

JOB DESCRIPTION

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| **JOB DETAILS** | |
| **Job Title** | Quality Assurance/Quality Control Specialist |
| **Reports to** | Quality Assurance Manager |
| **Band** | Band 6 (Subject to formal matching) |
| **Department/Directorate** | Pharmacy/Clinical Specialist Services |

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| **JOB PURPOSE** |
| To maximise the effectiveness and influence of the Pharmaceutical Quality System in all preparation areas within Pharmacy Technical services, including both licensed and unlicensed areas. This is to ensure that high risk parenteral medicines are compounded and delivered in accordance with current Good Manufacturing Practice (cGMP). To work effectively as a team member to ensure regulatory compliance (Good Manufacturing Practice, Good Distribution Practice) across Pharmacy Technical Services departments  To take a key role in delivery of staff training, internal audits, maintenance of the e-Quality Management System (eQMS) in the drive for continuous improvement.  To act as a Releasing Officer in the licensed Production Units |
| **KEY RESULT AREAS/PRINCIPAL DUTIES AND RESPONSIBILITIES** |
| To support in order to ensure continued compliance to regulatory standards -Good Manufacturing Practice (GMP) related to Pharmacy Technical Services (Technical Service Unit (TSU), Exeter Pharmaceutical Services (EPS), Radiopharmacy (RP) and Quality Assurance (QA)). This involves:   * The maintenance of the electronic Quality Management System (eQMS) across Pharmacy Technical Services. * Leading on the scheduling and delivery of internal audits. * Addressing internal and external audit findings and self-inspection findings and supporting others to do likewise. * Acting as Quality Reviewer and Departmental Manager to review records on the electronic Quality Management System (eQMS) including performing and reviewing impact and risk assessments, review of action plans and review for closure. * Completing your assigned actions on the eQMS. * Raising and reviewing records and action plans on the eQMS including audits, exceptions/deviations, out of specification results, complaints and capacity issues in line with local procedures. * Review of records on the eQMS for closure. * Any other activities involved in the maintenance of the QMS. * Driving continuous improvement and promote a culture of quality across all Pharmacy Technical services. * Write and approve validation protocols and reports. * Complete validation protocols and reports. * Review of environmental monitoring data to identify trends and ensuring these are logged on the eQMS. * Participate in the department rota to ensure a pharmacy service is provided efficiently over 7 days including weekends, late duties and bank holidays |
| **KEY WORKING RELATIONSHIPS** |
| Areas of Responsibility: Pharmacy QA department (Eastern)  No. of Staff reporting to this role: 1    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** | | * Deputy Lead - Technical Services * Principal Pharmacist – Technical Services * Chief Technician – Aseptic Services * Chief Technician – EPS * Aseptic Team (Northern & Eastern) * R&D Pharmacy Team * Radiopharmacy (Nuclear Medicine) * Q-Pulse superuser * IT department | * Regional & National QA & QC services * Contractors * Service users | |
| **ORGANISATIONAL CHART** |
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| **FREEDOM TO ACT** |
| Post holder works independently within occupational, departmental policies & procedures in the Quality Assurance Department. Is the Lead for the eQMS and completes tasks autonomously  The post holder will be required to work independently with local policies and procedures within the Quality Assurance Department. The post holder will be required to plan their own workload to meet internal and external ie regional QA, deadlines. They will be responsible for escalating concerns and operational issues with the QA department to both the QC laboratory manager and the Quality Assurance manager. As the lead for the eQMS system for the department, the post holder will be responsible to ensuring the service has enough resources, escalating this issue when this is not met. |
| **COMMUNICATION/RELATIONSHIP SKILLS** |
