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#### **JOB DESCRIPTION**

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| JOB IDENTIFICATION |
|  Job Title: Senior Quality Assurance PharmacistResponsible to: Principal Radiopharmacist Department(s): Radiopharmacy, Nuclear MedicineDirectorate: Access and Patient Assurance DirectorateOperating Division: Diagnostics Clinical Care GroupJob Reference: Sco6-5898NNo of Job Holders: 1Last Update (insert date): 06/11/2023 |
| 2. JOB PURPOSE  |
| Management of the Pharmaceutical Quality System of the Radiopharmacy, which is a requirement of EU Good Manufacturing Practice published by the Medicines and Healthcare products Regulatory Agency (MHRA) and the Quality Assurance of Aseptic Preparation Services (QAAPS): Standards published by the Royal Pharmaceutical Society of Great BritainSupport and deputise for the Principal Radiopharmacist in all Quality Assurance matters, to ensure the Radiopharmacy operates according to the principles of EU GMP and the QAAPS standards). This will be achieved by coordinating and approving all (sterility and stability) quality control tests performed on all medicines manufactured; monitoring and acting on out of specification results from equipment and the clean room environment; investigation and closing deviations; leading and approving root cause analysis investigations; managing change control and training of new staff in quality control and quality assurance. |
| 3. DIMENSIONS |
| The Radiopharmacy provides radiopharmaceuticals for approximately 8,000 patients per year in the Nuclear Medicine departments and theatres across Tayside.The Radiopharmacy is responsible for the quality of medicines used in the PET Nuclear Medicine service, including medicinal products used in clinical research, conducted at the Clinical Research Centre, Tayside (CRC) in association with the University of Dundee.The Radiopharmacy is responsible for the purchase, receipt and delivery of all radioactive materials used for medicinal purposes for NHS Tayside, comprising a budget of £530,000 per year.**Staffing Responsibilities:**Direct line management of the Radiopharmacy Quality Systems Specialist, including annual appraisal, personal development, and performance review for this postDay to day supervision of pharmacists and technical staff within the specialist area. This role will include specified human resource functions e.g. participation in recruitment and selection for all Radiopharmacy posts, personal development, and performance review.Responsible ensuring that all staff in the Radiopharmacy are adequately trained and validated to perform their duties. Contribute to the education and training of Radiopharmacy staff and rotational technicians on Quality Assurance and current GMP regulations and standards.**Financial Responsibilities**Authorised signatory for the purchase of radiopharmaceuticals and supplies to the value of £20,000. |
| 4. ORGANISATIONAL POSITION |
|   Line managerially responsible to **\_\_\_\_\_\_** Professionally Accountable to ............. |

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| 5. ROLE OF DEPARTMENT |
| The aim of the Pharmacy Service is to assure quality of patient care in the provision of treatment with medicines. To this end, the objectives are:(i) To provide pharmaceutical care to individual patients by meeting their particular needs whilst maximising efficiency in the use of resources.(ii) To provide medicines through systems of quality control which ensure safe, effective, and economic use.The Radiopharmacy achieves the objectives as a section 10 unit managed by an “Accountable Pharmacist” to produce radiopharmaceuticals that comply with the Quality Assurance of Aseptic Preparation Services: Standards published by the Royal Pharmaceutical Society of Great Britain The Radiopharmacy is part of NHS Tayside’s Ninewells Nuclear Medicine department. The job holder is employed within NHS Tayside and there may be a requirement to work flexibly across Tayside to meet service demands.  |
| 6. KEY RESULT AREAS |
| **Main duties and responsibilities**1. Managing the Quality Systems Specialist and working with the Principal Radiopharmacist to ensure the Radiopharmacy operates according to the legal requirements of its Section 10 status, following QAPPS standards and EU Guidance on Good Manufacturing Practice (GMP). This will be achieved by assisting in the approval and review of standard operating procedures; training of new staff in quality control and quality assurance; monitoring quality control results of products, equipment, and facilities; raising, investigating, and approving deviations from out of specification results; and ensuring the Pharmaceutical Quality System (PQS) is kept up to date with current GMP standards.
2. Further development and maintenance of a comprehensive PQS to ensure the quality, safety and efficacy of the products manufactured, including the review and approval of standard operating procedures, change control reports, risk assessments, worksheets, and other approved documentation.
3. Perform monitoring and approval of critical tests and trend analysis of results, including environmental monitoring and instrument calibration to ensure the Radiopharmacy facility and equipment is performing within GMP specifications.
4. Raise and investigate, or review and close, deviation investigations, including root cause analysis investigations, arising from out of specification results from quality control checks of products, environmental monitoring, and corrective and preventative action (CAPA) reports.
5. Contribute to the development of the service, in response to legislative and regulatory changes, in-house research and validation, the evolving consensus of GMP and the availability of new diagnostic tests and treatments.
6. Perform and check final product quality control checks on radiopharmaceuticals, approving them for release for use in patients, or rejecting them if quality standards do not meet specifications according to EU Good Manufacturing Practice standards.
7. Participate in production sessions, including the sterile manufacture of radiopharmaceuticals, and the radiolabelling of autologous blood cells This requires maintenance of competency in aseptic manipulation.
8. Responsible for ordering radiopharmaceuticals and supplies to the total value of £20,000. Is an Authorised Signatory for this task.
9. Ensure that the quality assurance programme is carried out: meeting key performance indicators for the PQS and ensuring all quality system tasks are carried out to the Validation Master Plan.
10. Ensure that radiation protection principles are applied and compliance with the Scottish Environmental Protection Agency (SEPA) registration is maintained for the storage and disposal of radioactive materials.
11. Participate in internal and external audit of the Radiopharmacy service including regular inspection by the Regional Quality Assurance Service, the Office of Nuclear Radiation (ONR) and SEPA. Contribute to the development and completion of action plans to correct non-conformances identified by internal and external audits.
12. Ensure that Radiopharmacy and rotational staff are adequately trained in the principles of GMP by undertaking in-house training and supervision according to structured training plans to achieve the required competencies.
13. Provide specialist Radiopharmacy input to ensure the PET imaging service at the Ninewells Imaging Facility (Tayside Clinical Research Centre) are provided with a safe and appropriate PET radiopharmaceutical service for NHS patients and volunteers in research studies and clinical trials with the University of Dundee. This includes review of research study and clinical trial protocols for compliance with Good Clinical Practice, GMP and the Administration of Radioactive Substances Advisory Committee (ARSAC) recommendations for all studies involving radiopharmaceuticals.

