Title: Quality Control Assitant

Operational Relationships:

Responsible to Head of Operations
Report to Quality Control Manager & Quality Assurance Manager

Qualifications: In order to discharge these duties successfully the applicant must be able to perform the roles outlined below to the satisfactory level and have obtained the necessary qualifications.

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.

Documentation

1. To comply with the organisation's Documentation Policy
2. To ensure all documentation associated within QA and QC activities are recorded contemporaneously and is clearly written
3. To maintain the develop the documentation control system in accordance with cGMP
4. Review batch documentation and verify records are in accordance with cGMP principals
5. Generate and control batch documentation and other relevant documents to meet regulatory and business needs
6. To approve and assess manufacturing records.
7. To escalate any rejected batches to senior management and participate in investigation of any quality issues
8. Generation and updating of Raw Material Specifications, Product specification
9. Review certificate of analysis and other relevant testing documents from supply/manufacturer (contacting suppliers over discrepancies)
10. Revise, review and write new SOP's or update existing procedures in timely manner
11. To Maintain material release and testing log
12. To Maintain product quality data and trending of analytical results
13. Prepare quarterly environmental report for senior management to review.
14. Writing annual summary for environmental data and report to QA manager
15. Review and maintain MSDS data for all the raw material
16. Build and maintain microbial data library

Quality

1. Visual inspection of finished products
2. Visual inspection and checking integrity of raw material and consumables on receipt

3. Raw material sampling and organising or performing testing
4. Reporting test results to QA for approval to release the material
5. Releasing of raw materials to production for use once they met with set criteria
6. Facilitating microbial monitoring for site as per the set frequency
7. To perform environmental monitoring of the facility and to report all environmental monitoring data to the relevant personnel in a timely manner.
8. To ensure all finished product and raw material samples are sent to the contract laboratories in a timely manner and results are obtained within the expected time frame
9. Archive released product worksheets, monthly filing of all facility logs and product supply records
10. To initiate, review and assess quality exception reports, change requests and complaints
11. Perform impact assessment of QER and change request
12. To prepare and perform qualification of various equipment's used in analytical lab
13. Participate in investigation of out of specification test reports
14. Perform and participate in routine monitoring and maintenance of equipment used in analytical lab
15. To maintain ongoing supplier management program
16. Review and release finished product as per the final release procedure
17. Participate in recall exercise and support QA to investigate
18. To identify areas for continuous improvement within the organisation and take a lead to drive the process improvement. To be a role model for others.

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

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.

Employee Name **Date**

Employee Signature **Date**

Head of Operations Signature **Date**

Personal Specification – Quality assitant

Attribute	Essential	Desirable
Education and Qualifications	Education to degree level in Science related discipline or equivalent;	Degree in pharmaceutical science or Analytical chemistry is more desirable
Skills and Abilities	Good oral / written communication skills. Basic numeracy skills. Good time management skills. Must be methodical and pay attention to detail. Demonstrated ability to work to set procedures & processes Able to work independently and as a team member. Able to work under pressure accurately. Able to sit or stand in a restricted position at a work station for periods of the working time Able to prioritise and organise routine daily tasks using own initiative Able to clearly and accurately complete routine documentation Good manipulation skills. Basic IT skills including: email, word processing, spreadsheets and data entry Understanding of the principles of cGMP, ICH guideline & QA in a manufacturing environment	In depth understanding of QMS metrics in a manufacturing environment Understanding of the principles of a quality management system in a manufacturing environment Understanding of the principles of validation and qualification in a manufacturing environment

Experience	Previous experience working within a cGMP-related environment Previous experience in developing and executing training materials	Experience of working within a QA function in a manufacturing facility Experience of working within veterinary manufacturing facility
Personal Qualities	Punctual, honest, reliable. Polite and diplomatic. Motivated Adaptable & flexible Confident when dealing with all levels of staff both within and external to the department	Interest in pharmaceutical manufacturing processes Interest in veterinary medicines