

Terms of Reference

About Kalam Institute of Health Technology (KIHT)

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Kalam Institute of Health Technology (KIHT), Visakhapatnam (A WHO Collaborating Centre for Health Innovation & A Regional Resource Centre (RRC) of Health Technology Assessment in India (HTAI) under the Department of Health Research (DHR), Ministry of Health & Family Welfare, Government of India)

Company Website:

<http://amtz.in/>

<http://kiht.in/>

<http://biovalley-amtz.in/>

<https://medivalley-aic.in/>

Job Title

Scientist-Lead Auditor-KCS

Key Responsibilities

1. Plan, schedule, and conduct ISO 13485:2016 and ISO 9001:2015 certification audits, including Stage 1, Stage 2, Surveillance, and Recertification audits.
2. Review & Verify Quality Management Systems (QMS), technical documents, risk management files, and operational processes to ensure compliance with applicable standards.
3. Prepare audit plans, audit reports, certification recommendations, and verify the effectiveness of corrective actions submitted by clients.
4. Provide technical support and guidance to audit teams and contribute to the implementation of certification schemes as per ISO/IEC 17065
5. Conduct technical training, awareness programs, and workshops for clients, auditors, and other stakeholders on ISO standards, certification requirements and any other relevant topics.
6. Work closely with clients and internal teams to ensure the timely and effective completion of certification activities while maintaining impartiality, confidentiality, and professional standards.
7. To Undertake the assignments, which may be assigned from time to time.

Qualification & Experience

1. Qualification: Bachelors/Master's degree in Engineering/Biomedical Engineering
2. Experience: Minimum 5-10 years of experience in the relevant field.
3. Technical Skill Set Able to converse in technical terms specifically standards.
4. Knowledge in Certification, Auditing Procedures, Auditing skills, audit report writing
5. Knowledge in Technical Specifications of the Medical Devices/ Equipment
6. Domain Expertise Must have Domain Experience in Quality Assurance, Quality Control. MDQMS & QMS
7. Computer literacy including advanced proficiency with Microsoft Office (Excel, Word & PPT)
8. Must have advanced proficiency with Microsoft Office (Excel, Word & PPT)
9. Excellent communication and presentation skills, analytical, problem-solving skills and interpersonal abilities, Decision-making, excellent oral and written communication skills in English.
10. Must have Team Spirit, Agility, Leadership, Initiative, time management, prioritizing and the ability to handle a complex and varied workload.
11. Must maintain confidentiality and discretion in all aspects and be comfortable with flexible working schedule to meet the needs of the Company.
12. Ability to handle urgent matters, multiple tasks, simultaneously and quickly complete the assigned tasks.
13. Willingness to Travel.
14. Age up to **40** years