**Other departmental duties**14.Day to day management and appraisal of the performance of the Quality Systems Specialist, including agreement and review of their personal development plan derived from the Knowledge & Skills Framework and participate in recruitment and selection as required.15 Act as the Lead Pharmacist for the Radiology service across NHS Tayside. This involves being the primary pharmacy contact for the four Radiology departments, assisting with the development and approval of patient group directions and ensuring the safe and effective use and supply of medicines in the Radiology departments of NHS Tayside. 16.Attend Oncology MDT meetings with regards to Radionuclide therapy decision making and work with oncology to manage visits, blood results and therapies / medications through Chemo care. |
| 7a. EQUIPMENT AND MACHINERY |
| The post-holder requires specialist knowledge and experience of the principles of operation of the equipment and instrumentation in the Radiopharmacy. This involves practical use, quality control and first-line diagnosis of faults in equipment such as: radionuclide generators; laminar air-flow safety cabinets; the Amercare PET isolator; the fume cupboard; radionuclide calibrators; the high-performance liquid chromatograph (HPLC); the thin-layer radiochromatogram scanner with a gamma-ray spectrometer and radiation monitors (Geiger counters and scintillation detectors).An understanding of the operation of the air handing plant that supplies sterile air to the aseptic suite is also required, including the critical appraisal and response to maintenance and breakdown reports related to this equipmentBe responsible for the validation of new equipment introduced into the Radiopharmacy, to meet EU GMP standards for sterile medicine manufacture, and the safety standards of the Ionising Radiation Regulations, 2017. **Note:** New equipment may be introduced as the organisation and technology develops, however training will be provided.  |
| 7b. SYSTEMS |
| The following are examples of systems which will be used when undertaking the role:Radiopharmacy database to record workload and prepare worksheets, labels, delivery notes and despatch documentation.CRIS, ICE, TRAK, Clinical PortalSoftware systems: Pharmacy stock control and dispensing system CMM; Chemocare SPECTRA, LAURA, PECOSPharmacy management information reporting systemMicrosoft Office for word processing, spreadsheets, e-mail, internet accessMedicines Information databasePatient administration systemDatix incident management systemeKSF personal development and review systemThe Radiopharmacy Pharmaceutical Quality System Q pulseThe Pharmacy Quality System (BS EN ISO 9001:2015)Environmental Monitoring Systems**Note:** New systems may be introduced as the organisation and technology develops, with training provided.  |

