**Ajay Kumar Garg**

Mobile: 09816706747

Email: [ajaykumar.garg@glenmarkpharma.com](mailto:ajaykumar.garg@glenmarkpharma.com), [ajay.461514@gmail.com](mailto:ajay.461514@gmail.com)

A leadership position in Administration where my expertise in Pharmaceutical Quality Management system can positively impact the organizations quality, productivity and growth.

## Professionalprofile

* Approx 11 years of rich experience in Pharmaceutical Quality Assurance and Validation system with well known Organizations.
* Currently designated as Assistant Manager QA at Glenmark Pharmaceuticals Limited, Baddi and working as an IPQA incharge Tablet & liquid facility.
* Proficient in Documentation, validation in Solid oral dosage, External preparation and inhalers.
* Proven ability to handle internal and external quality / cGMP audits, Deviations, Incidents, Change controls, CAPA, Out of specifications.
* Strong planning, organizational and interpersonal skill.

## Key performance areas across the carrier span

**IPQA Activity**

* Review of Master Formula Card & review and approval of Batch Production Records.
* Co-ordination for performing technology transfer/method transfer at site before commencement of exhibit/submission batches and ensure the documentation/ prerequisites prior to manufacturing of the product batch at site.
* Handling the activities related to Manufacturing Assurance and overall compliance at shop floor as per written procedures and as per the expectation of cGMP.
* Release of the product batch.
* Handling the Change Controls, Deviations, Incidents, Market Complaints, Out Of Specifications.
* Tracking and Trending of the QMS documents and follow ups with stakeholders for compliance.
* Review of CAPA and ensure the timely implementation and effectiveness of CAPA.
* Review of Annual Product Quality Review.
* Handled the Process Validation activities
* Preparation, Review and Updating of SOP’s.

**Qualification Activity**

* Responsible for the qualification of all the three plants [Orals (tablet/ capsule/\liquid), External Preparation and Inhalers]
* Responsible for the qualification of Utility Systems (HVAC/ Purified Water/ WFI/ Compressed Air) and for the review of its maintenance and changes.
* Responsible for the equipment qualification (Process equipments/ Booths/ Dynamic Pass Boxes), Facility Qualification, Temperature Mapping of all areas and of equipments wherever required.
* Responsible for the preparation, execution, compilation and review of cleaning validation studies.
* Responsible for the review and risk assessment of the modifications/ changes proposed in utility, equipment, facility or in cleaning validation.
* Responsible for the preparation & review of Site Master File, Validation Master Plan.
* Responsible for facing external (regulatory & semiregulatory) and internal audits and for the compliance if any.

**PROJECT EXPOSURE**

* Responsibility for QA setup at other plant of Glenmark at Aurangabad (Steriod Oncology Plant)

## Organizational experience

**GLENMARK PHARMACEUTICALS LIMITED, Kishanpura Baddi As Assistant Manager QA; Dec. 2006 - Present**

* IPQA incharge for Tablet and Liquid Facility.
* Heading qualification team. Responsible for all qualification activities.
* Responsible for Documentaton activities.

**ALKEM LABORATORIES LIMITED, Baddi, (HP) Q A Officer; Jan 2006 – Dec. 2006**

* Preparation and review of SOPs, BMRs & BPRs.
* Issuance of batch Records, specification and SOPs to the concerned department.
* Reviewing BMR, BPR and test reports from QC and final release of batches for dispatch in SAP System.
* Documentation activities (Document issuance, retrieval, storage and destruction).
* Handling of Incident & Deviation and responsible for their closures.
* Handling of Change Control and responsible for their closures.
* Assisting for the handling of Market Complaints.

**UNICHEM LABORATORIES LIMITED, Baddi, (HP) As Q A Officer; Sep. 2004 – Jan 2006**

* Preparation and review of SOPs, BMRs & BPRs.
* Issuance of batch Records, specification and SOPs to the concerned department.
* Documentation activities (Document issuance, retrieval, storage and destruction).
* Handling of Incident & Deviation and responsible for their closures.
* Handling of Change Control and responsible for their closures.
* Assisting for the works related to License/ Product Permission/ Export product permission/ FDA/ COPP/ DCGI/ WHO Application.
* Assisting for the handling of Market Complaints.
* Preparing monthly report and submitting to CQA and management as per MIS (Management Information System)

## Academic Credential

* M.Sc. (Organic Chemistry)

## Personal details

* Father’s Name **:** Mr. Jagdish Chand Garg
* Date of Birth **:** 4th March 1979
* Nationality **:** Indian
* Permanent Address **:** Vill. – Kunihar (PO), Distt. – Solan (H. P.)
* Marital status **:** Married
* Language known **:** English, Hindi.

Signature and Date