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CAJE REF CYM/Wales/2024/0024

APPROVED 31/07/2024

# JOB TITLE Pharmaceutical Production Operator

# BAND 3

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| Job Summary |
| * The Production Operator plays a key role in pre-production, assembly and post-production of aseptically prepared medicines, providing clinical technical services under a Medicines and Healthcare products Regulatory Agency (MHRA) Manufacturer’s “Specials” Licence to ensure delivery of a timely, high quality and patient-focused service across Wales.
* They will undertake cleanroom activities using aseptic techniques and semi-automated equipment to batch manufacture medicines, under supervision, in accordance with cleanroom behaviour principles.
* They will participate in the Pharmaceutical Quality System (PQS), contributing process experience and knowledge to improve processes and ensure the medicinal products are safe and effective for patient use.
* They will participate in 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 |
| Aseptic Production* Participate in the manufacture of prepared medicinal products, in accordance with good manufacturing practice (GMP), good clinical practice (GCP) and good distribution practice (GDP) 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.
* This will involve wearing specialist cleanroom clothing for most of their shift.
* Set-up, assist in calibration, appropriate and safe use of high-cost, specialist equipment, dismantling and cleaning of it after use.
* Support technical product development, re-development and batch size changes, as requested.

Communication* Communicates technical information with other Production Operators in the cleanroom to ensure effective delivery of workflows, escalating any issues to the Production Supervisor.
* Identifies and delivers checking and environmental monitoring feedback to colleagues communicating the safety of products which may be sensitive or contentious.

Quality and Improvement * Participate in the Pharmaceutical Quality System (PQS), contributing process experience and knowledge to give feedback and improve processes.
* Support the effective management of the Pharmaceutical Quality System (PQS), using the appropriate software to access data and information to identify, document any deviations and product quality incidents, and escalate as appropriate.
* Participate in environment monitoring, identifying and avoiding risks to their safety or quality of product. This may include chemical, microbial or radiation monitoring.
* Participate in process and operator validations, and equipment verification, as part of the Validation Master Plan.
* Assist with the implementation of standard operating procedures (SOPs), proposing changes to improve service within Pharmacy Services.

Financial and Physical Resources* 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.
* Minimise the wastage of starting materials, components and consumables for individual batch production.
* Responsible for the security and personal safe handling of high cost and/or high risk, controlled drugs, hazardous materials and highly specialised equipment e.g. radioactive materials, related to production.
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| PERSON SPECIFICATION |
| Qualifications and Knowledge  |
| EssentialScientific qualification at level 3 (certificate, diploma, NVQ, A level or advanced Apprenticeship), or equivalent experience at a level which demonstrates a good understanding and knowledge of maths and science topics and an ability to understand and interpret relevant policies and procedures.DesirableHealthcare Science Level 2 qualification. |
| Experience |
| **Essential**Experience of using practical or theoretical knowledge to follow a range of routine procedures, adapting, problem solving or referring to others, as the situation requires.**Desirable** Experience working in a laboratory, cleanroom or comparable manufacturing environment. Experience of or interest in the pharmaceutical industry, in any form. |
| Skills and Attributes |
| **Essential**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 skills.**Desirable**Welsh 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.  |