CAJE REF CYM/Wales/2023/0040

APPROVED 20/12/2023







# JOB TITLE (Pharmaceutical) Lead Production Supervisor

# BAND Band 7

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| Job Summary | | |
| * The role holder is responsible for the strategic planning of tasks for a team of Production Supervisors and Operators engaged in the manufacture of aseptically prepared medicines, ensuring that the unit meets 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 (Medical Exposure) Regulations (IR(ME)R), The Human Medicines Regulations and any other relevant statutory requirements. * They are responsible for clinical governance and the operational management of equipment in the clean room. They analyse and interpret data from various information technology systems and make recommendations for improvement to process, product and equipment. * They will be a key member of the team developing new products and processes using Quality Risk Management (QRM) and Quality by Design (QBD) principles. * They play a lead role in the clinical training and professional development of staff, trainees and students, anticipating and planning for changes in the service particularly with regards to manpower and training requirements. | | |
| Responsible to | | |
| Reporting: | Accountable: | Professionally: |
| Responsibilities and Duties | | |
| The Lead Production Supervisor is responsible for the strategic planning within a specialist area which informs the manufacture of aseptically prepared medicines, providing clinical technical services under a Medicines and Healthcare Products Regulatory Agency (MHRA) Manufacturer’s “Specials” License, to ensure delivery of a timely, high quality and patient-focused service across Wales.  **Production** To be responsible for the strategic planning of tasks for a team of Production Supervisors and Operators engaged in the manufacture of medicinal products, in accordance with relevant regulations and statutory requirements (as above), and departmental procedures,  To analyse multi-stranded workload data to produce reports, make recommendations to Production Manager, and implement changes to schedules, as appropriate,  To be responsible for maintaining a variety of pharmacy specific computer systems which store and retrieve information and records which support the safe manufacture of medicines, creating content for use by others  To create and roll-out a variety of clean room schedules, planning on a large scale to ensure compliance, undertaking monitoring, and signing-off on completion,  To maintain their production operator skills and knowledge in order to participate in the manufacturing of a range of medicinal products, as required.  **Human Resources and Training** To be responsible for the line management of the Senior Production Supervisors, and support them in the management of others,  To lead on the recruitment and selection decisions, and support widening access to the service,  To identify clinical/technical and professional development training needs for staff, trainees and students, where appropriate and in response to changes to procedures and processes, and co-ordinate training delivery,  To plan and organise the supervision of trainees and students, act as lead mentor, and carry out educational assessments,  **Communication** To interpret and communicate a range of complex technical information from support systems, highly technical equipment and manufacturing processes, including clinical knowledge of specialist use of products, in order to monitor standards of service in line with existing and new regulatory requirements and develop standard operating procedures (SOPs) within service area,  To engage with multidisciplinary colleagues to propose and implement changes to policy relating to their specialist area, but which impact outside of pharmacy technical services,  To communicate with manufacturers and suppliers to develop specifications for equipment, consumables and components, relaying usage patterns and trends, and urgency of item manufacture,  To engage with colleagues across other healthcare professions, in both written and verbal communication, to understand their service requirements and analyse and interpret orders for pharmaceutical production in aseptic services.  **Regulatory Compliance and Risk Management** To be responsible for managing resources, utilising appropriate methodology and tools as they apply to their specialist area to meet pharmaceutical Quality Risk Management (QRM) responsibilities in a high risk, large volume, production environment,  To undertake risk assessment and analysis, identify trends and make recommendations for any necessary preventative and corrective actions,  To manage the development of new products (evaluate and control) and work within an interdisciplinary team to design processes that mitigate risk using the principles of Quality by Design (QBD)  To contribute to the improvement of the Pharmaceutical Quality System by creating system workflows.  To ensure that staff and environmental contamination monitoring is carried out and recorded. This may include chemical, microbial or radiation monitoring,  To create, plan and co-ordinate activities, and testing methodologies in support of the Validation Master Plan,  To co-ordinate regulatory self-inspections, plus inspection preparation, hosting and action plan development and completion,  To actively contribute to practice research, audit, service improvement and clinical trials carried out within the service.  **Financial and Physical Resources** To oversee the ordering and receipt of all raw materials and consumables to ensure satisfactory stock levels are maintained, and that they are appropriately stored and rotated / turned over. This will include responsibility for the security and safe handling of high cost and/or high risk, controlled drugs and hazardous materials e.g. radioactive materials,  To ensure that pricing / costing and invoicing records are up-to-date and accurate using the pharmacy computer systems, and produce reports detailing manufacturing expenditure,  To manage the monitoring of all equipment in the clean room, maintain accurate equipment records, respond to reports of any problems or unusual occurrences, and schedule the planned preventative maintenance of equipment. | | |
| PERSON SPECIFICATION | | |
| Qualifications and Knowledge | | |
| Postgraduate diploma Pharmaceutical Technology & Quality Assurance (PTQA) OR relevant scientific qualification at postgraduate diploma  and Pharmacy Science Training Programme (STP) or vocational training / practical experience and additional knowledge to post-graduate diploma level gained through relevant work experience,  Accredited Pre- and In-process Checking (or be able to undertake),  Management qualification or accreditation, or equivalent team management experience,  Appropriate Professional Registration  **Desirable**  Accredited Product Approver (S10 Medical Act) and Cleaning Supervision (CRS) accreditation (or be able to undertake),  Training qualification or accreditation, or equivalent experience | | |
| Experience | | |
| Experience working in a MHRA Licenced Manufacturing Unit or comparable production environment.  Experience of Quality Risk Management (QRM)  Experience of managing team of people, recruitment and selection, scheduling workplans, managing attendance and having difficult conversations.  Experience of stock management of hazardous and time-limited materials  **Desirable**  Wider experience of pharmaceutical industry including procurement, stores and distribution. | | |
| Skills and Attributes | | |
| Good communication skills including being able to present complex information, share knowledge and influence others  Strong organisational skills, including being able to plan and document complex schedules and processes  Confident user of computer systems, demonstrating attention to detail at all levels,  Manual dexterity to manipulate injections or prepare pharmaceutical products, and good hand-eye co-ordination.  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. | | |