Covering Letter

Mukunda M

Dear,
Sir/ Madam,

It is with great interest that I present to you the enclosed resume in response to Quality assurance/Quality control position you are looking to fill. As a highly skilled and accomplished professional with comprehensive expertise in quality assurance and validation, I possess a wide range of knowledge and experience that will allow contributing towards the success of your company.

My expertise lies in successfully managing teams, processes and strategic programs to drive continuous quality improvement efforts through audits and special projects. Through my experience, I have amassed a breadth of knowledge in analyzing data and orchestrating project implementations, as well as ensuring compliance with local and federal regulations. Additionally, my established success in training and directing staff positions me to make a significant contribution to your organization.

The following achievements demonstrate my qualification for this position:

Managing vital quality control initiatives, compliance concerns, audits, and operational processes and procedures within corporate guidelines.
Communicating and collaborating with cross-functional teams—including engineers, project managers, and business development teams to design new test methods to meet customer goals and realize continuous improvement.

Training, mentoring, and leading QA/QC team members to ensure full understanding of internal procedures and drive effective integration of processes.

Demonstrating outstanding analytical, staff leadership, problem-solving, and communication abilities.
My dedication to maximizing quality assurance and validation efforts, along with my acute knowledge of quality audits and compliance issues, will contribute immensely to the success of your team. Thank you for your consideration. I look forward to speaking with you soon.

Furthermore with a history of success of contributing to Medical devices industries i would immediately respond to any of the QC/QA and auditing activities.
Enclosed is my Resume for your review which contains additional details of my professional accomplishment. I welcome the opportunity to discuss with you personally how my skills and strengths can best serve your organization.

Skills: Microbiology aspects, QMS Implementation, Medical device regulations, validations, CAPA implementation, results oriented, process improvement.
Certification:

1. Certified internal auditor ISO 13485:2016 from BSI
2. Certified Lean Six Sigma Green belt from TUV SUD
3. ICMED Certification from TUV SUD South Asia

Sincerely
Mukunda M

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Career Objective:

Aspiring for a challenging career as a quality professional, to work for a reputed organization where there is an opportunity to share, contribute and upgrade the organization & learn all the aspects, which are important for the development for various projects for the organization & for Self.

Professional Summary:

Quality Assurance Manager with over 16 years of experience in the medical device industry and pharmaceutical, specializing in FDA and ISO 13485 compliance, QMS development, and cross-functional leadership. Proven success in managing audits, driving CAPA programs, ensuring design control compliance, and leading risk management processes. Adept at fostering a culture of continuous improvement and regulatory excellence. Manage Quality control and Quality assurance teams.

- Oversaw all Quality Assurance and Quality Control activities.
- Coordinated with Production, QC, Warehouse, and Maintenance regarding non-conformance and corrective actions.
- Managed the preparation of the Annual Product Review (APR).
- Managed the microbiology testing division, reinforcing expertise in the field.
- Managed vital quality control initiatives, compliance concerns, audits, and operational processes within corporate guidelines.
- Spearheaded the CAPA implementation process for product complaints and sterilization/environmental microbial control issues.
- Conducted and assisted in Internal and External Quality Systems Audits.
- Collaborated with cross-functional teams (engineers, project managers) to design new test methods and drive continuous improvement.
- Quality professional with 16 years of progressive experience with sound knowledge in quality assurance and quality control functions. Successful completions of regulatory audits viz, US FDA, TGA, WHO and EDQM, Expertise in product nonconformance, investigation, deviations, CAPA.
- Change management, vendor audits and quality document management. Analytical method validations (Bioburden, BET and Sterility etc) of medical devices. Knowledge on microbiology requirements.
- Knowledge on ISO 13485 and MDR 2017.
- Monitoring of Incoming materials
- Supplier Quality Management
- Knowledge of Ethylene oxide sterilization
- Risk management per ISO 14971
- Knowledge of ISO 17025.
- Ethylene oxide sterilization
- Develop Validation protocols (IQ, OQ, PQ)
- Handling of product complaints and providing CAPA for the same.
- Assist in Internal and External Quality Systems Audits and the CAPA implementation.

- Preparation and Review of MPR, BPR and analysis reports.
- Conducting Investigation and Root cause Analysis (RCA).
- Vendor qualification.
- Post Market surveillance
- Root cause analysis
- Failure investigations
- Risk Management
- HVAC System validations.
- Complaints management.
- Preparation of Annual Product Review (APR).
- Assisted in the resolution and approval for CAPA identified issues on sterilization and environmental microbial controls and implementing proactive programs.
- Logging and handling the investigations for deviations, OOS and providing CAPA for the same.
- Handling of recalls.
- Managed quality audit program including external and internal audits, corrective actions and follow up.
- Provide support to the various divisions for effective and efficient implementation of the Quality Management System.
- Upgrade Quality Control process.
- Co-ordinate with Production, QC, warehouse and Maintenance regarding non-conformance & corrective action for the same.
- oversee the activity of the quality assurance department and staff, developing, implementing, and maintaining a system of quality and reliability testing for the organizations products and/or development processes.

- AREAS OF EXPERTISE
  ISO 13485:2016 internal Auditing
  Supplier Quality Management
  Manufacturing of DES stents systems, Catheters and guidewires and other medical devices.
  MDR 2017
  Validation
  ICH
  Risk Management (ISO 14971)
  Internal & Supplier Audits
  CAPA and Nonconformance Investigations
  Post-Market Surveillance.
  Regulatory Compliance Readiness
  Quality System Documentation
  Supplier Quality Management.
  Audit Planning & Execution
  Root Cause Analysis & Remediation
  Ethylene oxide sterilization
  FMEA

Audits:

- Knowledge over CGMP, GLP, Validation documentation and various regulatory guidelines.
- Audit Experience
  - Ø USFDA
  - Ø ISO 13485
  - Ø MHRA

- Ø KFDA
- Ø TGA
- Ø EDQM.
- Ø WHO and other customer audits.

Professional Work Experience:

M/s Cipla Limited Bangalore Unit. Quality Control department from May 2008 to June 2016
M/s R L Fine Chem Pvt. Limited as Asst Manager QA from April 2016 to Feb 2018.
M/s Vascular Concepts Limited /SMT: Manager QA/QC from Feb 2018 to February 2023
M/s TUV SUD South Asia Pvt Ltd: Auditor PS-MHS Certification division From March 2023 June 2024.
M/s Veiva Scientific India Pvt Ltd: Manager QA/QC June 2024 to August 2025.
M/s Fibroheal Woundcare Pvt Ltd: Manager QA/QC September-present

Educational Qualification:

Qualification	College/university	Year of Passing
M.Sc (Microbiology)	Bangalore university	2007
B.Sc (Chemistry, Zoology and Microbiology)	Bangalore university	2005

Declaration:

I hereby declare that the information provided above is true to the best of my knowledge.

Date:

Place: Mukunda