Aurigene Oncology
Conquering Cancer

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 and has multiple compounds at different stages of pre-clinical development and several products in pipeline in clinical development. Aurigene has recently broadened spectra and initiated programs in large molecules like development of antibodies using different display platforms as well as development of high-class and affordable cellular therapy products. Aurigene is a profitable company that has continuously invested in its people resources, infrastructure, and expertise over the years.

Position	Assistant / Deputy Manager – Cell & Gene Therapy – QA
Location	Bangalore
Desired Profile	Master's or PhD (Quality Assurance / Biotechnology) with 10 years' experience. Must have experience in Biologics.
Job Description, Key Skills, and Competencies:	• Adhere to all applicable organizational policies & procedures on safety, data integrity, POSH and IT security, and ensure the same for the QA team. • Implementation, maintenance, and continual improvement of phase appropriate Quality Management Systems. • Lead and monitor QA team to ensure compliance to applicable cGMP and regulatory requirements/ expectations, to ensure manufacturing activities are performed accordingly. • Conduct periodic Management review meetings. • Ensure QA oversight on all the GMP areas, including but not limited to, Manufacturing, QC labs, Warehouse, Utilities, other support areas, etc. • Review and approval of all the GxP documents including, but not limited to, procedures, policies, protocols, specifications, BMR, risk assessments, STPs, etc. • Ensure timely review, approval & closure of change controls, deviations, OOS and ensure implementation of effective CAPA. • Support cross functional teams in deviation investigation and for proposing effective CAPA. • Oversee and manage vendors & GMP service providers, perform audits and approve/reject same based on assessment. • Lead internal audits to ensure adherence to implemented procedures & policies and compliance with applicable regulatory requirements and ensure implementation of CAPA. • Management and hosting of external audits (client and regulatory) and provide timely response to audit findings, including appropriate CAPA.

	• Review and approval/rejection of BMR of investigational medicinal product for intended purpose and its timely release. • Support preclinical related QMS activities by providing input and oversight in line with applicable regulatory requirements and internal procedures. • Coordinate with Regulatory Affairs department for providing necessary support preparation & filling of CMC sections of regulatory submissions. Review & approve periodic QMS trend reports and propose corrective actions, as applicable
Company Overview	Please visit http://www.aurigene.com
Apply Now	Please send your profile at careers@aurigene.com