***Title:** PRODUCTION MANAGER

Operational Relationships:

Accountable to Head of Operations and Productions.
Responsible for Production Supervisor, Production Technician & Production Assistants
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.

General

1. To be named as the Production Manager on the Bova manufacturing authorisation & host regulatory inspections in collaboration with QA
2. Demonstrate an ability to write reports and a variety of business correspondence;
3. Demonstrate an ability to read, analyse and interpret common scientific and technical journals & reports
4. Demonstrate an ability read and analyse professional journals, technical procedures or governmental regulations;
5. Demonstrate an ability to read and interpret documents which relate to safety rules and regulations, operating and maintenance instructions, and procedure manuals;
6. 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;
7. Demonstrate an ability to evaluate and coordinate responses to common enquiries, or evaluate and coordinate responses to complaints from customers, enquires from regulatory agencies or members of the business community in collaboration with QA where applicable
8. Demonstrate an ability to effectively present information to senior management;
9. Demonstrate an ability to apply advanced mathematical calculations as related to pharmaceutical manufacture;
10. Demonstrate an ability to define problems, collect data from the business, establish and identify relevant information from clients and staff, and draw valid conclusions on that information
11. Demonstrate effective leadership & management skills to the Production Department personnel
12. To identify areas and processes where continuous improvement can be applied in the organisation
13. Manage the production budget

Product Manufacture

1. To generate manufacturing schedules based on sales forecasts for one, three and 6months.
2. To ensure that products are produced and stored according to the appropriate documentation in order to obtain the required quality. Also, completion of documentation as per cGMP requirements.
3. To approve the instructions relating to production operations and to ensure their strict implementation throughout the department
4. To ensure that the production records are evaluated and signed by an authorised person prior to QA release
5. To ensure the qualification and maintenance of his department, premises and equipment in accordance with the site VMP and equipment management schedule.
6. To ensure that the appropriate validations are done in accordance with the site VMP
7. To ensure that the required initial and continuing training of his department personnel is carried out and adapted according to need
8. To manufacture sterile and non-sterile dosage forms in accordance with detailed manufacturing instructions & procedures
9. Must demonstrate excellent communication skills with other members of staff
10. Must be able to distribute manufacturing tasks and overseeing general management of workflow to ensure the scheduling and manufacture is conducted in the most efficient way
11. Work closely with the product development team for the ongoing Bova product pipeline
12. Contributes to the development, and drives implementation, of operational plans to achieve manufacturing strategy objectives; this will include the scaling up of asset area performance to accommodate new products, new processes or technology, new equipment.
13. To ensure new product implementation carried out as per the set timelines and any delays are communicated to senior management in timely manner.
14. To generate KPI for manufacturing activities agreed with Head of operations and present them in a weekly and a monthly meeting. i.e. Number of units made per operators and Right first-time measures.
15. Ensures compliance with Health, Safety, Environment, current Good Manufacturing standards and all other work standards
16. Manages the relationship with key clients and sales managers
17. Communicates business needs and helps translate these needs into requirements
18. Manages the co-ordination of resources within the business teams and across the department
19. Oversees the introduction of new processes from the identification of business need, through to the timely introduction and formal acceptance of the change by all customers
20. Leads individuals within own section of Manufacturing to deliver the highest levels of performance and maintain employee relations
21. Provides clear leadership, direction and development opportunities to own teams

22. Identifies and leads improvement initiatives in support of longer term business strategy
23. Resolves long term, complex issues while assessing the risk to product, people and plant
24. Develops and cultivates technical expertise and knowledge within Manufacturing function by disseminating best practices and sharing knowledge across functions and production teams

Stock Maintenance01

1. To ensure there is adequate starting materials, consumables and packaging material for product manufacture as well as for new product
2. To ensure starting materials are routinely checked for expiry dates and quantities remaining
3. To order starting materials & consumables in advance to ensure adequate stock levels are maintained
4. To periodically review stock level, costs and supplier performance with procurement officer.

Documentation

1. To comply with the organisation's Documentation Policy
2. To ensure all documentation associated within manufacturing activities is recorded contemporaneously and is clearly written
3. To draft & review procedures or qualification protocols relevant to the activities being performed

Quality

1. To open deviation reports and to perform production-led investigations, risk assessments and root causes analyses in collaboration with QA
2. To propose change control requests on behalf of production
3. To assist QA in deviation investigations, internal audits, recalls, complaint investigations and completion of corrective and preventative actions
4. Maintain the components of the QMS relating to the Production Department
5. To assist QA in performing supplier audits as a production expert
6. To ensure near miss and error logs are monitored and trended to review the performance of department or individuals.
7. To meet QA supervisors in regular meeting and review QMS trends to monitor the performance of department and personal.
8. To meet with QA supervisors & QC manager to discuss trend of analytical and microbial testing and determine the risk associated to the facility or products. Complete agreed corrective actions to reduce the risk applying ICH guideline principals.

General skill Set required by Bova UK:

1. Minimum education to degree level in Science related discipline or equivalent;

2. Demonstrate an ability to lead & mange teams
3. Demonstrate an ability to read and interpret documents which relate to health & safety and regulations, operating and maintenance instructions, and procedure manuals;
4. 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;
5. Must demonstrate an understanding of the importance of time management, following instructions and organisational skills;
6. Must possess exemplary computer skills and knowledge and be able to adapt to and learn any new computer software that may need be implemented;
7. Have an ability to follow manufacturing instructions for sterile and non-sterile dosage forms
8. Have an ability to follow complex, multistep manufacturing instructions and manufacture in compliance with good manufacturing practice;
9. Must be able to execute the physical demands required for this role including manual handling of equipment and materials;
10. 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;
11. Must demonstrate an ability to conduct complex procedures in an environment in which the noise level may be moderate, and be accurate and prompt;
12. Must demonstrate an ability to perform repetitive work within a busy manufacturing environment
13. Must have professional telephone etiquette skills for communicating with customers and suppliers
14. Must demonstrate excellent communication skills with other staff, suppliers and customers
15. Must be able to work on a multi-departmental level within the organisation to accomplish the overall business goals
16. Respond to correspondence (phone, email, mail or other) in a timely and efficient manner;
17. Other reasonable duties as assigned by senior management on an ad hoc basis.

Employee Name **Date**

Employee Signature **Date**

Supervisor Signature **Date**

Attribute	Essential	Desirable
Education and Qualifications	Education to degree level in Science related discipline or equivalent; Post graduate qualification in related field	Management related qualification Business related qualification Lean six sigma qualification
Skills and Abilities	In depth understanding of the principles of GMP & QA in a manufacturing environment Demonstrated ability to write prospective and retrospective risk assessments in a manufacturing environment Demonstrated ability to manage local QMS metrics and report to senior management Understanding of the principles of validation & qualification processes within a GMP environment Performing root causes analyses and implementation of preventative measures Ability to write detailed investigative reports and audit reports Demonstrated ability to lead and manage a production team 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	Preparing for and hosting of regulatory inspections

	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	
Experience	At least 5 years previous experience working within a GMP-related environment At least 5 years previous experience in managing and leading teams Previous experience in developing and executing training materials Experience of writing technical reports, audits, procedures, performing investigations and root cause analyses Experience of writing qualification and validation records and protocols	Being named as a Production Manager on a manufacturing authorisation Experience of working within veterinary manufacturing facility Experience in hosting regulatory inspections (MHRA or VMD) Auditing experience (internal & external) Experience in pharmaceutical product formulation and development

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 Leadership and mentoring qualities	Interest in pharmaceutical manufacturing processes Interest in veterinary medicines