

CURRICULUM VITAE

Mr. Udayabhaskhar Kilari

Quality Assurance & Regulatory Compliance Expert

Professional Summary

Quality Assurance (QA) and Regulatory professional with 10+ years of experience in ISO 15189, ISO 13485, and ISO/IEC 17025-based systems across diagnostics, medical devices, and healthcare. Skilled in internal audits, risk management, CAPA, documentation control, and accreditation processes for laboratories and MedTech organizations.

Core Skills

- ISO 15189, ISO 13485, ISO/IEC 17025 Auditing
 - Clinical Laboratory QA/QC Systems
 - Internal Audits, Risk Management & CAPA
 - SOP Development & Regulatory Documentation
 - Conformity Assessment for Diagnostics & Medical Devices
 - Training & Capacity Building
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Professional Experience

- Scientist D – KIHT, AMTZ (May 2023 – Present)
 - Assistant Director – NABL (Feb 2023 – May 2023).
 - Executive Officer – NABL (Sep 2016 – Aug 2020)
 - Technical Support Specialist – Ortho Clinical Diagnostics (May 2016 – Sep 2016)
 - Clinical Biochemistry Incharge – Manipal Super Speciality Hospital (May 2013 – May 2016)
 - Tutor – Krishna Teja Pharmacy College (Sep 2012 – Apr 2013)
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Education

- Master of Science in Medical Biochemistry – Sri Venkateswara University of Medical Sciences.
 - ISO 15189 Auditor Course – Siddhartha Medical College (2016)
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Key Achievements

- Led quality systems implementation aligned to ISO 13485, facilitating clinical validation readiness for MedTech startups.
 - Guided ISO 15189 accreditation for diagnostic labs that supported early-phase trials and disease surveillance programs.
 - Trained over 150 lab professionals and auditors in regulatory-compliant QA practices relevant to research and diagnostics.
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CURRICULUM VITAE

Ms. K L N V Durgankitha

Biomedical Engineering & Quality Systems Professional

PROFILE SUMMARY

Biomedical engineering professional with 10+ years of experience in clinical engineering, calibration, metrology, ISO-based quality systems, NABL accreditation, preventive maintenance, documentation, and technical training. Certified Internal Auditor for ISO 17025:2017 and ISO 13485:2016 with strong capability in biomedical operations, equipment lifecycle management, and organizational quality excellence.

CORE COMPETENCIES

- Biomedical Operations Management
 - Calibration & Metrology
 - ISO 17025 / ISO 13485 / ISO 9001 Documentation
 - NABL Accreditation & Audit Compliance
 - Preventive Maintenance & Breakdown Management
 - Technical Training & Skill Development
 - Vendor & Contract Coordination
 - Equipment Lifecycle & Asset Management
 - Project Leadership & Team Coordination
 - Quality Assurance & Internal Audits
 - SOP Development & Documentation Control
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PROFESSIONAL EXPERIENCE

- Scientist A – Indian Biomedical Skill Consortium (AMTZ) (Sep 2024 – Present)
 - Senior Quality Executive – Trimed Solutions India Pvt. Ltd. (Nov 2020 – Aug 2024)
 - Biomedical Incharge – OMNI Hospitals (Nov 2016 – Oct 2020)
 - Biomedical Engineer – TBS India Pvt. Ltd. (Nov 2015 – Oct 2016)
 - Biomedical Trainee – Manipal Hospitals Vizag (Jul 2011 – Dec 2011)
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EDUCATIONAL QUALIFICATIONS

- B.Tech in Biomedical Engineering – BVRIT College (72.45%)
 - Diploma in Biomedical Engineering – S.V.G.P Polytechnic College (65%)
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CERTIFICATIONS

- ISO 13485:2016 Internal Auditor – Completed
 - ISO 17025:2017 Internal Auditor – Completed
 - Biomedical Equipment Calibration & Analyzer Handling Certification
 - Training & Assessment Skills (Internal)
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