University of Washington, Seattle

Certifications:

American Society for Quality Certified Quality Auditor (ASQ CQA)

RABQSA Certified Lead Auditor ISO13485 (Exemplar Global)