

# Arun Baby

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## Summary

- Specializing in quality engineering and risk 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.
- Well versed in ISO 9001 (QMS), ISO 13485 (Medical Devices), 21 CFR 820 (Medical Devices), ISO 14971 (Medical Devices Risk Management) and IEC 62304 (Medical Device Software)
- Leader in all aspects of risk management and quality engineering for a complex FDA Class III medical device.
- Key leader in successful achievement of MDSAP certification for Arrayus, recently achieved an ASQ Certified Reliability Engineer certification and dabbling in data science for professional growth.
- 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 Management, Asset Management, Training, ECO's, and root cause analysis.
- Promote awareness of regulatory, risk and quality requirements, ensuring processes required for QMS are documented, and reporting to management with executive responsibilities on the effectiveness of QMS and any need for improvement.
- Draft, review and verify technical and quality system documentation.
- 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.
- Lead and/or manage internal and external audits and their resulting correction plans.

#### **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 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.
- Analysed 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.

### **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