CAJE REF CYM/Wales/2024/0011

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

**BAND Band 3**

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| **Job Summary** | | |
| * The Quality Assurance / Quality Control Support Analystis responsible for 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 participate in a 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), gathering environmental data from 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 correctly and accurately results from QA and QC testing results to ensure validity and data integrity.  To analyse a range of information and produce trend data using appropriate software,  **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,  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,  **Financial and Physical Resources** 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, | | |
| **PERSON SPECIFICATION** | | |
| **Qualifications and Knowledge** | | |
| **Essential** Scientific qualification at level 2 (certificate, diploma, NVQ or GCSE grades A\*-C / 1-4), demonstrating a good understanding and knowledge of maths and science topics  On the job training to Level 3 with the ability to understand relevant policies and procedures  **Desirable**  Healthcare Science Level 2 qualification  Science Manufacturing Tech (SMT) Level 3  Accredited Pre- and In-process Checking (or be able to undertake)  Appropriate Professional Registration (not essential on entry) | | |
| **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, clean room or comparable manufacturing environment.  Understanding of or experience in a Quality Assurance / Quality Control role  Experience of or interest in the pharmaceutical industry, in any form. | | |
| **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 syringes or prepare pharmaceutical products, and good hand-eye co-ordination  Strong organisational skills  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 | | |