



Career Opportunities in Pharma Quality Assurance and Quality Control

Pharma quality control remains extremely important and specialists as in this field will continue to be needed, because of automation, more tasks that once fell to quality assurance engineers can be handled by production workers. There are probably more opportunities in other sectors of the economy, particularly in health care where quality assessment is a relatively new idea. A wide range of quality assurance/quality control positions exist in government, industry and research.

Job Profiles in Pharma QA & QC includes positions as of:

- QC supervisors and technicians utilizing chemistry and microbiology
- Validation managers
- QA documentation specialists
- Senior management positions in QA/QC regulatory affairs
- Quality assurance technicians or analysts
- Quality assurance or control managers
- Quality Researcher
- Quality Assurance Engineer
- Quality Assistant
- Compliance Officer
- Quality Assurance Auditor



The detailed Job Description of some of the major positions available in Pharma QA & QC is as follows:

Quality Control Executive

Job Description: Analysis of Raw Materials, Packing Materials & formulated products, Handling Analytical method validation, Review of analytical reports, stability study, Calibration & qualification of equipment

Desired Skills: 2-5 yrs of experience with Stability, Validation, method transfer & qualification

Validation Executive

Job Description: Shall be responsible for Writing protocols, perform validation work, Equipment Qualification, Generation and maintenance for the Site Validation Master Plan and customer specific Validation Master Plans. Failure Investigation; Internal Audit; Preparation of validation protocols & Reports for Equipment Qualification; Product Release

Desired Skills: 3-5 yrs of hand in experience of pertaining to validation, should have understanding and working experience of change control, deviation / investigation procedures, validation protocols, review and release of validation reports and manufacturing batch documentation.

Quality Documentation and Compliance

Job Description: The Quality Documentation and Compliance position is responsible for the technical quality check of regulatory Documentation in DRA and to support the regulatory compliance in a global context.

Key Roles and Responsibilities:

- Provide technical quality check (i.e. format check) for regulatory documentation in DRA and promote documents to the next state in TEDI/REDI as necessary.
- Check the format of documentation for IRDDS compliance.
- Work collaboratively with DRA colleagues to ensure timelines are met.



- Proactively troubleshoots technical/quality issues relating to the documents. Liaise with other DRA for problem solving
- Perform compliance tracking and deliver status reports to ensure agreement with DRA procedures
- Support key processes are in place and functioning efficiently to facilitate team-work and communication
- Work within the Support systems and processes to enable accurate documentation and data in a validated environment
- Provide support in organisation of workshops and training on a need basis.
- Manage and /or support the Quality Procedures & Compliance communication
- Ensure key processes are in place and functioning efficiently to facilitate teamwork and communication within QP & C and to users worldwide
- Manage and /or support up-to-date application functionality and User support to enable accurate registration status of regulatory relevant parameters for all registered products world wide (compliance)
- Manage and /or support change control
- Identify new initiatives/processes across departments which create more efficient and productive processes
- Support key processes are in place and functioning efficiently to facilitate teamwork and local communication
- Work within the Support systems and processes to enable accurate documentation and data in a validated environment

Desired Skills:

- A minimum of 3 - 4 years total experience, of which about 2 years experience in QA field in Pharmaceutical, Chemical, Healthcare or allied industry.
- Good knowledge and experience of Internet technology and IT applications word processing/ complex document formatting skills.
- Experience in electronic publishing or related areas and document management systems
- High Computer proficiency in MS Word, MS Excel and having the ability to easily acquire knowledge on IT applications
- Global Regulatory Affairs/ QA experience would be desirable.
- Knowledge of scientific terminology and experience of working in a GxP environment.
- Current knowledge of electronic publishing standards, worldwide HA requirements (mainly EU and US guidelines), and legal requirements.
- Knowledge of scientific / medical terminology.

Quality Assurance Manager

Job Description: This position is responsible for ensuring that the quality assurance aspects of company's quality system are completed in an appropriate and timely manner including auditing, trend analysis, complaint review, and document review.



Key Roles & Responsibilities

1. Primary duty or responsibility – maintain Company’s system for documenting, investigating nonconformities and evaluating the efficacy of corrective actions • Key task – Directs the review deviation, OOS and CAPA reports and corrective action plans. • Directs the compilation and review of trend data. • Assist departments in developing appropriate corrective actions. • Directs audit team in evaluating effectiveness of corrective actions. • Develops audit schedule and ensures internal and external audits are completed as required. • Participates in Quality Review Board.

2. Primary duty or responsibility – Direct the activities of the Lot Release, Quality Audit and Quality Assurance Teams. • Ensures departments complete assigned tasks in a timely manner. • Assigns department tasks. • Ensures new and existing personnel are adequately trained in the proper performance of their assigned tasks. • Ensures personnel are adequately trained on the quality system regulations and our quality policies. • Prepares monthly reports of department performance. • Prepares department budget. • Prepares department quality objectives.

3. Primary duty or responsibility – Establishes, implements and maintains department procedures to ensure the appropriate functioning of the Quality Assurance departments.

Other Desired Skills

- Capable of using Microsoft Word, Excel and PowerPoint.
- Capable of performing statistical evaluations, preparing trend charts
- Working knowledge of federal regulations, ISO standards, OSHA regulations.

Research and Development Quality Assurance Manager

Job Description

The QA Manager assists in the development and implementation of R&D Quality Assurance activities for Cubist. Responsible for assuring the adequacy of company clinical and non-clinical systems through internal and external auditing, involvement in systems development, and training of personnel. Serves as a lead resource to R&D project sub teams.



