Title: QA Manager

Operational Relationships:

Accountable to Head of Quality

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.

Batch release

1. Review batch documentation and verify records follow cGMP, 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 cGMP
5. To escalate any rejected batches to senior management

Quality

1. To ensure that the PQS is maintained and developed in accordance with the specials manufacturing authorisation, EudraLex guidelines, VMD regulations and local procedures and in response to changes in regulations and legislation.
2. Manage the PQS, processes, SOP to ensure product quality and patient safety.
3. To perform & review investigations, risk assessments and root causes analyses in collaboration with relevant department stake holder for all deviations reports and Corrective and preventative action lists.
4. To review and assess risk and impact all change control requests and approve if it deemed suitable. Assess implemented change for effectiveness and reassess if required.
5. To initiate change control requests where appropriate
6. To lead quality investigations, internal audits, recalls, complaint investigations and completion of corrective and preventative actions
7. To assist Head of Quality in performing supplier audits and regulatory audits.
8. To perform internal audits of the facility and submit a report on regular basis for senior management to review and assess.
9. To review and update PQS metrics and to track all PQS related actions to completion

10. To maintain and develop the ongoing supplier management process and maintain supply chain visibility. Report any discrepancies to head of Quality and all the other relevant manager in timely manner.
11. To respond to customer complaints and perform complaint investigation for products manufactured by Bova UK
12. To perform trend analyses of all PQS metrics and ongoing stability data for senior management review
13. To deputise for the Head of Quality when required
14. 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.
15. To advise the product development team in matters relating to QA and assess new product assessment and toxicology aspects of the product. Also assess the H&S aspect of handling material on site and determine preventative actions to reduce the risk of cross contamination and Health and safety.
16. To perform environmental monitoring of the facility and to report all environmental monitoring data to the relevant personnel in a timely manner.
17. Prepare quarterly Environmental report for senior management to review.

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. To highlight training needs of the department managers and to senior management during monthly quality meeting
4. To ensure all updates to relevant regulations and legislation is communicated within the organisation
5. Maintain training matrix for all the BOVA UK team.
6. Perform periodic peer observations of various team members for critical process steps and report your observations to department managers and Head of Quality
7. To carry out internal cGMP and VMD regulations training
8. To arrange external cGMP and VMD training for key team members

Documentation

1. To comply with the organisation's Documentation Policy
2. To ensure all documentation associated within QA 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
5. To ensure the QA requirements for the VMP are fully completed and documented

General skill Set required by Bova UK:

1. Minimum education to degree 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 – QA 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. Basic IT skills including: email, word processing, spreadsheets and data entry Understanding of the principles of GMP & QA in a manufacturing environment	In depth understanding of GMP, PQS 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 GMP-related environment Previous experience in developing and executing training materials Experience of writing technical reports, audits, procedures, performing investigations and root cause analyses	Experience of working within a QA function in a manufacturing facility 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