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	Sr. Executive / Executive – Cell & Gene Therapy – QA
Location	Bangalore
Desired Profile	Masters in (Quality Assurance / Biotechnology) with 2 - 8 years' experience. Must have experience in Biologics.
Job Description, Key Skills, and Competencies:	• Review of qualification (IQ, OQ & PQ) documents related GMP Mfg. facility for Cell & Gene Therapy products. • Initiation, review, assessment, verification, closure of qualification related QMS (Change Control, Deviations, CAPA, Discrepancies, risk assessments etc.). • Review of qualification protocols for clean room qualification, HVAC systems and support users for execution of qualification activities. • Review of qualification protocols for equipment/instruments for DQ, IQ, OQ, PQ and support users for execution of qualification activities. • Involve in qualification/re-qualification activities of BSC, Deep Freezers, HVAC, process equipment, Utilities, • Review of Master Equipment List, various planners (calibration, PM, re-qualification/validation) • Support for Qualification Engineering Service providers. • Review of executed PM, calibration, and re-qualification documents. • Review process validation and process simulation (media fill) protocols and reports. • Review and provide support and guidance for CSV documents and activities. • Participate and support technology transfer projects. • Support for all internal and external audits. • Support for review of change control, deviations, CAPAs and ensure timely closure of same. • Support for review of Batch Manufacturing Records (executed & Master).

	• Support/participate in investigations related to facility, utility, and environmental monitoring (OOS/OOT) • Ensuring quality oversight in manufacturing areas.
Company Overview	Please visit http://www.aurigene.com
Apply Now	Please send your profile at careers@aurigene.com