| * Accurately completing and maintaining written and electronic records, technical reports and other documentation in accordance with current legislation, recommendations and guidelines. * Presenting complex information to staff at all levels in the departments and at regional and national meetings Provides and receives complex information that needs to be compiled and analysed and to be summarised for section managers and senior managers within the Trust * Addressing comments and concerns from staff in a timely and respectful manner. * Excellent literacy, numeric and written communication skills. * The post holder will be responsible to maintaining the eQMS to meeting internal and external regulatory compliance requiring excellent written communication skills. * The post holder will be required to produce, communicate technical reports that will remain impactful for both experts and non-experts alike. * Presenting complex information to staff at all levels in the departments and at regional and national meetings * Addressing comments and concerns from staff in a timely and respectful manner. * Excellent literacy, numeric and written communication skills. * While communicating with the wider team, physical, neurodivergence and service understanding needs will vary the postholder will be expected to adapt own communication styles (oral & written) to overcome any barriers to understanding Post holder will need to understand complex systems and identify issues that need following up with section managers as well as issues that can be resolved by the post holder. |
| **ANALYTICAL/JUDGEMENTAL SKILLS** |
| * Specialist knowledge and experience of dealing with highly complex pharmaceutical issues which require the scientist to analyse information from a range of sources, which may not be in agreement, to formulate a response. In such situations, it may be necessary to find an innovative solution to an unusual pharmaceutical situation, including the development or refinement of data collection and analysis tools. * The post holder will also be required to periodically review the eQMS wizards and reports to ensure that data remains relevant, complete and regulatory compliant. * The post holder will need to investigate data discrepancies and test result failures using their knowledge of the systems and instruments in use to identify the root cause of an incident and suggest corrective actions to prevent this occurring in the future. * The postholder is required to make judgement of best- or worst-case process and needs to complete interpretation of results following the completion of these validation processes * Performing root cause analysis and recording and implementing corrective and preventative actions in line with local procedures. * Performing gap analysis to identify areas of non-compliance in relation to GMP and areas for improvement; supporting departments to action accordingly |
| **PLANNING/ORGANISATIONAL SKILLS** |
| * Leads a small team of technical staff, as required, in the Quality Assurance Service ensuring they have appropriate induction, regular appraisals, personal development plans and challenging but realistic objectives. * Ensures equipment and facilities are subject to an appropriate programme of validation * Plans activity workload for self and others within the team to ensure compliance with departmental requirements (validation plan) * To ensure that the ePharmacy Quality System (ePQS) is fully qualified and remains in a validated status when in operation. Any change to software or application must be subject to revalidation through the change control mechanism. * To ensure that there is robust governance infrastructure over the ePQS, including configuration, access permission, audit trails and secure access. To ensure that robust Data Integrity is maintained in accordance with all related regulations. * To ensure that all related ePQS SOPs are raised, approved, controlled and maintained. |
| **PATIENT/CLIENT CARE** |
| * Provides specialist clinical technical services including suggestions for controlling microbial growths, product rejections and regulatory compliance. * Acts as a releasing officer within the licensed facilities and ensures that medicinal products are of the required quality to ensure patient safety. This includes knowledge of the validation status of facility, equipment & operators * Reviewing eQMS records and data, including errors, exceptions/deviations, out of specification results, and complaints to identify trends and record these on the eQMS. Provides specialist technical services advice and assessment for example reviewing incidents and controlled changes to ensure that these are recorded and handled in line with SOPs and the relevant standards. * Acts as a releasing officer within the licensed facilities and ensures that all products produced under the MS licence are of the required quality to ensure patient safety. This includes knowledge of the validation status of facility, equipment & operators as well as regulatory requirements for labelling and supply. * Reviewing eQMS records and data, including errors, exceptions/deviations, out of specification results, and complaints to identify trends and record these on the eQMS |
| **POLICY/SERVICE DEVELOPMENT** |
| * Update and write new documentation including Standard Operating Procedures (SOPs). * Review and approve documentation including SOPs. * Create and implement new SOPS or policies that fit within the existing framework for documentation within the quality assurance department and ensures that they are impeded into the service areas as required. * To lead, manage, implement, maintain and develop the Quality Management System, * To ensure that the Quality Management System is comprehensive and meets MHRA GMDP and appropriate related standards. |
