

JOB DESCRIPTION

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| **JOB DETAILS** | |
| **Job Title** | Senior Assistant Technical Officer – Quality assurance and aseptics. |
| **Reports to** | Senior Quality Assurance Technician |
| **Band** | Band 3 |
| **Department/Directorate** | Pharmacy |

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| **JOB PURPOSE** |
| To support the efficient running of the Quality Control Laboratory by undertaking technical and non-technical duties to support environmental monitoring and laboratory testing for Pharmacy Aseptics.  To support the aseptic manufacturing unit in technical duties. |
| **KEY RESULT AREAS/PRINCIPAL DUTIES AND RESPONSIBILITIES** |
| * Complete daily checks of the temperature management system, respond to alarms during normal working hours and general laboratory checks used as indicators of Good Manufacturing Practice (GMP). These systems are computer and paper based. * Accurately check and process samples for testing. This includes logging and labelling samples as they are received into the lab using various sample processing mechanisms both paper based and on the computer. Samples are incubated in-house, but may need to be sent to a contract laboratory for identification of microorganisms. * Accurately read microbiological plates and samples i.e. settle plates, contact plates, active air samples, finger dabs and liquid media and basic laboratory analysis of microbiological cultures. Accurately complete records and identify and report out of specification results in line with laboratory GMP. * Safely control and dispose of test samples including, potentially hazardous laboratory chemicals and biological material (bacteria and fungi) through appropriate waste streams. * Report any non-conformances and out of specification results; assist with investigations where appropriate. * Process non-microbial sample results, accurately complete records and identify out of specification results. Report out of specification results to the Senior Quality Assurance Technician. * In the absence of the Quality Assurance ATO perform microbiological and physical monitoring of clean rooms and product storage facilities to ensure the quality of high risk aseptic products as defined in local procedures. * Temperature monitoring and mapping of controlled storage areas within the pharmacy. * Ensuring purchased media is stored and tested appropriately and Certificates of Analysis obtained and reviewed where appropriate. * Responsibility for general laboratory tidiness in accordance with laboratory GMP standards. The disposal of clinical waste bags, sharps bins, confidential and general waste through appropriate waste stream. * Enter data in to multiple electronic management systems, including microbiological and analytical results, product details, validation records, non-conformances and change controls. These systems involve the use of MS Word, MS Excel, MS Access, Q-Pulse, MRS and the Pharmacy stock control system. * Update documents and standard operating procedures under the supervision of the Senior QA Technician. * Participate in the training of other pharmacy staff e.g. Pharmacy Assistants, Pharmacy Technicians, Student Pharmacy Technicians and Trainee Pharmacists * Processing of defective medicines and contacting external companies to initiate investigations, where appropriate. * Coordinating the annual calibration of QC Instrumentation. * Assist in the preparation of aseptic products. Assembly, setting up and label production as per Standard Operating Procedures and preparation of injectable medication using aseptic technique * Undertake cleaning of the Aseptic unit and equipment as per Standard Operating Procedures to ensure that the quality of products made within the unit are not compromised and potentially cause harm to a patient. * Assist with stock control – including ordering, and topping-up of medications, IV’s and consumables within the aseptic unit. * Undertake other reasonable duties as required, appropriate to grading. * The post holder is expected to comply with Trust Infection Control Policies and conduct him/herself at all times in such a manner as to minimise the risk of healthcare associated infection. * To participate in flexible working arrangements including late duties, weekends and bank holidays as appropriate. Please note that in order to deliver a high standard of care to patients the Pharmacy service operates 7 days a week and staff are therefore required to work some weekends as part of their contracted hours. |
| **KEY WORKING RELATIONSHIPS** |
| The post holder is required to deal effectively with staff of all levels throughout the Trust as and when they encounter on a day to day basis  In addition the post holder will deal with the wider healthcare community, external organisations and the public.  This will include verbal, written and electronic media.  Of particular importance are working relationships with:   |  |  | | --- | --- | | **Internal to the Trust** | **External to the Trust** | | * Senior Quality Assurance technician | * Suppliers of environmental monitoring equipment | | * QC staff | * Companies providing support to QC | | * Aseptics staff |  | |  |  | |
| **ORGANISATIONAL CHART** |
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| **FREEDOM TO ACT** |
| The post holder works with supervision close by and will be guided by Standard Operating Procedures |
