



Title	Job Description for Quality Assurance Executive		
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Title: Quality Assurance Executive

Operational Relationships:

Responsible to Operations Director
Accountable to Quality Assurance (QA) Manager
Report to Quality Assurance Manager

Qualifications: Educated to science bachelor's degree level or equivalent knowledge/expertise in the field.

Experience: 1-3 years within a relevant QA role.

Main Duties & Responsibilities

This job description gives a general outline of the duties of the post and is not intended to be an inflexible or finite list. It may therefore be varied so that changing needs of the service can be met, in consultation with the post holder.

Role Responsibilities

Batch release

1. Review batch documentation and verify records are in compliance with GMP, validation records and relevant associated documentation to release the product for use
2. To inspect the finished product for compliance to relevant specifications
3. To review all relevant in process tests results and QC data relating to the batch
4. To document the batch release process in compliance with GMP
5. To escalate any rejected batches to senior management

Documentation

1. To comply with the organisation's Documentation Policy.
2. To generate and maintain documentation ensuring contemporaneously completion and in a clear written language.
3. To maintain the documentation control system in accordance with cGMP and company SOP
4. Generate, review and approve batch manufacturing records (Worksheets, etc).
5. Generate and maintenance of technical documents i.e. master batch documentation, validation documentations, specification documents, standard operating procedure and technical agreements.

Quality Management System

1. Work with the quality management system to ensure compliance to regulations.
2. Coordinate, write and review quality exception reports, corrective and preventive actions (CAPA), change controls, customer complaints and quality investigations.
3. Facilitate timely follow up and closure of deviations, change controls and corrective and preventive actions (CAPA).
4. Write and review quality reports.
5. Tracking of documents and validation activities.
6. Ensure compliance to cGMP standards and provide support to the quality management operations.
7. Review of site environmental monitoring programs.
8. Monitor and maintain all quality system process to identify improvement opportunities.

Training

1. To draft and execute training materials for all BOVA UK staff members.
2. To maintain all training records and review training files on periodic basis.
3. Perform periodic peer observations of various team members for critical process steps and report your observations to department managers.
4. To participate in training programs for quality assurance staff.

General skill Set required by Bova UK:

1. Minimum education to a degree or NVQ 3 level in Science related discipline or equivalent;
2. Demonstrate an ability to read and interpret documents which relate to health & safety and regulations, operating and maintenance instructions, and procedure manuals;
3. Demonstrate an ability to calculate basic and advanced figures which may include, but are not limited to, discounts, solutions strengths, concentrations, proportions, percentages, weights and volumes;
4. Must demonstrate an understanding of the importance of time management, following instructions and organisational skills;
5. Must possess exemplary computer skills and knowledge and be able to adapt to and learn any new computer software that may need be implemented;
6. Have an ability to follow complex, multistep procedures and processes
7. Must be able to execute the physical demands required for this role including manual handling of equipment and materials;
8. Must demonstrate a willingness to work with chemicals in knowledge of potential side effects, and must ensure that all staff follow the procedures to ensure safe handling of hazardous chemicals;
9. Must demonstrate an ability to conduct complex procedures in an environment in which the noise level may be moderate, and be accurate and prompt;

10. Must demonstrate an ability to perform repetitive work within a busy manufacturing environment
11. Must have professional telephone etiquette skills for communicating with customers and suppliers
12. Must demonstrate excellent communication skills with other staff, suppliers and customers
13. Must be able to work on a multi-departmental level within the organisation to accomplish the overall business goals
14. Respond to correspondence (phone, email, mail or other) in a timely and efficient manner;
15. Other reasonable duties as assigned by senior management on an ad hoc basis.

Personal Specification – Quality Assurance Executive

Attribute	Essential	Desirable
Education and Qualifications	Education to degree level in Science related discipline or equivalent	Degree in pharmaceutical science
Skills and Abilities	<p>Good oral / written communication skills.</p> <p>Basic numeracy skills.</p> <p>Good time management skills.</p> <p>Must be methodical and pay attention to detail.</p> <p>Demonstrated ability to work to set procedures & processes</p> <p>Able to work independently and as a team member.</p> <p>Able to work under pressure accurately.</p> <p>Able to sit or stand in a restricted position at a work station for periods of the working time</p> <p>Able to prioritise and organise routine daily tasks using own initiative</p> <p>Able to clearly and accurately complete routine documentation</p> <p>Good manipulation skills.</p>	<p>In depth understanding of QMS metrics in a manufacturing environment</p> <p>Understanding of the principles of a quality management system in a manufacturing environment</p> <p>Understanding of the principles of validation and qualification in a manufacturing environment</p>

	<p>Basic IT skills including: email, word processing, spreadsheets and data entry</p> <p>Understanding of the principles of cGMP, ICH guideline & QA in a manufacturing environment</p>	
Experience	<p>Previous experience working within a cGMP-related environment</p> <p>Previous experience in a QA role</p>	<p>Experience of working within a QA function in a manufacturing facility</p> <p>Experience of working within veterinary manufacturing facility</p>
Personal Qualities	<p>Punctual, honest, reliable.</p> <p>Polite and diplomatic.</p> <p>Motivated</p> <p>Adaptable & flexible</p> <p>Confident when dealing with all levels of staff both within and external to the department</p>	<p>Interest in pharmaceutical manufacturing processes</p> <p>Interest in veterinary medicines</p>

Employee Name		Date
Employee Signature		Date
QA Manager Signature		Date