

# **M S KARTHIKEYAN**

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## **Professional Summary**

Quality Assurance and Process Improvement professional with 8+ years of experience in healthcare, molecular diagnostics, including Quality Management Systems, internal audits, CAPA, change control, risk assessment, KPI monitoring, and regulatory compliance. Lean Six Sigma Black Belt with hands-on experience applying DMAIC methodology, data-driven decision-making, process optimization, defect reduction, and operational efficiency improvement in compliance-driven environments. Strong working knowledge of ISO 15189:2022, CAP, NABL, and quality reporting, with stakeholder coordination across operations, laboratory, and business teams.

## **Core Skills**

- Quality Assurance, Quality Management Systems, Process Improvement, Lean Six Sigma, DMAIC, CAPA, Root Cause Analysis
- Internal Audits, Quality Review Meetings, Non-conformance Management, Change Control, Risk Assessment, Corrective and Preventive Actions
- KPI Monitoring, Data Analysis, Dashboard Reporting, Power BI, Advanced Excel, LIMS, Operational Excellence
- ISO 15189, ISO 14971, CAP, NABL, Regulatory Compliance, Laboratory Quality
- Stakeholder Management, Cross-functional Collaboration, Continuous Improvement, Team Mentoring, Training Support

## **Professional Experience**

### **LifeCell International Private Limited | Quality Assurance Assistant Manager | June 2024 - Present**

- Lead quality management activities for laboratory operations by planning, scheduling, and conducting internal quality audits as per NABL ISO 15189:2022 and CAP requirements.
- Drive CAPA, non-conformance handling, change control, and monthly quality review meetings to support compliance, defect reduction, and continuous improvement.
- Monitor and analyze operational KPIs including Process TAT, Logistics TAT, EQAS/ILC performance, rejection percentage, amendments, complaints, and repeat percentage for data-driven decision-making.
- Conduct risk assessments and implement mitigation actions to reduce quality gaps and improve process control across pre-analytical, analytical, and post-analytical workflows.
- Maintain QMS documentation and regulatory compliance for NABL & CAP accreditation requirements while collaborating with cross-functional stakeholders to sustain quality objectives.

### **Nucleome Informatics Pvt Ltd | Genomics Application Specialist | January 2024 - May 2024**

- Applied Six Sigma-based process improvement approaches to optimize sales workflows, improve performance tracking, and support revenue growth initiatives.
- Used data-driven analysis to improve market penetration, reduce sales cycle time, and enhance customer satisfaction through process optimization.
- Worked with clients and internal teams to strengthen stakeholder engagement, retention, and solution-focused communication.

### **PrimeGen Healthcare Laboratory Pvt Ltd | Molecular Executive | August 2020 - September 2023**

- Supported implementation and maintenance of ISO 15189:2022-compliant Quality Management Systems for molecular diagnostic operations.
- Conducted internal audits, managed CAPA processes, maintained regulatory documentation, and ensured audit readiness in compliance-driven laboratory environments.

- Strengthened data integrity, traceability, and workflow efficiency through LIMS support and risk-based quality control practices.
- Contributed to continuous process improvement initiatives focused on patient safety, compliance, and operational consistency.

### **MicroGenomics India Pvt Ltd | Jr. Molecular Technologist | April 2018 - July 2020**

- Supported end-to-end molecular diagnostic workflows with focus on sample integrity, accuracy, consistency, and high-throughput process execution.
- Improved operational discipline in sample handling and logistics processes to maintain quality and reduce process variation.

### **Six Sigma Project Experience**

#### **DMAIC Project: Sample Rejection Reduction**

**July 2025- February 2026**

- Led a DMAIC project to reduce controlled sample rejection rate from 5% to below 1% by identifying root causes in pre-analytical handling, standardizing controls, and improving process compliance.
- Strengthened control mechanisms through KPI monitoring, audit follow-up, and CAPA tracking, improving operational efficiency and reducing quality-related waste. This project saved 2 lakhs in monthly cost.

#### **DMAIC Project: Non-conformance and CAPA Effectiveness Improvement**

**July 2024- March 2025**

- Led a process improvement initiative to reduce recurring non-conformities by strengthening change control, CAPA closure tracking, and monthly quality review governance using risk-based prioritization.
- Improved compliance effectiveness through structured root cause analysis, mitigation planning, and control measures aligned with ISO and accreditation requirements. It increased operational efficiency by 2% and reduced costing.

#### **DMAIC Project: TAT and Quality KPI Optimization**

**February 2025- Present**

- Executed a Six Sigma project focused on Process TAT, Logistics TAT, complaint trends, repeat percentage, and amendment reduction using KPI analysis and workflow standardization.
- Improved process visibility through data review and reporting, enabling faster decisions, better stakeholder communication, and higher operational consistency. This is control project helps to monitor Waste in Lab operations

### **Key Achievements**

- Completed two audits with minimum non-conformities and participated in NABL and international CAP/CLIA audit environments.
- Reduced sample rejection rate from 5% to below 1% through structured process improvement initiatives.
- Supported quality systems that improved audit readiness, compliance performance, and process discipline in diagnostic operations.

### **Certifications**

- Lean Six Sigma Black Belt by Hendry Harvin
- ISO 15189:2022 Medical Laboratories - Requirements for Quality and Competence and Internal Audit.
- Business Analysis by Henry Harvin.
- Power BI.
- Advanced Excel.
- Certified 5S Auditor.

### **Education**

- MBA in Healthcare Management, Suresh Gyan Vihar University. **2020-2022**
- B.Tech in Biotechnology, Karpaga Vinayaga College of Engineering and Technology. **2013-2017**