

Arun Baby

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Kepler Communications
Toronto, Ontario

Sept 02, 2023

RE: Quality Assurance Engineer

Dear Hiring Manager:

I am writing to express my interest in the Quality Assurance Engineer position posted on your website. After carefully reviewing the job posting, I am confident that as a candidate with several years of quality engineering experience in highly regulated industries ranging from aerospace, medical devices, and automotive, where I have successfully managed progressively complex systems, I will be a great fit for this role.


I currently lead all aspects of quality engineering for a company operating in a highly regulated medical devices industry, including engaging with external stakeholders, and championing continuous improvement actions and organizational change. I also act as the project manager for all quality assurance and risk management initiatives for a high-risk medical device. I played a pivotal role in the transfer of research technologies into manufacturing including developing process from the ground up and implementing cGMP's and driving engineering changes by engaging in negotiations with over 100+ personnel and suppliers. With this experience combined with my ability to quickly adapt and grasp new concepts; I am confident that I will be an excellent fit for the role.

This opportunity to join your family significantly interests me because my experience and education perfectly align with the opportunity, and I am confident I will be able to make meaningful contributions to the organization. My education, experience in highly regulated industries and peer-recognized certifications in the domain of quality, project management and continuous improvement are a testament that I can competently execute the role's responsibilities. My zeal to constantly improve, both in my knowledge and in my skills, would be an asset to you.

Throughout my career, I have demonstrated the highest levels of service and commitment to the mission of any organization I have worked for. I'd be delighted if you'd give me a chance to discuss how I might add value to Kepler Communications.

Thank you for your time and consideration. Looking forward to discussing how I might be fit and contribute to the company!

Yours sincerely,


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Summary

- Specializing in quality assurance and reliability engineering, and risk management in highly regulated industries with over 5 years of experience and an ASQ Certified Quality and Reliability Engineer.
- Leader in implementing organizational wide change to lift a startup from a research lab to a GMP manufacturing facility which obtained its ISO certification.
- Proficient in data analysis and mathematical modelling using Minitab, MATLAB, SQL and Python
- Well versed in ISO 9001 (QMS), ISO 13485 (Medical Devices), ISO 14971 & ISO 31000 (Risk Management) and AS9100 (Aerospace), IPC-A-610 & IPC-J-STD-001 (Electronics)
- Leader in all aspects of quality engineering in the development and manufacturing of a complex precision manufactured FDA Class III medical device.
- Proven leader in lean and six sigma projects and passionate about implementing lean manufacturing philosophy in achieving waste reduction and improving process flow
- Project lead for the development and deployment of an organization-wide quality management system and getting it ISO certified in a highly regulated industry for a startup.
- Currently dabbling in data science and working on PMP certification for professional growth.

Work Experience

Arrayus Technologies Inc. (Harmonic Medical)

Toronto, ON

Quality Assurance Specialist

Oct 2022 – Present

- Planned and implemented organization-wide change to move a startup company from a large research lab to a class-leading manufacturing facility which obtained its ISO certification within 2 years by developing and delivering training, managing stakeholder onboarding, implementing GMP and developing an entire quality management system from scratch.
- Lead all aspects of the company's quality system including but not limited to QC, QE, supplier management and auditing, asset management, training, managing engineering changes, audit management, and root cause analysis.
- Lead and oversee reliability engineering and risk management initiatives for a precision manufactured, high-risk medical device including identification, estimation, risk assessment, mitigation and their verification using advanced tools such as FTA, FMEA, Markov Chain analysis, Monte Carlo simulations and design of experiments
- Lead the development, implementation, maintenance, and continued improvement of the Quality Management System and Risk Management in the organization.
- Project manager for a multi-year project plan to automate major aspects of manufacturing
- Managed non-conformances (NC) and champion corrective and preventive actions (CAPA) in production including quarantine management, root cause analysis and timely problem resolution resulting in a drop of 40% for non-conformance in manufacturing within a year.
- Analyzed large volumes of data on key performance indicators on the functioning on the QMS and provided reports on the status of the entire quality system to top management.
- Act as the overall subject-matter-expert in quality for the entire organization

Quality Coordinator

Dec 2021 – Sept 2022

- Key specialist in positioning company for MDSAP (ISO 13485) certification for the manufacturing facility by coordinating between various departments.
- Acted as the sole project executer in developing and implementing a company-wide calibration

program along with selection and management of service providers.

- Coordinated with Director of Ultrasound Engineering (Manufacturing) to implement GMP and played a pivotal role in aligning the current operations to better position the company to obtain MDSAP and Health Canada and FDA approvals.
- Developed the company's first process validation (V&V) and asset qualification protocols. Trained staff and oversaw development and implementation of the rest.
- Acquired one of the rarest (and surprisingly difficult) experiences in the field of quality and regulatory affairs- the development of a QMS from scratch.
- Designed and developed an automated system to capture the entire manufacturing processes for a high-risk high-complexity medical device reducing human errors and removing the overhead of tedious data entry for operators improving their throughput by 72% using SQL, Python and MATLAB.

