Title	Job description for Quality Control Analyst	
Publication date	14 May 2020	Version 2

Title: Quality Control Analyst

Operational Relationships:

Responsible to Operations Director
Report to Quality Control (QC) 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 (Worksheets, etc) 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 Material Safety Data Sheet (MSDS) data for all the raw material
16. Build and maintain microbial data library
17. Participate in planning and co-ordination of Stability and analytical testing project

Quality

1. Perform and participate in routine testing of raw materials and finished products using various testing techniques. i.e. HPLC, UV, FTIR, Titration, GC and others etc. Perform interpretation of results generated.
2. Perform Method validation, method transfer and method development using HPLC or any other instruments as per ICH/USP/EP/BP/VICH and other guidelines.
3. Perform and participate in reviewing raw data for routine testing, method validation and method transfer and interpretation of the result.
4. Perform and participate in the maintenance and troubleshooting of the HPLC systems and other laboratory equipment. Plan and co-ordinate routine maintenance of instruments and equipment as per the company VMP.
5. Perform and co-ordinate stability studies for new or existing products
6. Perform and participate in out-of-specification and failure investigations.
7. Participate to implement the CAPA.
8. To initiate, review and assess quality exception reports (QER), change requests and complaints
9. Perform impact assessment of QER and change request
10. To maintain ongoing supplier management program
11. Visual inspection of finished products
12. Visual inspection and checking integrity of raw material and consumables on receipt
13. Raw material sampling and organising or performing testing
14. Reporting test results to QA and QC manager for approval to release the material
15. Releasing of raw materials to production for use once they met with set criteria
16. Facilitating microbial monitoring for site as per the set frequency
17. To perform environmental monitoring of the facility and to report all environmental monitoring data to the relevant personnel in a timely manner.
18. Prepare annual and quarterly environmental monitoring trend report for all the critical areas.
19. 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
20. Archive released product worksheets, monthly filing of all facility logs and product supply records
21. To prepare and perform qualification of various equipment's used in analytical lab
22. Participate in investigation of out of specification test reports
23. Participate in recall exercise and support QA to investigate
24. 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 level in Analytical or Chemistry 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**

QC manager Signature **Date**

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Personal Specification – Quality Control Analyst

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/GLP-related environment Previous experience of handling HPLC, GC, Mass or FTIR instruments> Previous experience of sample booking, Preparing and sampling experience. Previous experience in developing and executing training materials Perform range of finished product and raw material analysis using HPLC technique independently and provide interpretation of results generated. Previous experience in Method validation, method transfer and method development using HPLC as per ICH/USP/EP. Experience in reviewing raw data for routine testing, method validation and method transfer and interpretation of the result. Experience in the maintenance and troubleshooting of the HPLC systems and laboratory equipment Experience in handling out-of-specification and failure investigations and completing the CAPA	Experience of working within a QC function in a manufacturing facility or CRO Experience of working within veterinary manufacturing facility/Pharmaceutical manufacturing facility/ contract pharmaceutical lab
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