| **FINANCIAL/PHYSICAL RESOURCES** |
| * Responsible for safe use of equipment by QC lab personnel as well as those in training and placements. * Orders supply for area of work and his responsible for storage of material used within the QA department * To ensure that sufficient licenses are in place for the eQMS system. |
| **HUMAN RESOURCES** |
| * Primarily responsible for day-to-day supervision or co-ordination of staff within the department/service * Leading on the delivery of staff training on GMP and for changes to processes, equipment, procedures. * Supporting all staff within QA & Pharmacy Technical Services in the use of the eQMS including mentorship and training as needed * To ensure that there is a mechanism in place that all staff receive appropriate training (induction, refresher and update) and have access to the ePQS and pharmaceutical quality matters information issued by NHS Quality Assurance * Is responsible for the direct day-to-day management of the Validation Co-ordinator within the QA/QC team * Conducts sickness and initial stages of disciplinary/grievance reviews as required. |
| **INFORMATION RESOURCES** |
| * Records and actions personally generated reports in relation to the eQMS system. Records and assigns remedial actions as required by cGMP * Supporting quality meeting by: Writing agendas, gathering Quality Indicator metrics, trend analysis, attending meetings and minute taking for Quality meetings as required |
| **RESEARCH AND DEVELOPMENT** |
| * Regularly participates in equipment testing that is used within the Technical Services. * Supports the R&D Clinical Trials Pharmacy through validation of critical equipment including temperature monitoring equipment, temperature mapping of fridges/freezer and specialized pharmaceutical software to ensure Investigational Medicine Products (IMP) handling requirements are met. * To undertake and collaborate on research and audit projects within own area as required. * To participate in internal audits, providing feedback and recommendations to the Principal Pharmacist- Technical Services and to participate in external audits in order to improve practice. |
| **PHYSICAL SKILLS** |
| * High level of accuracy and skill required for inputting data within a timely manner. The ability to analyse any microbial out of specification trends including trending, thematic review and tests for statistical significance. |
| **PHYSICAL EFFORT** |
| * There is a frequent requirement for sitting or standing in a restricted position for a substantial proportion of the working time including use of VDU. * The post requires a combination of sitting, standing, and walking. The ability to work in clean rooms is essential i.e. to be able to don appropriate clothing and negotiate step over stiles whilst carrying equipment. The post holder may be required to access plant rooms and occasionally work in restricted positions. |
| **MENTAL EFFORT** |
| * Frequent requirement for prolonged concentration for quality checks. The post requires frequent amounts of concentration for batch release and performing complicated calculations etc. Post holders will frequently be interrupted by urgent or non-urgent enquiries, received verbally, or by telephone, at any time, including during breaks. |
| **EMOTIONAL EFFORT** |
| * Rare exposure to distressing or emotional circumstances including negative treatment outcomes for patients or high workload demands |
| **WORKING CONDITIONS** |
| Frequent VDU use for IT systems work e.g. electronic Quality system (Q-pulse)  The post holder will be required to travel to all trust sites for meetings, training sessions or to support core service provision.  The post holder must be able to work in a clean room environment and adhere to the associated hygiene and clothing requirements. This involves:   * Absence of make-up in clean rooms * Removal of jewellery * Wearing of clean room garments including hoods and face masks * Working in a confined workspace for periods up to three hours at a time * Working within environments that are used for the processing of cytotoxic medicines, biological agents, biocidal and, peroxide chlorine-based cleaning agents and laboratory reagents in line with COSHH regulations. |
| **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 (DES) if appropriate to role. |
| **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.  At the Royal Devon, we are committed to reducing our carbon emissions and minimising the impact of healthcare on the environment, as outlined in our Green Plan available on our website. We actively promote sustainable practices and encourage colleagues to explore and implement greener ways of working within their roles. |