Ultrasound Quality Control Associate

Nov 2020 – Dec 2021

- Developed and implemented processes and procedures for incoming inspections and work-in-progress (WIP) testing and quality control of delicate electronic components and subassemblies for an innovative new product.
- Analyzed and interpreted test data and performed Root Cause Analysis (RCA) in a growing start-up company, that was putting a manufacturing system in place, to optimize performance, assembly processes and yield in co-ordination with manufacturing lead.
- Drafted, reviewed, and verified technical documentation, including test procedures and work instructions
- Played a key role in educating staff coming from a research background on the principles of quality assurance as they transition to manufacturing. Demonstrated the need for a quality system in manufacturing by demonstrating the benefits based on the processes they performed during manufacturing.
- Initiated CAPA to address recurring issues in manufacturing. Implemented continuous improvement activities to increase manufacturing output. Aggressively worked to identify inefficiencies in manufacturing and other aspects that affected overall product quality and lead improvement actions to address them.

Ryerson University

Toronto, ON

Research Assistant (Quality)

Oct 2019 – May 2020

- Performed statistical (DOE) and reliability analysis of subsystems to ensure satisfactory end- product performance using software like Minitab and MATLAB on Bombardier Aerospace's next generation cabin program.
- Implemented continuous improvement of a CNN based personnel recognition system onboard a new aircraft cabin.

Bombardier Aerospace & Ryerson University

Toronto, ON

Graduate Researcher (Product Development)

Sept 2018 – Oct 2019

- Spearheaded the development of an entire neural network to categorize large image data sets for facial identification to be used to automate and reduce workload of cabin crew members using MATLAB and Python
- Employed statistical analysis to improve process flow, resource utilization and aide project management.
- Ensured that the designs of the project moved into prototype stage and eventually was manufacturable. This included quality assurance and methods engineering.

Honda of Canada Manufacturing

Alliston, ON

Internal Parts Auditor (Quality)

Aug 2017-Jan 2018

- Employed statistical process controls (SPC) techniques, metrological testing and root cause analysis to identify and enforce quality control and to ascertain products are within specification.
- Conducted routine audit of raw material supplies and production line output of 500+ automotive parts everyday inside a high-volume manufacturing facility.
- Performed Measurement System Analysis (MSA) and equipment calibration.
- Put lean manufacturing philosophy to practice to achieve waste reduction and employed advanced quality tools like Kaizen, 5S and 5-Why techniques to ensure on-time operations
- Performed receiving inspection and acceptance sampling operations. Participated in APQP.

Indian Space Research Organization

Kerala, India

Engineering Intern

June 2016-Dec 2016

- Key player of a team responsible for the development of a multi-axis tuning loop for a two degree of freedom Dynamically Tuned Gyroscope (DTG) at India's prestigious space agency (ISRO).
- Spearheaded the modelling of the system and the proposed cross-axis and direct-axis combination control loop in Simulink and MATLAB based on the gyroscope equations of motion, then developed a deflection sensing system, analyzed the generated signal, and developed a system to apply the appropriate amount of torquer current to rebalance the spinning rotor.
- Achieved success in this project resulting in improved performance and reliability compared to the then in use cross-axis control loop.
- Played a key role in the integration of the developed technology into the inertial guidance system of ISRO's sounding rockets.
- Supported senior engineers in testing, maintenance and statistical process control of equipment.
- Developed fault-tree analysis and assisted in reliability estimations of subsystems

Education

CS50: Introduction to Computer Science

Harvard University | USA

Status: In progress

Master's in Engineering – Aerospace/ Mechanical Engineering

Toronto Metropolitan (formerly Ryerson) University | Toronto

Status: Graduated in 2019

Ontario College Graduate Certificate in Quality Assurance - Manufacturing & Management

Sheridan College | Brampton

Status: Graduated in 2017

Bachelor's Degree in Mechanical/Aeronautical Engineering

University of Calicut | India

Status: Graduated in 2016

Certifications

- **Certified Six Sigma Green Belt (CSSGB)** – Six Sigma Academy and Ryerson University
- **Certified Process Quality Analyst (CPQA)** - American Society for Quality (ASQ)
- **Certified Quality Technician (CQT)** - American Society for Quality (ASQ)
- **Certified Quality Engineer (CQE)** - American Society for Quality (ASQ)
- **Certified Medical Devices Auditor (CMDA)** - American Society for Quality (ASQ)
- **Certified Reliability Engineer (CRE)** - American Society for Quality (ASQ)
- **Engineer-in-Training (EIT)** - Professional Engineers Ontario (PEO)
- **Professional Engineer (P.Eng.)** - Professional Engineers Ontario (PEO) –*Experience review in progress*
- **Project Management Professional (PMP)** – Project Management Institute (PMI) – *In progress*