

Applicants are required to appear for **Virtual Interview** with prior intimation to hr@kiht.in before **23rd February 2026**. Kindly send your profile with educational certificates, pay-slips for the recent three months, experience certificates and other documents. Shortlisted Applicants will be intimated over email with interview dates (**04.03.2026, 05.03.2026, 06.03.2026 and 07.03.2026**) along with the virtual link on or before **2nd March 2026**.

Scientist - Quality Assurance & Regulatory Affairs

Terms of Reference:

1. QMS Implementation: Develop and maintain the Quality Management System (QMS) in compliance with ISO 13485:2016 and FDA 21 CFR 820.
2. Document Control: Manage Device Master Records (DMR), Design History Files (DHF), and Device History Records (DHR).
3. Audit & Inspection: Conduct internal audits and manage external inspections (FDA, Notified Bodies).
4. CAPA & Compliance: Manage Corrective and Preventive Actions (CAPA), nonconforming material reports, and complaint handling.
5. Risk Management: Perform risk analysis according to ISO 14971.

Regulatory Affairs (RA):

6. Regulatory Strategy: Develop strategies for product registration and launch in target markets (e.g., US FDA, EU MDR, CE Marking).
7. Submissions: Prepare and submit technical files, 510(k), PMA, or CE technical documentation.
8. Post-Market Surveillance: Monitor product performance, handle recalls, and manage vigilance reporting.
9. Labeling & Advertising: Review product labels, user manuals, and marketing materials for compliance.

Required Skills and Qualifications

10. Education: Bachelor's degree in Biomedical Engineering, Pharmacy, Life Sciences, or related technical field.
11. Experience: 3-8+ years of experience in medical device QA/RA.
12. Knowledge: Deep understanding of ISO 13485, ISO 14971, FDA 21 CFR 820, and EU MDR/IVDR.