

RAJENDRA KHULE

SUMMARY

Result oriented Quality Assurance professional with 12 years of experience in the regulated pharmaceutical industry. Expertise in Sterile, Non-sterile, and Peptide API processes.

Holds a Master's in Organic Chemistry, a PG Diploma in Operations Management, and an LLB. Completed Auditor certification for GMP requirements in API Manufacturing, Investigators Certification Programme, Effective Communication Skills Programme, and Lean Six Sigma Yellow Belt.

Currently a Sr. Executive in Quality Assurance at Piramal Pharma Limited with prior experience at Solara Active Pharma Sciences Ltd, Pfizer Healthcare India Pvt Ltd, Dr. Reddy's Laboratories Ltd, and Sequent Scientific Ltd.

EXPERIENCE

Sr.Executive Quality Assurance, 02/2022 – Current

Piramal Pharma Limited - Turbhe

- ⇒ Responsible for Management of e-QMS activities through Track wise like Initiation, Review & Approval of Change control, Deviations & CAPA.
- ⇒ Ensure authorized customer quality agreements are maintained & to ensure activities conducted in accordance with approved quality agreements to meet customer requirement.
- ⇒ To notify Customer about major changes, failures in Product/ Process as per quality agreement.
- ⇒ To escalate long pending QMS issues to Site Leadership Team.
- ⇒ To prepare and review Nitrosamine and Elemental impurities Risk Assessment.
- ⇒ Training: To provide the necessary training and support to cross functional employees.
- ⇒ Audits: Maintain any time inspection readiness level.
- ⇒ To provide the necessary support by active participation as an QMS SME in any Regulatory inspection of agencies like USFDA, Health Canada, AIFA, WHO GMP, MHRA, CDSCO or Customer audit.
- ⇒ To support activities related to Vendor qualification Program & Internal Audit.
- ⇒ R&D Support: To Provide quality assurance oversight for peptide R&D for Implementation of QA procedures and Technology Transfer.

Sr. Executive Quality Assurance, 01/2019 - 02/2022

Solara Active Pharma Sciences Ltd – Ambarnath

- ⇒ To ensure that all the activities carried out as per approved standard operating procedures and regulatory norms.
- ⇒ To support Regulatory Affairs for DMF submission, provide necessary documents from Site for DMF submission & Query Response to meet business requirement.
- ⇒ To prepare Application & Compile supporting documents for application of Drug Manufacturing License, COPP (Certificate of Pharmaceutical Product), WC (Written Confirmation) & CT-15 for new Drug Products to meet Business requirements & timeline.
- ⇒ To Respond Customer Questionnaire & Queries on time to meet business requirements.
- ⇒ To prepare Product Quality Review (PQR).
- ⇒ To participate in all qualification and validation related activities.



CONTACT

Address: Badlapur, Thane-421503
Phone: +91-7756023081/9423790681
Email: khule.raj@gmail.com

SKILLS

- ⇒ Quality Management System.
- ⇒ Data Integrity (ALCOA+)
- ⇒ Risk Assessment-Nitrosamine and EI.
- ⇒ IPQA – Nonsterile API & Sterile API (Aseptic Processing).
- ⇒ Validations and Qualifications.
- ⇒ APQR.
- ⇒ Any Time Inspection Readiness
- ⇒ Regulatory Support-to DMF Submission,
- ⇒ Manufacturing License, COPP, WC & CT-15: Application for New drug substance.
- ⇒ Quality Agreements.
- ⇒ Vendor Qualification.
- ⇒ TrackWise, SAP, DMS, LMS

EDUCATION

- ⇒ **LLB, Legal Studies**, 08/2024
University of Mumbai
- ⇒ **PGDM, Operations Management**, 06/2023
Welingkar Institute of Management and Research
- ⇒ **Master of Science**, Organic Chemistry, 06/2010
University of Pune
- ⇒ **Bachelor of Science**, Chemistry, 06/2008
University of Pune

Jr. Executive Quality Assurance, 08/2015 - 01/2019

Pfizer Healthcare India Pvt Ltd - Aurangabad

- ⇒ To provide QA oversight for production (Aseptic Processing) to ensure procedures are being followed in accordance with GMP compliance.
- ⇒ Responsible for review of executed batch production records, batch cleaning records, Sterilization Cycles (SHS, DHS) Area Monitoring Trends (Aseptic Processing), CIP & SIP Records.
- ⇒ Responsible for Personnel Monitoring in Aseptic processing area in absence of microbiology personnel.
- ⇒ Maintain any time inspection readiness level and provide the necessary support in any Regulatory audit of agencies like USFDA, WHO GMP, MHRA, CDSCO or Customer audit.
- ⇒ To review Events, change control and CAPA and to provide support for manufacturing investigations.
- ⇒ Responsible to ensure that material & equipment are in compliance prior to start manufacturing.
- ⇒ To ensure that the retention samples and its records related to products maintained.

Quality Assurance-Associate, 06/2014 - 08/2015

Dr. Reddy's Lab Limited - CTO-V. Miryalaguda

- ⇒ To performed & monitoring In Process Quality Assurance activity.
- ⇒ Responsible for review of executed batch production records, batch cleaning records
- ⇒ Responsible for preparation of Annual Review Reports for each product of APIs, general systems & Purified Water System
- ⇒ To perform the unannounced audits & routine self-inspections at site
- ⇒ To ensure cGMP compliance & Keep site ready for any time inspection readiness.

Quality Assurance-Officer, 05/2012 - 05/2014

Sequent Scientific Limited - Ambernath

- ⇒ Review & Evaluation of Change controls and providing necessary support for closure of CC.
- ⇒ Investigation of OOT and OOS.
- ⇒ Handling of Deviations and CAPA and ensuring their implementation.
- ⇒ Responsible for preparation of Standard Operating Procedure (SOPs).
- ⇒ Responsible for review of executed batch production records, batch cleaning records.
- ⇒ Review of master documents such as, specifications, Standard testing procedures.
- ⇒ Responsible for preparation of Annual product review reports for each product of APIs.
- ⇒ Issue of documents to Audit & Compliance Department for pre-submission audits.
- ⇒ Manage and issue documents, reconcile records, update vendor lists, and oversee the storage and retrieval of completed documents.
- ⇒ Dispatch.

LANGUAGES KNOWN

- ⇒ English,
- ⇒ Hindi,
- ⇒ Marathi.

PERSONAL DETAILS

- ⇒ **Legal Name:** Rajendra Ramdas Khule
- ⇒ **Date of Birth:** 6/4/1988
- ⇒ **Nationality:** Indian
- ⇒ **Sex:** Male
- ⇒ **Marital Status:** Married
- ⇒ **Passport No.:** Z8004597 (Valid till August 2034)
- ⇒ **Native Address:** Kumbhargaoon, Tal-Karmala, Dist-Solapur-413203

COMPENSATION/SALARY EXPECTATIONS

Compensation :

- ⇒ **Current:** INR 13.57 LPA
- ⇒ **Expected:** INR 20.00 LPA (Negotiable)