

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. Revathi Korupolu

Quality Management & Regulatory Affairs Professional

Professional Summary

Experienced Quality Assurance and Regulatory Affairs professional with strong expertise in ISO 13485, ISO 9001, and ISO 17021-1-based certification systems. Skilled in medical device QMS audits, documentation control, CAPA, risk management, SOP development, and regulatory compliance. Demonstrated background in diagnostics, CROs, and medical device industries.

Core Skills

- ISO 13485:2016 & ISO 9001:2015 Lead Auditor
 - QMS & MDQMS Auditing
 - Regulatory Documentation & Technical File Management
 - Risk Management & CAPA
 - Internal Audit Planning & Implementation
 - SOP Development & Quality Documentation
 - Regulatory Compliance for Medical Devices
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Professional Experience

- Quality Manager – KIHT Certification Services (KCS), AMTZ (Jun 2022 – Present)
 - Executive – QARA, Trivitron Healthcare Pvt. Ltd. (Nov 2021 – May 2022)
 - Assistant – QA, DNA Xperts Pvt. Ltd. (Dec 2020 – Aug 2021)
 - Team Lead – Longdom Group (Dec 2017 – May 2020)
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Education

- Master of Pharmacy (Regulatory Affairs & Pharmaceutical Management) – Andhra University (2017)
 - Bachelor of Pharmacy – Andhra University (2015)
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Certifications

- ISO 13485:2016 Lead Auditor – BSCIC
 - ISO 9001:2015 Lead Auditor – Intertek
 - ISO/IEC 17021-1 & 17021-3 Accreditation Training – APAC
 - Biomedical Quality Assurance Certification – IBSC
 - Training on Indian Medical Device Rules (IMDR 2017)
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Publications

- Review on Coronary Bioresorbable Vascular Scaffold System – JOCCT (2017)
 - Review on European Medical Device Regulations – PharmaTutor (2018)
 - Pre-Clinical Requirements for Drug-Eluting Stents – IJRASET (2023)
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CURRICULUM VITAE

Mr. Karthik Raj V

Biomedical Engineering & Regulatory Affairs Professional

PROFILE SUMMARY

Biomedical engineering professional with 14+ years of experience across quality, regulatory affairs, teaching, biomedical equipment maintenance, and ISO standards implementation.

CORE COMPETENCIES

- ISO 13485 Lead Auditor
 - ISO 9001 Lead Auditor
 - Risk Management (ISO 14971)
 - Biomedical Equipment Training
 - Regulatory Documentation
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PROFESSIONAL EXPERIENCE

- Scientist-B – AMTZ (2021 – Present).
 - Assistant Professor – Vel Tech University (2020 – 2021)
 - General Manager – TDAC Solutions (2019 – 2020)
 - Assistant Professor – SRM University (2011 – 2019).
 - Service Engineer – Trinity Healthcare Systems (2008 – 2009)
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EDUCATIONAL QUALIFICATIONS

- ME – Medical Electronics, Anna University (2009–2011)
 - B.Tech – Biomedical Engineering, University of Calicut (2004–2008)
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JOURNAL PUBLICATION

- More than 18 research articles published in various International or Scopus-Indexed Journals.
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