Title: Deputy Quality Control Manager

Operational Relationships:

Responsible to Quality Manager; Accountable to Operations Director

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.

Key Responsibilities

1. To Ensure timely sampling and testing of all raw materials, packaging components and finished product according to specification
2. To perform analysis on finished product and raw materials
3. To perform testing using High Performance Liquid Chromatography (HPLC) and Gas Chromatography (GC) techniques
4. To conduct Out of Specification (OOS) investigations
5. To Prepare stability protocols and perform stability studies on new and existing products
6. To Monitor the performance and delivery of services by contract labs
7. Organise and plan all the external testing needs (Microbial testing and Analytical testing
8. Monitor budget and provide Quarterly review on expenditure on testing in house and externally
9. Plan and organise microbial monitoring with QA and Production team
10. Contribute in annual maintenance programme for all the activity related to Quality control department
11. Maintain and monitor equipment maintenance status and manage all the service or breakdown needs
12. Approve analysis performed by the QC Analysts when required
13. The development, application and training of scientifically valid testing procedures
14. The validation and regular review of all test procedures
15. The development, application and training of scientifically valid specifications for materials and finished product
16. Establish specifications and standards for all new products and materials well in advance of production
17. Ensure all equipment is qualified, validated and calibrated regularly
18. Ensure all laboratory tasks performed are in keeping with the principles of Good Laboratory Practice
19. Regular review and application of all applicable pharmacopoeia methods and updates
20. Continuous improvement of QC functions

21. Self-inspections to regulatory standards to ensure all practices and within the guidelines of GMP/GLP
22. Fronting inspections by VMD/MHRA/FDA and other regulatory agencies as the SME for Quality Control

Quality

1. To ensure that the QMS is maintained and developed in accordance with the manufacturing authorisation, Eudralex GMP, VMD regulations and local procedures and in response to changes in regulations and legislation
2. To perform & review investigations, risk assessments and root causes analyses in collaboration with relevant department stake holder for QC related deviations reports and Corrective and preventative action lists.
3. To review and assess risk and impact all change control requests and approve if it deemed suitable.
4. To initiate change control requests where appropriate
5. To support production in deviation investigations, internal audits, recalls, complaint investigations
6. To assist Quality assurance team in performing supplier audits or supplier approval
7. To review and update senior management on environmental monitoring and product quality reviews on bi-annual basis
8. To Report any discrepancies to senior management with supplier approval or stock issues and all the other relevant manager in timely manner.
9. To perform trend analyses of all QMS metrics and ongoing stability data for senior management review
10. 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.
11. To advise the product development team in matters relating to QC and determine how the testing needs can be met
12. To organise environmental monitoring of the facility and to report all environmental monitoring data to the relevant personnel in a timely manner.
13. Prepare quarterly Environmental report for senior management review during quality meeting
14. To ensure all production samples are sent to the contract laboratory in a timely manner and results are obtained within the expected timeframe. Any delay are communicated to senior management

Training

1. To draft and execute training materials for QC team members.
2. To maintain personal and team training records and review training files on periodic basis
3. To highlight training needs of the department managers and to senior management during quality meetings

4. To ensure all updates to relevant regulations and legislation is communicated within the organisation
5. Perform periodic peer observations of various team members for critical process steps and report your observations to Quality assurance manager
6. To carry out internal cGMP/GLP and VMD regulations training
7. To arrange external cGMP/GLP and equipment related training for key team members

Documentation

1. To comply with the organisation's Documentation Policy
2. To ensure all documentation associated within QC activities is recorded contemporaneously and is clearly written
3. To draft & review procedures relevant to the activities being performed
4. To maintain the develop the documentation control system in accordance with cGMP/GLP
5. To ensure the QA/QC requirements for the Validation Master Plan are fully completed and documented

General skill Set required by Bova UK:

1. Minimum education to degree level in Analytical or Microbial 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, correct and efficient manner;
15. Other reasonable duties as assigned by senior management on an ad hoc basis.

Personal Specification – Deputy QC Manager

Attribute	Essential	Desirable
Education and Qualifications	Education to degree level in Science related discipline or equivalent;	Post graduate qualification in related field
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.	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

	Basic IT skills including: email, word processing, spreadsheets and data entry Understanding of the principles of GMP & QA in a manufacturing environment Supervisory experience in a Team leader or equivalent role Working knowledge of MHRA/FDA audits and participating in the audits Good knowledge of regulations specifically those of MHRA and FDA. Experienced in analytical test method development and validation Good knowledge of High Performance Liquid Chromatography (HPLC) and Gas Chromatography (GC) techniques Experience in conducting Out of Specification (OOS) investigations Experience of testing and establishing specifications for raw materials and components Experience of Thin Layer Chromatography (TLC) techniques Knowledge of MRP/ERP systems Experience of pharmaceutical production processes for various dosage form	
Experience	Previous experience working within a GMP-related environment Previous experience in developing and executing training materials	Experience of working within a QA function in a manufacturing facility

	Experience of writing technical reports, audits, procedures, performing investigations and root cause analyses	Experience of working within veterinary manufacturing facility Auditing experience (internal & external)
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

Employee Name **Date**

Employee Signature **Date**

Line managers Signature **Date**