Aurigene is a development stage biotech company engaged in discovery and clinical development of novel and best-in-class therapies to treat cancer and inflammatory diseases, and a wholly owned subsidiary of Dr. Reddy's Laboratories Ltd. Aurigene is focused on precision - oncology, oral immune checkpoint inhibitors, and the Th-17 pathway. Aurigene currently has several programs from its pipeline in clinical development and multiple compounds at different stages of pre-clinical development. Aurigene has partnered with many large and mid-pharma companies in the United States and Europe and has 15 programs currently in clinical development. Aurigene is a profitable company that has continuously invested in its people resources, infrastructure and expertise over the years.

Position	Deputy Manager
Department	Development Quality Assurance (CMC)
Location	Bangalore
Desired Profile	Masters (Pharmaceutical Chemistry / Quality Assurance / Analytical Chemistry / Organic Chemistry) with 8 - 12 years' experience.
Job Description, Key Skills and Competencies:	• Prepare Revise and Peer Review Standard Operating Procedures and Guidelines for DQA. • Responsible for review of analytical documents from early & late-stage development, technology transfers to GMP manufacturing across CMOs for drug products. • Review drug product analytical documentation such as protocols, SOPs, test methods, data, ROAs, COAs and reports through collaboration with ARD and QC scientists, to achieve the highest quality from technical and compliance perspectives. • Review pre-formulation development documents of analytical method development/validation reports, stability protocols & reports, and pre-formulation studies. • Review data for specifications proposals, test methods and Master formula cards for finished products. • Responsible for investigations against laboratory Incidents, OOS, OOT encountered with aim of root cause identification and CAPA implementation. • Responsible for assessing the impact, review and closure of Change control requests. • Responsible for CAPA implementations, verification of and effectiveness. • Review and approval of Stability management activities of Drug substance and Drug products such as Stability Protocol, data and stability summary report. • Responsible for maintaining the Quality Metrics and preparation of Quality Metrics. • Plan, execute internal audits and communicate audit schedules, outcomes to audit stakeholders ensuring CAPA appropriateness for closer, audit trending for continual quality improvement.

	Competencies: • Presentation & Communication Skills • Excel Skills • Interpersonal Skills • Team Player • Negotiation Skills
Company Overview	Please visit http://www.aurigene.com
Apply Now	Please send your profile at careers@aurigene.com