

**Quality Assurance Manager****Category:** Medical/Pharma**Silva Pharmaceuticals Limited****Vacancy**

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**Job Responsibilities**

- The major job is to establish procedures and quality standard and to monitor these against agreed target of the organization.
- Independently manages review and approval of master batch records, labels, specifications, and other manufacturing documents of clinical and commercial drug substances and drug products in compliance with all applicable requirements.
- Independently manages review and approval of executed manufacturing records, analytical data, and associated documentation, including deviations and investigation reports related to production and disposition.
- Leads, trains others and approves Quality investigations.
- Leads the review and approval of change control requests to ensure compliance with all applicable requirements.
- Lead QA representative, including compliance responsibility, on the internal Silva team.
- Leads and trains others in internal audit and vendor management programs.
- Prepares and presents quality metrics.
- Independently initiates and approves SOP updates and creation of new SOPs. Additionally, oversees review of SOPs and associated documentation to ensure biennial review requirements are met.
- Lead Quality representatives for regulatory inspections.
- Lead establishment of Quality-specific documents (e.g., Quality Risk Management Plan, Quality Agreements, Site Master File, and Validation Master Plan).
- Ensure Quality processes at PCYC and across the supply chain comply with all applicable regulations and guidelines.
- If this position has direct reports:
  - Provide technical guidance and timely performance feedback through routine 1:1 meetings.
  - Provide technical development through OTJ training.
  - Work with HR to ensure opportunities for professional development.
  - Assist with developing individual goals and objectives.
- Ensure that all quality and regulatory requirements (as per cGMPs, ICH and ISO 9001 standard) is effective, implemented and continuously improving for all products and processes.
- Ensure that concerned personnel of the organization are trained in relation to Quality Management System Requirements
- Develop and maintain internal audit program and standing systems, which deal with nonconforming product (NCR), customer inquires (CI), corrective and preventive actions (CAPA), track and monitor

these actions until closure.

- Acts as a quality liaison with regulatory authorities and external auditors during inspections.
- Schedule and conduct Management Review Meeting as required by ISO 9001 standard.
- Prepare detailed summary reports, review data, analyze trends, and drive corrective actions for significant issues.
- Additional duties as assigned.

### **Employment Status**

Full-time

### **Educational Requirements**

- Master of Pharmacy (M.Pharm) in Pharmacy
- Must have the A-Grade Registration of Bangladesh Pharmacy Council (BPC).
- Training/ Trade Course: cGMPs, ICH, ISO 9001
- Skills Required: Compliance, Computer skill, Documentation, Excellent communication skill, Pharmaceuticals, QUALITY ASSURANCE, Quality Management

### **Experience Requirements**

- At least 10 year(s)
- The applicants should have experience in the following area(s):
  - Pharmaceuticals, QUALITY ASSURANCE, Quality Controller/ Assurance, Quality Management
- The applicants should have experience in the following business area(s):
  - Pharmaceuticals

### **Additional Requirements**

- Age 35 to 45 years
- Excellent working knowledge of global GMP regulations, ICH guidelines and robust Quality Systems.
- Broad experience in the pharmaceutical industry with a strong analytical and/or manufacturing background.
- Detail oriented with demonstrated problem solving acumen.
- Ability to work effectively in a team environment with great organization skills.
- Ability to independently analyze and reconcile complex issues.
- Must be an individual with proven initiative and accountability
- Must be able to lead in a fast paced environment.
- Excellent verbal and written communication and interpersonal skills.
- Proficient with computers and typical office software (i.e., Microsoft Office products).

### **Job Location**

Noakhali

**Salary**

- Negotiable

**Compensation & other benefits**

- T/A, Mobile bill, Tour allowance, Medical allowance, Provident fund, Gratuity
- Lunch Facilities: Full Subsidize
- Salary Review: Yearly
- Festival Bonus: 2 (Yearly)
- As per the Company rules.

**Job Source**

Bdjobs.com Online Job Posting.

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**Read Before Apply**

**\*Photograph must be enclosed with the resume.**

## Apply Procedures

Apply Online

**Email**

Send your CV to [recruit@silvapharma.com](mailto:recruit@silvapharma.com)

**Hard Copy**

Apply with an updated CV and recent passport size color photograph addressing Head of HR, Silva Pharmaceuticals Limited, House # 65, Road # 8/A (New), Dhanmondi, Dhaka-1209 mentioning the position applying for on top of the envelope or in the subject field of e-mail attachment.

Application Deadline: **January 10, 2020**

**Company Information**

Silva Pharmaceuticals Limited

House # 65, Road # 8/A (New), Dhanmondi, Dhaka-1209, Bangladesh

Web: [www.silvapharma.com](http://www.silvapharma.com) (<http://www.silvapharma.com>)

Business: Medicine Manufacturing, Marketing & Distribution Operation