



PharmaGend

JOB DESCRIPTION

Position- QA Specialist (Validation)

KEY DUTIES AND RESPONSIBILITIES:

- Preparation and review of qualification documents e.g., User requirement specification, DQ, IQ, OQ and PQ protocol for equipment, utilities & facility in compliance with the regulatory guidelines.
- Execution of qualification and validation activities including process, cleaning, computer system, equipment, utilities, and facility.
- Candidate must have knowledge and experience of qualification/validation principles and their practical application.
- Preparation and review of process and cleaning validation protocols and reports.
- Coordinate with the cross functional team and external service provider to meet qualification & validation schedules and maintain equipment, systems, and processes in validated state.
- Review equipment and process related change control; perform Risk Assessment to determine criticality of the proposed changes.
- Write, review, and revise validation SOPs in compliance with regulatory guidelines.
- QA oversight and/or review during the validation process.
- Manage incidents and deviations related to validation & qualification.
- Perform compliance reviews of all applicable deviations, investigations, and CAPAs related to qualification and validation.
- Review and suggest continuous improvements to the Validation Master Plan, current quality system practices, validation protocols and procedures for newly installed equipment, and overall validation strategies.
- Cross train and develop expertise in other areas of validation.
- Must be able to interact and lead effectively in a team-based environment.
- Familiarity with regulatory/compliance environment.

EDUCATION & EXPERIENCE

- Degree a scientific discipline or equivalent.
- Experience in a regulated industry preferred.
- A minimum of 5-7 years' relevant experience in pharmaceutical manufacturing environment.
- Proficient in the use of Microsoft Word, Excel, Access, PowerPoint, and Explorer.

TO APPLY:

Candidates are encouraged to apply this position via email to Phghr@pharmagend.com with the following information in the resume.

- Work experiences and job responsibilities.
- Current and Expected salary
- Reason for leaving.
- Date of availability
- Education background

We regret that only shortlisted candidates will be contacted.