PERSON SPECIFICATION

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| **Job Title** | Quality Assurance/Quality Control Specialist |

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| **Requirements** | **Essential** | **Desirable** |
| **QUALIFICATION/ SPECIAL TRAINING**  Honours degree in Pharmaceutical Sciences, Chemistry, Biology, Microbiology, Biomedical Sciences (or similar)  OR  Registered Science Manufactured Technician with the Sciences Council or Registered Pharmacy Technician with the GPhC  Eligible for registration with the Health and Care Professions Council (HCPC), Science Council, General Pharmaceutical Council (GPhC), Royal Society of Chemistry (RSC), Institute of Biology or equivalent professional body  Post-graduate certificate or diploma in relevant field or equivalent knowledge  Further education in Pharmacy Technical Services  e.g. PTQA (PGDiP/MSc Pharmaceutical Technology and Quality Assurance) or STP (MSc Clinical Science (Pharmaceutical Science) | X  X  X  X | X |
| **KNOWLEDGE/SKILLS**  Aseptic preparation and Good Manufacturing practice  Experience of training others  Accuracy checking training  Customer care  Good dispensing, distribution, manufacturing practice  Incident and error reporting  Developing and implementation of procedures  Knowledge of clean room design and functioning  Managing change  Risk assessments  Incident and error reporting  Health &Safety / COSHH assessments  Project management | X  X  X  X  X  X  X | X  X  X  X  X  X |
| **EXPERIENCE**  Experience and knowledge of pharmaceutical Quality Management Systems  Experience and knowledge of regulatory guidance and standards relating to pharmaceutical quality management (e.g. GMP, GDP and ICH Q10)  Experience and knowledge of risk management  Experience in supporting change management  Experience in audit  Experience in training and presenting  Hospital pharmaceutical QA/QC and/or manufacturing/aseptic preparation service experience  Management/Supervisor experience | X  X  X  X | X  X  X  X |
| **PERSONAL ATTRIBUTES**  Flexible/adaptable  Enthusiastic & reliable  Professionalism  Able to lead and motivate staff  Support and value staff and colleagues  Able to cope with conflict and handle difficult situations  Able to work as a team member. | X  X  X  X  X  X  X |  |
| **OTHER REQUIREMENTS**  The post holder must demonstrate a positive commitment to uphold diversity and equality policies approved by the Trust.  Ability to travel to other locations as required. | X  X |  |

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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 | N |  |  |  |  |
| Contact with patients | N |  |  |  |  |
| Exposure Prone Procedures | N |  |  |  |  |
| Blood/body fluids | N |  |  |  |  |
| Laboratory specimens | /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) | N |  |  |  |  |
| Respiratory sensitisers (e.g isocyanates) | N |  |  |  |  |
| Chlorine based cleaning solutions  (e.g. Chlorclean, Actichlor, Tristel) | Y | xx |  |  |  |
| Animals | N |  |  |  |  |
| Cytotoxic drugs | Y |  | x |  |  |
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| **Risks requiring Other Health Surveillance** | |  |  |  |  |
| Radiation (>6mSv) | N |  |  |  |  |
| Laser (Class 3R, 3B, 4) | N |  |  |  |  |
| Dusty environment (>4mg/m3) | N |  |  |  |  |
| Noise (over 80dBA) | N |  |  |  |  |
| Hand held vibration tools (=>2.5 m/s2) | N |  |  |  |  |
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| **Other General Hazards/ Risks** | |  |  |  |  |
| VDU use ( > 1 hour daily) | Y |  |  |  | x |
| Heavy manual handling (>10kg) | Y | x |  |  |  |
| Driving | Y |  | x |  |  |
| Food handling | N |  |  |  |  |
| Night working | N |  |  |  |  |
| Electrical work | N |  |  |  |  |
| Physical Effort | Y |  |  |  | x |
| Mental Effort | Y |  |  |  | x |
| Emotional Effort | Y | x |  |  |  |
| Working in isolation | N |  |  |  |  |
| Challenging behaviour | N |  |  |  |  |