| **COMMUNICATION/RELATIONSHIP SKILLS** |
| Communication with Lead Technician Technical Services and other members of the Aseptic Services team on a day to day basis, as well as liaising with staff from microbiology and other departments. Occasional phone calls from staff members across the organisation, as well as other staff members from the wider pharmacy team. |
| **ANALYTICAL/JUDGEMENTAL SKILLS** |
| Straightforward job related facts, using procedures to aid in decision making. Will need to be able to follow Standard Operating Procedures, worksheets and notify senior staff of any problems regarding these or any equipment being used.  Be able to interpret environmental monitoring plates and record results effectively into electronic systems.  Determine quantities required when dispensing pharmaceuticals or gathering ingredients. |
| **PLANNING/ORGANISATIONAL SKILLS** |
| The post holder will need to, under supervision:  i) organise own day-to-day activities,  ii) plan straightforward tasks,  iii) plan & organise on-going activities and work together to achieve this |
| **PATIENT/CLIENT CARE** |
| Limited contact with patients via the phone relating to queries. Undertakes activities which contribute to quality management and sterile manufacture which impacts on patient care. |
| **POLICY/SERVICE DEVELOPMENT** |
| The post holder is expected to work to defined policies. |
| **FINANCIAL/PHYSICAL RESOURCES** |
| Responsible for receiving and storing stock. Stock Checks. Stock Rotation. Distribution of prepared items. |
| **HUMAN RESOURCES** |
| Will be required to demonstrate their roles to new staff of all grades. Will be required to supervise other staff and assist with training of rotational staff and students |
| **INFORMATION RESOURCES** |
| Post holder is required to record information manually, enter data using computer software, inputting, storing & providing information on database or other systems, and produce labels etc for prescriptions/worksheets. |
| **RESEARCH AND DEVELOPMENT** |
| The post holder may be required to handle clinical trial drugs and have an awareness of clinical trials within pharmacy. |
| **PHYSICAL SKILLS** |
| Accurate placement and management of environmental monitoring equipment  Accurate measurement and manipulation of cytotoxic drugs during aseptic processing  Donning of protective equipment within clean rooms  Standard keyboard skills.  Regular lifting of stock.  Moving of heavy pallets using the equipment provided.  Standing for long periods.  Manual dexterity to lay plates. |
| **PHYSICAL EFFORT** |
| Standing for long periods. Sitting at an isolator for long periods during chemotherapy preparation  Occasionally work using a stepladder |
| **MENTAL EFFORT** |
| Concentration is required frequently in all routine tasks; interpreting environmental monitoring, preparing aseptic products, recording data |
| **EMOTIONAL EFFORT** |
| Ability to deal with demanding staff.  Deal with high stress levels. |
| **WORKING CONDITIONS** |
| Handling cytotoxic drugs/chemicals, wearing PPE, interruptions |
| **OTHER RESPONSIBILITIES** |
| Take part in regular performance appraisal.  Undertake any training required in order to maintain competency including mandatory training, e.g. Manual Handling  Contribute to and work within a safe working environment  You are expected to comply with Trust Infection Control Policies and conduct him/herself at all times in such a manner as to minimise the risk of healthcare associated infection  As an employee of the Trust, it is a contractual duty that you abide by any relevant code of professional conduct and/or practice applicable to you. A breach of this requirement may result in action being taken against you (in accordance with the Trust’s disciplinary policy) up to and including dismissal.  You must also take responsibility for your workplace health and wellbeing:   * When required, gain support from Occupational Health, Human Resources or other sources. * Familiarise yourself with the health and wellbeing support available from policies and/or Occupational Health. * Follow the Trust’s health and wellbeing vision of healthy body, healthy mind, healthy you. * Undertake a Display Screen Equipment assessment (DSE) if appropriate to role. |
| **DISCLOSURE AND BARRING SERVICE CHECKS** |
| This post has been identified as involving access to vulnerable adults and/or children and in line with Trust policy successful applicants will be required to undertake a Disclosure & Barring Service Disclosure Check. |
| **GENERAL** |
| This is a description of the job as it is now. We periodically examine employees' job descriptions and update them to ensure that they reflect the job as it is then being performed, or to incorporate any changes being proposed. This procedure is conducted by the manager in consultation with the jobholder. You will, therefore, be expected to participate fully in such discussions. We aim to reach agreement on reasonable changes, but if agreement is not possible, we reserve the right to insist on changes to your job description after consultation with you.  Everyone within the Trust has a responsibility for, and is committed to, safeguarding and promoting the welfare of vulnerable adults, children and young people and for ensuring that they are protected from harm, ensuring that the Trusts Child Protection and Safeguarding Adult policies and procedures are promoted and adhered to by all members of staff. |