Key Role & Responsibilities

- Serve as primary contact for Cubist development teams to provide expert GCPGLP and general QA support; act as liaison between product development teams and QA.
- Oversee and/or perform audits of non clinical and clinical research sites, systems and processes to ensure compliance with current Good Clinical Practices, ICH guidelines and Good Laboratory Practices.

- Investigator Site Audits
- System / Process Audits
- Vendor audits (CROs, Labs)
- Data Audits Ø Trial Master File Audits
- Document Audits
 - ·Develop and maintain audit plans and schedules in line with organizational goals and objectives (aligned with audit strategy).
 - Evaluate significance of audit findings and coordinate timely responses and implementation of corrective actions.
 - Analyze audit findings and prepare and present results to management.
 - Oversee selection and work of contract auditors to ensure they are properly qualified, trained in Cubist procedures, and work products meet Cubist standards.
 - Review clinical documents including protocols, amendments, sample Case Report Forms, and sample/master Informed Consent Forms for adequacy and compliance, as required.
 - Support effort in preparing for and hosting FDA and other regulatory agency inspections.
 - ·Participate in the continued development and monitoring of Cubist's internal quality systems; write SOPs, as assigned.
 - Reviews SOPs to assure compliance with regulations, Cubist policies and procedures.
 - ·Participates in the development and execution of internal training programs; Prepare and deliver GCP related training at investigator's meetings, as required.
 - Keep abreast of changes in regulations and enforcement action and make recommendations for changes to Cubist policies and practices as needed.



Required Skills

·Experience 5-8 years of pharmaceutical industry experience in an area regulated by GCP and GLP regulations with at least 2 years in a Quality Assurance role with direct auditing experience.

Technical Skills

- Strong working knowledge of GCP regulations, ICH guidelines and EU Directive for Clinical Trials
- Good understanding of 21CFR Part 11 with respect to clinical processes and systems. Familiar with government compliance programs, HIPAA and Subject Data Protection regulations and laws.
- Working knowledge of drug development process and clinical trial operations
- Excellent communication, organizational, interpersonal and computer skills
- Strong process orientation; ability to develop clear and concise procedures and related documentation
- Proven ability to work on multiple projects simultaneously and set priorities.
- Proficiency in a Windows environment (Microsoft Word, Excel, Project, Visio, PowerPoint, Outlook)

Senior Manager Quality Assurance

Roles & Responsibilities

- Monitors, maintains and improves QA System based on cGMP and ISO requirements and assures that it fits in the global QM system.
- Ensures that all the company's personnel are trained in relation to QM System requirements.
- Ensures that all quality and regulatory requirements (as per ISO and cGMPs) are implemented for all products and processes.
- Responsible to develop an Internal Audit Program as per cGMP and ISO requirements and executes the audits.
- Responsible to develop and maintain supplier qualification audit program to ensure suppliers ability to perform work that meets with company's quality standards. Perform supplier/vendor audits per cGMP/ISO requirements.
- Develops and implements CAPA system
- Establishes and maintains a monitoring and trending program to ensure general state of quality systems compliance is effective and continuously improving.
- Hosts internal authority inspections, incl. follow-up of findings.
- Acts as consultant for clinical and marketing teams with regard to all quality related questions.



Minimum Requirements:

2-5 years professional experience in a Quality Management function within the pharmaceutical industry

Principal QA Engineer

Job Description: Develops, implements, and maintains technical quality assurance systems and activities

Experience: 6-8 years of pharmaceutical validation.

Preferred Skills/Qualifications: Computer (including application and control system), laboratory equipment, and cleaning validation experience are desired. **Skills/Competencies:** Experience with sterilization, equipment, cleaning, and utility validation is required.

Quality Auditor

Job Description: We are a fully integrated life sciences company that manufactures markets and distributes a broad range of innovative diagnostic test kits, purified reagents and related products and offers biopharmaceutical enabling technologies. Utilizing a variety of methods, these products provide accuracy, simplicity and speed in the early diagnosis and treatment of common medical conditions, such as gastrointestinal, viral, urinary and respiratory infections.

Key Roles & Responsibilities:

1. Monitor all activities relative to Quality Systems proficiency, testing, and data evaluation as well as those associated with company-wide equipment calibration/preventive maintenance and incoming goods.
2. Assist in the maintenance of standing systems, which deal with nonconforming product (NCR), customer inquires (CI), corrective/preventive action (CAPA). As well as innovate and install ideas to streamline or update said systems.
3. Assist, as needed, in daily activities of the QC Lab, Specimen Qualification, Incoming Goods, and Equipment Maintenance groups.
4. Manage the internal audit program. Lead internal and external quality systems audits.



5. Limited to moderate travel associated with training, corporate acquisitions, audits, and mergers.

6. Work closely with document control and devise history records.

Specific skills:

- Strong understanding of immunological principles and test methods (ELISA, IFA, Latex Agglutination).
- Strong attention to detail. Proficient at Quality Analyst activities.
- Familiarity with computer applications (MS Word, Excel, Access, SPC).
- Strong working knowledge of QSR and ISO Quality Systems.

Associate Director, Process Quality Assurance

Job Description

Responsible for overseeing the development, monitoring and maintenance of QA standards and processes to ensure compliance with Federal, State, Local, and International regulations associated with cGMP and Quality Systems.

- Acts as a quality liaison
 - With regulatory authorities during inspections.
 - With corporate SQE
 - With international business partners (Supply chain, logistics, Quality etc.)
- Directs the development and maintenance of process quality programs, systems and procedures.
- Manages the Technical Product Information and Complaint assessment program.
- Directs and manages the staff of the Process Quality Department.
- Develop and administer departmental budget.