Dear Employer,

I would like to submit my resume in consideration for your Quality Assurance position. I am a dedicated professional, looking for a fulfilling direct hire/contract to hire position. Below are some mention worthy details over my results-based employment history.

* Exact, Onsite Quality Assurance representative for all that necessitates QA guidance. This department from 3 (including an AD and a Specialist) to just me.
* Millipore, I was assigned as the Dedicated Investigator for the company’s largest client.
* Illumina, I brought the CAPA system into the green lowering several metrics: Global Overdue down 100%, Global Not Implemented down 88%, Global Average Age down 19%, Global Days Until 90 Days Old down 47% and Organization Overdue down 34%.
* I started at Dexcom INC as a QA Complaint Supervisor in April of 2016. By the end of the year, on the QA Complaints side, brought my team’s highest volume complaint failure code down from 7,000 complaints up to 100 days old down to 349 complaints up to 3 days old.

In the same period, on the Returned Good Lab side, I set the lab up to be 5S recertified and ran an employee Development Plan to change the process of scrapping Field Failure Analysis samples, saving 3-4 hours of productivity time.

* Inovio, I quickly put into effect a Biohazard Program complaint with OSHA guidelines for the safe receiving and investigation of contaminated failure samples with a sequester area and procedures for those investigations, essentially, streamlining the Complaint Investigation process.
* CareFusion, in my first month, I took over device investigations for a company that was acquired by CareFusion and was subsequently the SME for these products. As a direct result of that experience, I managed all escalated files, Risk Assessments, and related works.

I’ve taken the initiative to further my knowledge base, extending my experience into Risk Management, Regulatory Affairs, and Manufacturing as they feel like a natural transition in my development. I’d like to use that same ingenuity to acquire a position in your company.

**Summary of Qualifications**

* CAPA
* Onsite Investigations
* Complaint Handling
* MDR’s
* Document Control
* Risk Management
* RA Submissions
* Change Order/Control
* Failure Investigations
* PSDM Method
* Ishikawa
* DMAIC
* 5 Why’s
* 4 P’s
* NCMR
* Hazard Analysis
* Batch Release
* Review BOM and Schematics
* Liaison US/Mexico/EU
* Quality System Regulation
* Recall Management
* OSHA
* Auditor
* FMEA
* Project Management
* Data Analysis/Trending
* Medical Device Reports
* 21 CFR
* Device/Component Drawings
* ISO 13485:2016
* Materials/Finished Goods Hold
* Leadership
* Labor Planning
* Test Protocols
* Author SOP/WI/PI
* Author Test Protocol
* Deviations
* Quality Events

Regards,

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Taara S. Maharaj

**Professional Experience**

**Apr 2021-present**

**Sr. Post-Market Spec, QA SeaSpine Carlsbad, CA**

Perform root cause analysis, including review, update, creation of risk management files. Prepare summary and trend reports, participate in quality management reviews, file reportable complaints to the appropriate US and international bodies, prepare SI site for MDSAP certification and updated ISO 14791/24791 compliance, coordinate and host reviews of post-market data, author hazard analysis analyzing potential field product issues, coordinate recall activities, establish and implement post-market related processes, support audits, ad hoc engineering duties. As the Sr. member of the team, lead the team in daily activities along with mentoring and training team as a cross-functional body with emphasis on root cause analysis, CAPA and CAPA subsystems. Monthly/Quarterly complaint review, Annual PMS review, PMSP, PSUR implementation and updates, Franchise level reviews, Clinical Affairs support and approver for CER updates, PMCF P/R. Review engineering documentation, changes, BOMs in preparation for new launches for completion and compliance. Manage work streams and act as a subject matter expert on various projects for design and post-market surveillance, coordinating resources and their respective activities. Analyze progress of projects and stipulate changes in course when necessary. Prepare presentations to report metrics and state of the department or other updates to executive management. Provide support for other projects as the point of contact for the post-market surveillance department.

**Aug 2019-Apr 2021 Exact Sciences San Diego, CA**

**Sr. Quality Assurance – Complaints, CAPA, NC Investigations, MRB, Exception Control**

The Senior QA is the onsite Quality leader in a variety of Quality functions.

