Title	Job Description for Head of Quality		
Publication Date	23/06/2020	Version	2

Title: Head of Quality

Operational Relationships:

Accountable to Operations Director and Managing 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.

Management

1. Responsible for planning, developing, and guiding the quality assurance team.
2. Provide leadership and technical expertise to the quality team.
3. Prepare training and development programmes for QA executives and QA officers and maintain the skills required for the business.
4. Responsible for implementing good quality culture throughout the business and working with various department managers to develop a blame-free environment
5. To deputise for Operations Director in his absence.
6. To provide a cover for Quality control manager if required.
7. Flexible in working hours to accommodate any business requirements. (Normal working hours are 7.5 hrs a day)

Quality

1. To ensure that the Product Quality System (PQS) is maintained and developed in accordance with the specials manufacturing authorisation, EudraLex guidelines, VMD regulations, ICH guideline and local procedures and in response to changes in regulations and legislation.
2. Manage and monitor VMR regulations are strictly followed in all areas of business. Provide a continuous update on any guidelines and regulations to the relevant team.
3. Manage the PQS, processes, SOP to ensure product quality and patient safety.
4. To initiate change control requests where appropriate
5. 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.

6. 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.
7. To initiate a Quality Exception report/Deviation where the process is not followed.
8. To lead quality investigations and completion of corrective and preventative actions
9. To set up and perform routine self-inspection/internal audits as per the Quality management system and cGMP requirements to monitor and improve the product quality
10. To prepare a report with findings from internal audits of the facility, process and people to operations director and other department managers on a monthly basis.
11. To perform & review investigations, risk assessments, and root causes analyses in collaboration with relevant department stakeholder for all deviation's reports (QER) and customer complaints.
12. To prepare and execute all the corrective and preventative actions coming out from QER investigations or complaint investigations.
13. To perform & review investigations, risk assessments, and root causes analyses for any recalls. Perform annual recall exercise with various stakeholders to confirm the companies ability to recall products from the market place. Report recall exercise report to senior management.
14. To respond to customer complaints and perform complaint investigation for products manufactured by Bova UK
15. To perform supplier audits and regulatory audits with Quality control manager as per the supplier approval programme of the company
16. To maintain and develop the ongoing supplier management process and maintain supply chain visibility. Report any discrepancies to Operations Director, Managing Director and all the other relevant manager promptly.
17. To review and update PQS metrics and to track all PQS related actions to completion
18. To perform trend analyses of all PQS metrics and ongoing stability data for senior management review
19. To identify areas for continuous improvement within the organisation and take the lead to drive the process improvement. To be a role model for others.
20. Review and approve environmental monitoring of the facility and to report all environmental monitoring out of specification data to the relevant personnel in a timely manner. Prepare Six monthly environmental reports for each critical area and discuss during a quality meeting with senior management to review.
21. Perform product quality review on a monthly basis and confirm all the products manufactured by BOVA UK are suitable as per the ManSA Specials license

22. Perform product quality review based on test results, QER's and quality complaints discuss your findings with relevant department managers and put CAPA in place to improve
23. Prepare and execute Validation Master plan for each year and include all the planned preventative maintenance as well as cleaning and process validation requirements
24. Prepare, organise and implement the process validation and equipment qualification protocols. Review the results and provide feedback to relevant department managers in a timely manner.

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 a periodic basis
3. To highlight the training needs of the department managers and to senior management during the monthly quality meeting
4. To ensure all updates to relevant regulations and legislation is communicated within the organisation
5. Maintain a 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 with 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

Product 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 with 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 production manager and senior management

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Publication Date	23/06/2020	Version	2

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 to 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 the knowledge of potential side effects, and must ensure that all staff follow the procedures to ensure safe handling of hazardous substances;
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.

Title	Job Description for Head of Quality		
Publication Date	23/06/2020	Version	2

Personal Specification – Quality Assurance Manager

Attribute	Essential	Desirable
Education	• Education to degree level in Science related discipline	• Postgraduate qualification in a related field • Education in QMS, Quality Audits or GMP related field
Experience	• Minimum 5-7 years of QA/QC management experience • Previous experience working within a GMP-related environment of Specials or license manufacturer • Good experience min 2-3 yrs in managing regulatory audits and H&S audits • Previous experience in developing and executing training materials • Experience of writing technical reports, audits, procedures, performing investigations and root cause analyses • Auditing experience (internal & external)	• Experience in senior QA management role for >5 yrs is more desirable. • Experience of working within a QA function in a Special (Unlicensed) manufacturing facility • Experience of working within a veterinary manufacturing facility
Skills and Abilities	• In-depth understanding of cGMP, ICH and MHRA/ VMD guidelines. • In-depth understanding of PQS metrics in a manufacturing environment • Excellent knowledge of the principles of a quality management system in a manufacturing environment • Knowledge of the principles of validation and qualification in a manufacturing environment • Excellent oral / written communication skills. • Must be methodical and pay attention to detail.	• Good understanding of manufacturing operations and worked in the production environment

Title	Job Description for Head of Quality		
Publication Date	23/06/2020	Version	2

	• 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 workstation 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. • Necessary IT skills including email, word processing, spreadsheets and data entry	
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**
Director Signature		**Date**