CAJE REF CYM/Wales/2024/0013

APPROVED 07/03/2024







**JOB TITLE Pharmaceutical Quality Assurance (QA) / Quality Control (QC) Analyst**

**BAND Band 5**

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| **Job Summary** | | | |
| * The Quality Assurance / Quality Control Analystholds a key supervisory and co-ordination role ensuring the effective monitoring and testing of environments, product and process in the aseptic manufacturing, microbiological and laboratory 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. | | | |
| **Responsible to** | | | |
| **Reporting to:** | **Accountable:** | | **Professionally:** |
| **Responsibilities and Duties** | | | |
| **Monitoring and Testing** To co-ordinate and schedule the programme of physical and microbiological monitoring and testing, in accordance with 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 to confirm that control of the environment is maintained within standards.  To participate in the Pharmaceutical Quality System (PQS), undertake environmental data checking, including isolators and facilities in which the aseptic products are manufactured, to ensure the medicinal products are safe and effective for patient use, and identify, document and escalate any out of specification and deviations to the QA Practitioners and Production Manager,  To conduct environmental, aseptic process and product testing, using a variety of growth media and techniques,  To participate in the Pharmaceutical Quality System (PQS), using the appropriate software to transcribe data accurately, record deviations and out of specification results, and escalate as appropriate,  To conduct temperature mapping of storage areas according to protocols and escalate any out of specifications results to the QA Practitioners and Production Manager,  To participate in equipment verification, validation, and calibration, as part of the Validation Master Plan,  To record results from QA and QC testing correctly and accurately using pharmacy computer system and other software packages to ensure validity and data integrity,  To analyse a range of information from a range of technical apparatus and produce trend data using appropriate software, compiling and presenting reports for review.  **Supervision and Training** On a day-to-day basis, to schedule and deliver the daily QA/QC workload, plan rotas and supervise the duties conducted by the Quality Assurance Support Analysts,  To deliver training within the QA specialism to multidisciplinary teams, new and existing staff where appropriate, and in response to changes to procedures and processes,  To assist in the development, review and writing QA standard operating procedures (SOPs) within Pharmacy Technical Services, and adjust schedules and plans to implement any changes.  **Communication** To contribute to the accurate collation and sharing of a range of complex technical information, both verbal and written, from support systems, highly technical equipment and manufacturing processes, including benchmarking and trend data, with multidisciplinary colleagues,  To identify and deliver testing and monitoring output and feedback to multidisciplinary colleagues where the information may be sensitive or contentious and require tact and diplomacy e.g. communicating out of specification results.  **Financial and Physical Resources** To be responsible for the maintenance and supplies of microbiological media and laboratory consumables,  To take responsibility for maintaining effective stock control and security of starting materials and consumables required for monitoring and testing. This includes using the pharmacy computer systems to organise, manage and document a system of checking the expiry dates of growth media and ensuring rotation of stock and disposal of hazardous waste,  To supervise the cleaning and maintain of laboratory equipment,  To minimise the wastage of high cost starting materials, components and consumables used in monitoring and testing, | | | |
| **PERSON SPECIFICATION** | | | |
| **Qualifications and Knowledge** | |  | |
| **Essential**  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,  Appropriate Professional Registration  **Desirable**  Supervisory management qualification or accreditation, or equivalent experience  Training qualification or accreditation, or equivalent experience | | | |
| **Experience** | |  | |
| **Essential**  Experience working in a laboratory, MHRA Licenced Manufacturing Unit, or comparable production environment  **Desirable**  Understanding of or experience in a Quality Assurance / Quality Control role | | | |
| **Skills and Attributes** | |  | |
| Effective 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, and prioritise tasks to meet deadlines,  Ability to analyse data, identify improvements and solve complex problems,  Computer skills to include word processing and data entry i.e. spreadsheets and databases,  Manual dexterity to use highly scientific instruments and equipment, 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, | | | |