**Feb 2019-Apr 2019 Obalon Therapeutics (Contractor) Carlsbad, CA**

**Sr. Quality Engineer – Complaints, CAPA, NC Investigations**

RCA Managed complaints, CAPA, NC, Deviations. MDR/Vigilance Reporting, Design Control, metrics, trending, risk assessment, HHA, calibration, internal auditing. Created a comprehensive Investigation program.

**Nov 2018-Feb 2019 Abbott Formerly Alere (Contractor) San Diego, CA**

**Quality Engineer V, Product Support - Complaints**

Align Alere’s complaint procedures with those of Abbott, while ensuring the company remains in compliance with MDSAP and 13485:2016. Streamline the complaints and risk assessment processes.

**Apr 2018-Sep 2018 MilliporeSigma (Contractor) Carlsbad, CA**

**Quality Assurance - Investigations**

RCA, CA/PA for quality events.  All investigations inclusive, facilities, drugs, devices, etc.

**Apr 2018-Sep 2018 Illumina (Consulting) San Diego, CA**

**Senior Quality Engineer, Project Manager – CAPA Ninja**

Facilitate and drive all actions for the CAPA program. Root Cause Analysis using 6 Sigma Methodologies, , facilitate and run blitzes to find what roadblocks are preventing the forward movement of a CAPA and provide relief for those. Train on RCA, CAPA

Additionally, have been tasked with assisting in the QMS overhaul for the Post-Market Surveillance activities and adaptation to ISO 13485:2016.

**Apr 2016-Apr 2018 Dexcom, INC. San Diego, CA**

**Supervisor, QA Complaints and Returned Good Lab**

**Supervisory Duties:** 11 Complaint Specialists and 9 Failure Investigators in the Quality Assurance Department.  Carried out supervisory responsibilities in accordance with the organization's policies and applicable laws. Interviewing, hiring, training, labor planning and developing employees.

**Technical Quality Duties**: Write policies and procedures, Change Orders. Audits, compliance to ISO 13485, and related CFR’s. Work to improve CMS system and procedures, investigations.

**Dec 2015-Apr 2016 Inovio Pharmaceuticals San Diego, CA**

**Quality Systems Management**

Authored SOPs, work instructions, change orders and other policies and procedures.

Streamlined the complaints management process, bringing the QMS to CFR compliance and ready for commercial.

CAPA. Signature authority on Quality, Manufacturing and Engineering documents and releases such as NCMRs, audits, batch releases, QC approvals.

**Oct 2011-Dec 2015 BD – Formerly CareFusion San Diego, CA**

**Failure Investigations, CA (Failure/Complaint Investigations)**

SME, Disposable and Instrument: CAPA’s, Risk Assessments, SCAR’s and HA, DHR, Change Management, manufacturing, SOP/WI, liaison, (international and domestic), field investigation and service.

**2006-2010 Glanbia Nutritionals (NA), Inc. Carlsbad, CA**

**Human Resources Manager - Bilingual**

Maintained and enhanced the organization's Human Resources by planning, implementing, and evaluating employee relations and Human Resources policies, programs, and practices.

**2005-2006 Tyco Healthcare Puritan Bennett Carlsbad, CA**

**QA Recall Coordinator/QA Complaint Handling - Contractor**

**QA Recall Coordinator Duties**: Managed recall actions, coordinating, tracking, recall classifying, population analysis and information dissemination based on metrics gathered from complaints.

**Regulatory Affairs Duties**: Reviewed and approved submission documentation. MDR reporting to FDA and International regulatory bodies.

**QA Complaint Handling Duties:** Classify/close complaints on the respiratory devices, classifying and closing complaints, preparing baseline reports and ASR’s, recording adverse events, audited service reports, MDR reporting, gathered complaint and trending data.

Worked directly with government agencies in the US and abroad.

**Education**:

**Western International University Online**

Some coursework in Business Management

**ASQ, CQE San Diego, CA**

Completed Certification Course, no certification

**CQE San Diego, CA**

Self-study, no certification

**Certified Manager of Quality/Organizational Excellence (CMQ/OE)  Online**

Certifying in Q1 2023

**1998 – 2000 US Army Fort Gordon, GA**

Multi-Channel Transmissions System Operator-Maintainer

**Mount San Jacinto College Menifee, CA**

Certified as Emergency Medical Technician