

Arun Baby

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The Ontario Public Service
Toronto, Ontario

Aug 06, 2023

Dear Hiring Manager:

RE: Program Advisor

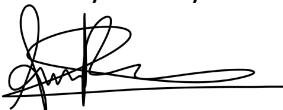
I am writing to express my interest in the Program Advisor position as advertised on your website. After carefully reviewing the job posting, I am confident that as a candidate with several years of engineering and policy development experience in highly regulated industries ranging from medical devices,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

I currently lead all aspects of the quality department for a company operating in a highly regulated medical devices industry, including developing company policy, engaging with external stakeholders, analyzing large volumes of data and communicating findings to executive management, recommending policy changes to management, championing improvement actions and organizational change. I played a pivotal role in the transfer of research technologies into manufacturing including implementing cGMP's and driving engineering changes by engaging in negotiations with over 100+ personnel. 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 greatly interests me because my experience and education perfectly aligns with the opportunity, and I am certain 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 is a testament that I can competently execute the responsibilities of the role. My zeal to constantly improve, both in my knowledge and in my skills, would be an asset to you. I am also an ASQ certified Reliability Engineer (CRE) and Quality Engineer (CQE).

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 The Ontario Public Service.

Thank you for your time and consideration and I look forward to hearing from you.



Yours sincerely,

Arun Baby

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EIT, ASQ-CQE, CRE, CMDA

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Summary

- Specializing in quality engineering, risk and project management in highly regulated industries with over 5 years of experience and an ASQ Certified Quality and Reliability Engineer (CQE, CRE).
- Leader in implementing organizational wide change to lift a startup from a research lab to a GMP manufacturing facility which obtained its ISO certification.
- Expert in ISO standards and national and international regulations and developing organizational policies and procedures.
- Proficient in data analysis and management using Minitab, MATLAB, SQL and Python.
- Key leader in identifying long term goals, long term policy planning, project management and managing multiple priorities.
- Peer recognized leader in continuous improvement initiatives for process improvement and organizational change.

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 by promoting awareness, 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 QMS including but not limited to QC, QE, supplier and asset management, training and mentoring, etc.
- Communicate results of large data analytics, recommendations on future policy, guidance and regulatory changes to top management for decision making
- Lead and oversee risk management initiatives for a high-risk medical device including identification, risk assessment, mitigation and their verification.
- Lead investigations, champion continuous improvement (DMAIC/ Lean-Six Sigma) initiatives including implementation of best-in-class practices.
- Experienced manager managing direct reports from engineering and development, operations, development, and manufacturing.

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 executor in developing and implementing a company-wide calibration program along with selection and management of service providers.
- Coordinated with Director of Quality and 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.

Ultrasound Quality Control Associate

Nov 2020 – Dec 2021

- Developed and implemented processes and procedures for testing and quality control of completed transducer 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.
- Drafted, reviewed, and verify technical documentation, including test procedures, work instructions and other quality documents including the Quality Management System (QMS) of the entire organization. Verified and approved records of manufacturing
- 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.
- Performed as the sole quality professional within the company for almost half a year.

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

Downsview Park, 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 as per transportation industry best practices.

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 and implementation of a multi-axis tuning loop for a two degree of freedom Dynamically Tuned Gyroscope (DTG) at India's prestigious space research 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.
- Developed and maintained detailed documentation (FMEA) of mission-critical subsystem
- Supported senior engineers in testing, maintenance and statistical process control of equipment.
- Developed fault-tree analysis and assisted in reliability estimations of subsystems for sounding rockets.

Education

Master's in Engineering – Aerospace/ Mechanical Engineering

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 & Professional Memberships

- **Engineer-in-Training (EIT)** - Professional Engineers Ontario (PEO)
- **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)
- **Professional Engineer (P.Eng.)** – Experience review in progress
- **Introduction to Project Management** – University of Adelaide/edX