Arun Baby

Ph: 647-877-9762   EIT, ASQ-CQE, CRE, CMDA   **Email:** arunbaby.gc@gmail.com
LinkedIn: arunbaby1   **Address:** Toronto, Ontario

Summary

- Specializing in quality and process 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.
- Well versed in ISO 9001 (QMS), ISO 13485 (Medical Devices), 21 CFR 820 (Medical Devices), ISO 14971 (Medical Devices Risk Management) and IEC 62304 (Software)
- Leader in all aspects of risk management, process and quality engineering for a complex FDA Class III medical device.
- Experienced developer specializing in automating redundant manual tasks in manufacturing and data acquisition and synthesis.
- Currently dabbling in data science and Large Language Models (LLMs) for professional growth

Work Experience

Arrayus Technologies Inc. (Harmonic Medical)   Toronto, ON

Quality Assurance Specialist   Oct 2022 – Present
- Designed and developed an automated system (software and hardware) 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.
- 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 Management, Asset Management, Training, ECO's, and root cause analysis.
- 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 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
- Developed a central data repository for operations using MySQL which currently handles large volumes of mission critical data daily.
- 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 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 software and hardware validation (V&V) plans 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
- Analyzed and interpreted large volumes of test data and developed a system to automate the acquisition process 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.
- Played a key role in educating staff coming from a research background on the principles of quality assurance, process and software V&V.
- As project leader, developed a multi-year project plan to automate major aspects of manufacturing, data acquisition and synthesis

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 to improve detection accuracy of the system by 61%.

Bombardier Aerospace & Ryerson University   Downsview Park, ON

Graduate Researcher (Product Development)   Sept 2018 – Oct 2019
- Spearheaded the development of a novel entire convolutional neural (CNN) network to categorize large image data sets for facial identification to be used to automate and reduce workload of business aircraft cabin crew members using MATLAB and Python. This CNN was designed from the ground up to remove bias based on skin tone and to protect privacy.
- Integrated the developed CNN to Bombardier's next generation cabin program for their business jets along with other concurrent technologies under development.
- Supervised a team of 5 undergraduate students from various engineering departments for the CNN development.
- 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 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

CS50: Introduction to Computer Science
Harvard University |USA   *Status: In progress*

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