

Quality, Regulatory and Compliance Executive (Looking for Remote Head or VP Opportunity-Full-Time Employee/No Contract)

Organized and detail-oriented compliance and quality control expert with 10 years' success resolving and avoiding complications in delivery of products and services.

Analytical and action-oriented quality assurance and regulatory affairs professional with strong background in business development and operations. Solid business acumen; able to interface with internal stakeholders to effectively integrate regulatory strategies and quality control measures into operations and guide change management processes. Expert in developing training curricula to raise compliance across operations. In-depth legal and business administration expertise. International and national public speaker and corporate trainer.

AREAS OF EXPERTISE

- Regulatory Compliance
- Risk Management
- Change Management
- Business Consulting
- Corporate Law
- Quality & Regulatory Affairs
- ISO 9000 & 13485
- Six Sigma Master Black Belt
- Project Management Certified

ACCOMPLISHMENTS

- Recovered \$1.2 million in supplier non-compliance and contractual issues
- Concurrently led regulatory and quality compliance for two companies operating across seven countries.
- Led non-partisan internal investigations, resulting in a detailed 150-page internal report (with recommendations)
- Published several scholarly articles in major journals and publications
- Garnered domestic and international notoriety via a televised TEDx talk
- Internationally advocated for the human rights of all as a United Nations Delegate for an acclaimed NGO

PROFESSIONAL EXPERIENCE

Confidential, Salt Lake City, Utah **Head of Regulatory Affairs and Compliance**

11/2021 – present

Oversee company's regulatory function. Responsible for handling regulation, registration, submissions, and certification of products (globally). Prepare dossiers, technical files and product reports. Develop regulatory strategy. Perform internal audits to assure regulatory and quality compliance. Provide regulatory support and guidance in manufacturing, product design and development and distribution. Train staff on cGMP and other relevant standards and regulations. Medical devices: IVDs & RUOs (Molecular Biology-Real Time PCR) and IVD Instruments. Countries and regions: EU (MDR/IVDD/IVDR/CE Mark), Canada, USA, Australia, Africa, United Kingdom, WHO, Middle East (Saudi Arabia), Asia, and Latin America (Mexico, Brazil, Chile, Ecuador, Honduras, Guatemala, Colombia, Bolivia, Venezuela, El Salvador, etc.).

Celsius, Boca Raton, FL **Quality Assurance Manager**

2/2020 – 11/2021

Led company's quality department and function (globally). Coordinated quality programs and procedures, including CAPAs, deviations, quarantines, reviews, and investigations to integrate FDA, FTC, GMP, and HACCP regulations into company processes. Drafted and maintained SOPs, quality and regulatory documentation. Conducted auditing of quality processes and supplier qualifications. Held accountability for label compliance (NLEA) across federal regulations (21 CFR 101 & 21 CFR 111) for nutrition and packaging. Area of Regulatory Focus: Dietary Supplements & Food (Energy Drink, Powders and Protein Bars).

- Recovered \$1.2 million in quality-related claims and chargebacks in contract manufacturer non-compliance.
- Corrected critical and major deficiencies in third-party internal audit, placing company into compliance.
- Resolved critical shortcomings in labeling compliance, avoiding fines and license suspension.

Traatek, Inc. & OMT Medical, Ft. Lauderdale, FL **Compliance and Regulatory Affairs Officer**

2/2018 - 2/2019

Led regulatory risk analysis and mitigation across two international companies. Held direct responsibility for licensing as well as compliance (ISO 9000, ISO 13485 & ISO 14971), reporting, tracking, and resolution of key regulatory obligations. Pursued positive communications with regulatory agencies and internal stakeholders to align operations with industry standards and best practices. Drafted legal, regulatory, technical, and compliance documentation for domestic and international product registrations, including 510k, CFG, STED, design inputs and outputs, technical files, and dossiers. Medical device classification: Class II/IIa/IIb (Surgical Devices). Countries and regions: USA, Middle East (Syria & Lebanon), and Latin America (Mexico, Brazil, Chile, Ecuador, Honduras, Guatemala, Colombia, etc.).

- Gained membership into regional purchasing organization, facilitating expansion of customer base.
- Standardized internal auditing processes for product traceability, logistics, and regulatory compliance.

Gift of Adoption Columbia River Chapter, Portland, OR
Board Member

2/2012 – 1/2017

Reviewed and approved adoption assistance grants for large agency operating across United States. Attended annual and special fundraisers and assisted in fundraising by soliciting donations and funding grants. Leveraged relationships with other non-profits, individuals, and corporations to garner support of chapter and its mission.

- Secured interest of prospective board members for formulation of a new Gift of Adoption Seattle chapter.

Shaan Consulting & Development, Portland, OR
Business and Legal Consultant

10/2010 – 9/2017

Guided individuals and businesses through the early stages of business development to strategic development and market placement. Conducted market research and competitive analysis to accelerate new market entry. Leveraged strong legal background to advise and expedite business registration and formation and resolve licensing concerns.

- Spearheaded market research which secured Angel investment funding for children's language app.
- Developed free safety Android app through self-directed learning.

Additional Experience:

Adjunct/Associate Professor • Center for Legal Studies, Excelsior College, U of Phoenix • 2003 – 2022

Assistant City Attorney (MCR 8.120) • City of Flint • 2003 – 2004

First Year Associate/Paralegal • Brown & Stanley, P.C. • 2002 – 2003

EDUCATION

Master of Business Administration (MBA)

Northeastern University School of Business • Boston, Massachusetts • 2016

Master of Laws (LL.M.) in Transnational Law

Willamette University College of Law • Salem, Oregon • 2014

Juris Doctor (J.D.)

Thomas M. Cooley Law School • Lansing, Michigan • 2003