CAJE REF CYM/Wales/2023/0038

APPROVED 20/12/2023





# JOB TITLE (Pharmaceutical) Production Supervisor

# BAND 5

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| Job Summary |
| * Participate in and supervise the manufacture of prepared medicinal products, ensuring that the unit and operations meets good manufacturing practice (GMP) and good distribution practice (GDP) and good clinical practice (GCP) requirements, Health and Safety at Work, Control of Substances Hazardous to Health (COSHH) and Ionising Radiations regulations (Medical Exposure) Regulations (IR(ME)R), The Human Medicines Regulations, and any other relevant statutory requirements.
* Supervise clean room activities, including clean room behaviours, aseptic techniques and the use of semi-automated equipment, to batch manufacture medicines, perform post-production product inspection, packaging and labelling with reconciliation, and participate in the Pharmaceutical Quality Control System.
* Take responsibility for maintaining effective stock control, security and minimising waste of starting materials and consumables required for individual batch production.
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| Responsible to |
| Reporting:        | Accountable:       | Professionally:       |
| Responsibilities and Duties |
| **Supervisory Management of Production**To supervise, on a day-to-day basis, the duties carried out by the Senior Production Operators and Production Operators participating in the assembly and manufacturing of medicinal products, in accordance with GMP legislation requirements, Health and Safety at Work and COSHH regulations and departmental procedures. This will include corrective and preventative action feedback to staff,To supervise the Senior Production Operators and Production Operators during technical product development, re-development and batch size changes, as required,To participate in the Pharmaceutical Quality Management system, undertake pre- and in-process accuracy checking activities to ensure the medicinal products are safe and effective for patient use, and identify, document and escalate any deviations in output to the Production Manager and Quality Assurance Team,To prioritise and plan the daily production schedule, prepare workload data, and organise rotas for Production Operators and Senior Production Operators,To participate in the manufacturing of a range of medicinal products, when required. This will require setting -up, assisting in calibration, appropriate and safe use of high-cost, specialist equipment, dismantling and cleaning of it after use. **Policy and Training**To be responsible for the day-to-day supervision of a team of Senior Production Operators Production and Production Operators,To provide clinical supervision and deliver the technical training, professional development and competency assessment of new and existing staff where appropriate and in response to changes to procedures and processes, To supervise internal and external visitors e.g. engineers, specialists, trainees and students, who enter the unit, To assist in the development, review, writing and implementation of standard operating procedures (SOPs) within Pharmacy Technical Services, **Communication**To interpret and communicate a range of complex technical information, both verbal and written, from support systems, highly technical equipment and manufacturing processes, including clinical knowledge of specialist use of products, urgency of item manufacture, usage patterns and trends, and stock holding, to the Senior Production Supervisor, **Quality and Improvement** To participate in the Pharmaceutical Quality System, using the appropriate software to record deviations and product quality incidents, and escalate as appropriate,To perform product inspection activities including segregation, post-production monitoring and reconciliation.To participate in environment monitoring, including contamination and environmental dose-rate, to identify risks which may effect the operators’ safety or quality of product. This may include chemical, microbial or radiation monitoring.To participate in process and operator validations, and equipment verification, as part of the Validation Master Plan,**Financial and Physical Resources**To take responsibility for maintaining effective stock control and security of starting materials and consumables required for production. This includes using the pharmacy computer systems to organise, manage and document a system of checking the expiry dates of drugs in the production areas, and ensuring rotation of stock and disposal of hazardous waste. Minimising the wastage of starting materials, components, and consumables for individual batch productionTo be responsible for the security and personal safe handling of high cost and/or high risk-controlled drugs and hazardous materials e.g. radioactive materials, related to production. |
| PERSON SPECIFICATION |
| Qualifications and Knowledge |
| BTEC Pharmaceutical Sciences with NVQ Level 3 Pharmacy Services or The Principles of Aseptic Pharmaceuticals Processing (Level 3), OR equivalent scientific qualification at degree level, Accredited Pre- and In-process Checking (or be able to undertake). Appropriate Professional Registration**Desirable**Supervisory management qualification or accreditation, or equivalent experience Training qualification or accreditation, or equivalent experience |
| Experience |
| Experience working in a MHRA Licenced Manufacturing Unit or comparable production environment. **Desirable** Wider experience of pharmaceutical industry including procurement, stores and distribution |
| Skills and Attributes |
| Computer skills to include word processing and data entry i.e. spreadsheets and databases. Good numeracy skills including calculations, percentages, decimal, fractions. Manual dexterity to manipulate injections or prepare pharmaceutical products, and good hand-eye co-ordination. Strong organisational skillsWelsh Language Skills are desirable levels 1 to 5 in understanding, speaking, reading, and writing in Welsh |
| Other |
| Approachable and professional manner. Ability to remain calm in a busy environment. Committed to continuing professional development.  |