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. 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	Senior Executive – Quality Assurance
Location	Bangalore
Desired Profile	Masters/M.Tech (Biotechnology/Molecular Biology/Biochemistry with prior experience in Quality Assurance) with 6 - 8 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. • Preparation of Qualification protocols for Manufacturing equipment for DQ, FAT/SAT, IQ, OQ, PQ 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/Vaccine manufacturing QMS is must • 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