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 Manager / Deputy Manager – Quality Assurance (Biopharmaceuticals)
Location	Bangalore
Desired Profile	Masters/M. Tech (Biotechnology/Molecular Biology/Biochemistry with prior experience in Quality Assurance) with 8 - 12 years' in Biopharmaceutical Industry.
Job Description, Key Skills, and Competencies:	• Implement quality systems for GMP manufacturing activities. • Prepare, implement system SOPs in GMP facility to ensure compliance as per regulatory requirements. • Preparation of Qualification protocols for clean room qualification, HVAC (Heating ventilation and air conditioning) systems and execution of qualification activity. • Review of technology transfer documents and initiate the validation accordingly in plant scale by coordinating with CFT. • Review of Master Batch Manufacturing records executed Batch manufacturing records. • Oversee change control, Deviations and follow-up with CFT members for effective and timely implementation of CAPA. • Investigate against OOS and OOT, encountered for root cause identification/analysis (RCA) through QRM tools. • Conduct cGMP training sessions to educate all employees for better understanding of regulatory requirements. • Maintain and update internal departmental procedure in accordance with ICH and global regulatory guidelines. • Ensuring compliance of quality systems by continuous monitoring on shop floor. **Competencies:** • Sound knowledge of ICH, cGMP, 21CFR part11, MHRA, USFDA and ISO guidelines. • Prior experience in biopharma/cell & Gene Therapy QMS is desirable • Presentation & Communication Skills • Excel Skills • Interpersonal Skills • Team Player • Negotiation Skills • Stakeholder Management

Company Overview	Please visit http://www.aurigene.com
Apply Now	Please send your profile at careers@aurigene.com