PERSON SPECIFICATION

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| **Job Title** | SATO QC and Aseptics |

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| **Requirements** | **Essential** | **Desirable** |
| **QUALIFICATION/ SPECIAL TRAINING**  BTEC Level 2 Unit 7 Principles of Safe Preparation and Manufacturing of Medicines and Medicinal Products (or work towards  Experience to GPhC recognised level 3 qualification or equivalent level or willing to work towards qualification  Quality Assurance training, for example NWPQA course in principles of quality control (or work towards) | E  E  E |  |
| **KNOWLEDGE/SKILLS**  VDU (computer)  Stock control  Ability to solve problems | E  E  E |  |
| **EXPERIENCE**  6 months experience within Quality Control and/or aseptics (progressive role if required)  Retail/hospital/ industrial pharmaceutical work | E  E |  |
| **PERSONAL ATTRIBUTES**  Commitment to CPD  Methodical approach  Team worker  Flexible  Honesty/Integrity  Enthusiastic  Good communicator  Professional attitude | E  E  E  E  E  E  E  E |  |
| **OTHER REQUIREMENTS**  Ability to work effectively and accurately in a busy environment  Ability to travel to other locations as required | E | D |

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|  | | **FREQUENCY**  **(Rare/ Occasional/ Moderate/ Frequent)** | | | |
| **WORKING CONDITIONS/HAZARDS** | | **R** | **O** | **M** | **F** |
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| **Hazards/ Risks requiring Immunisation Screening** | |  |  |  |  |
| Laboratory specimens | Y/N | √ |  |  |  |
| Contact with patients | Y/N |  |  |  |  |
| Exposure Prone Procedures | Y/N | √ |  |  |  |
| Blood/body fluids | Y/N |  |  |  |  |
| Laboratory specimens | Y/N | √ |  |  |  |
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| **Hazard/Risks requiring Respiratory Health Surveillance** |  |  |  |  |  |
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| Solvents (e.g. toluene, xylene, white spirit, acetone, formaldehyde and ethyl acetate) | Y/N | √√ |  |  |  |
| Respiratory sensitisers (e.g isocyanates) | Y/N | √√ |  |  |  |
| Chlorine based cleaning solutions  (e.g. Chlorclean, Actichlor, Tristel) | Y/N | √ |  |  | √ |
| Animals | Y/N | √√ |  |  |  |
| Cytotoxic drugs | Y/N |  |  |  | √ |
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| **Risks requiring Other Health Surveillance** | |  |  |  |  |
| Radiation (>6mSv) | Y/N | √ |  |  |  |
| Laser (Class 3R, 3B, 4) | Y/N | √ |  |  |  |
| Dusty environment (>4mg/m3) | Y/N | √ |  |  |  |
| Noise (over 80dBA) | Y/N | √ |  |  |  |
| Hand held vibration tools (=>2.5 m/s2) | Y/N | √ |  |  |  |
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| **Other General Hazards/ Risks** | |  |  |  |  |
| VDU use ( > 1 hour daily) | Y/N |  |  |  | √ |
| Heavy manual handling (>10kg) | Y/N | √ |  |  |  |
| Driving | Y/N | √ |  |  |  |
| Food handling | Y/N | √ |  |  |  |
| Night working | Y/N | √ |  |  |  |
| Electrical work | Y/N | √ |  |  |  |
| Physical Effort | Y/N | √ |  |  |  |
| Mental Effort | Y/N |  | √ |  |  |
| Emotional Effort | Y/N | √ |  |  |  |
| Working in isolation | Y/N | √ |  |  |  |
| Challenging behaviour | Y/N | √ |  |  |  |