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| 8. ASSIGNMENT AND REVIEW OF WORK |
| Meets and consults with the Principal Radiopharmacist on a regular basis to review service provision and determine future developments.Review of performance is carried out by the Principal Radiopharmacist in accordance with the principles of personal development and the Knowledge & Skills Framework.Agree objectives with the Principal Pharmacist, with three monthly review and annual appraisal.Act independently within appropriate guidance and consult line manager when necessary.**Responsibility for Records Management**All records created in the course of the business of NHS Tayside are corporate records and are public records under the terms of the Public Records (Scotland) Act 2011. This includes email messages and other electronic records. It is your responsibility to ensure that you keep appropriate records of your work in NHS Tayside and manage those records in keeping with the NHS Tayside Records Management Policy and with any guidance produced by NHS Tayside specific to your employment. |
| 9. DECISIONS AND JUDGEMENTS |
| High degree of autonomy in managing all risks to the patient attributable to sterile manufacture of licenced and unlicensed medicinal products and the use of ionising radiation for diagnostic tests and therapy. This may involve analysis and interpretation of complex information in relation to the product quality, radiation exposure and the function of the Radiopharmacy sterile suite (environmental monitoring results, air pressure differentials, air change rates and microbiological results) and the necessary actions based on critical risks to patient safety. Independently make judgements on the quality of manufactured medicinal products by performing or assessing in-process and final product quality control checks and approving the release of these products to patients.Perform final release of radiopharmaceuticals for injection into patients if the quality standards are met or reject batches in the event of deviation from specification.Perform the appropriate supplier and product quality checks to ensure all radiopharmaceutical products and research study tracers used in NHS Tayside patients and volunteers are fit for purpose and meet the quality requirements appropriate to their classification as medicinal products or investigational agents. Responsible for ensuring the provision of radiopharmaceuticals for PET imaging at the Ninewells Imaging Facility is safe and appropriate for NHS Tayside patients receiving PET scans, by conducting quality audits and reviews of PET radiopharmaceutical suppliers. |
| 10. MOST CHALLENGING / DIFFICULT PARTS OF THE JOB |
| Ensuring the safety, quality and efficacy of licenced and unlicensed medicinal products manufactured, by analysis of data obtained within a Quality Control laboratory within available resources. Working with the Tayside Imaging PET centre and the University of Dundee to determine which studies, clinical trials and radiopharmaceutical products are appropriate for use in NHS Tayside patients and volunteersContinuing to meet the increasing quality standards of EU Good Manufacturing Practice as published by the Medicines and Healthcare products Regulatory Agency (MHRA) and the Quality Assurance of Aseptic Preparation Services: Standards published by the Royal Pharmaceutical Society of Great Britain. To achieve the above by means which maintain radiation safety and radiation protection issues as key considerations in all procedures.  |
| 11. COMMUNICATIONS AND RELATIONSHIPS |
| Communication is either on a one-to-one basis or in a group setting. Communication, either verbal or written, takes place between healthcare professionals as appropriate to ensure the highest quality medicinal products and services are delivered from the Radiopharmacy and external providers. This communication will be highly complex, sensitive, or contentious where it challenges others’ clinical or technical judgement, when deciding to accept or reject a product manufactured in the Radiopharmacy, or by an external provider. Communicate with the Medicines and Healthcare products Regulatory Agency, or other agencies, their Inspectorate and appointed auditors.Provide advice to consultant clinicians, clinical trial principal investigators, superintendent radiographers, and medical physics technicians about the quality of radiopharmaceuticals.Provide feedback on performance during appraisal and other line management duties to the Quality Systems Specialist.Communicate with suppliers and resolve resulting issues concerning the quality of raw materials and radiopharmaceuticals, including radiopharmceuticals purchased for the PET centre.Communicate with Quality Risk and Governance staff and Microbiology concerning the microbiological monitoring results of the aseptic suite and aseptic processes.Participate in the Radiopharmacy team meetings.Respond to product quality complaints from customers, including communication of the outcome of investigations.Communicate effectively in a manner in keeping with the NHS Tayside and Radiopharmacy team values regarding the professional operation of the Department.Provide reassurance and support to new members of staff that have concerns about working with hazardous chemicals and ionising radiation.Demonstrate duties and techniques to less experienced members of staff. |
| 12. PHYSICAL, MENTAL, EMOTIONAL AND ENVIRONMENTAL DEMANDS OF THE JOB |
| Physical:A high degree of manual dexterity is required. Frequent manipulation of liquid radioactive materials using needles, syringes and small vials requires great care to avoid radioactive contamination and rapid working to avoid radiation exposure. Frequent handling of organic solvents and hazardous chemicals in the Quality Control Laboratory is also required. Aseptic manipulation skills are essential and will be regularly validated. The post holder will require hepatitis B vaccination.Mental:Consideration of highly technical data, pertaining to radiation safety and quality control of sterile medicinal products to make informed decisions regarding product quality under strict time constraints. High levels of concentration, precision and accuracy required during aseptic manipulation of precise volumes of radioactive material during manufacture. Emotional: Support members of staff who experience personal problems or work-related performance issues. Investigate and deal with complaints from customers or patients and deal with product quality issues with potentially serious consequences.Environmental:Exposure to ionising radiations, hazardous chemicals, blood components and bodily fluids in the laboratory setting. Work in an aseptic environment using aseptic techniqueThe post holder is required to become a radiation worker and will be required to become a classified radiation worker and undergo an annual medical |

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| 13. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB |
| The post-holder should be a qualified pharmacist, Pharmacists: Master’s degree in pharmacy (MPharm)Registered on the General Pharmaceutical Council (GPhC) register as a pharmacistCompletion of the Scottish Hospital Pharmacists Vocational Training (Stage II) or documented evidence of equivalent competency from the pharmaceutical industryPost-qualification experience as a hospital pharmacist, in the pharmaceutical industry, or in an MHRA licensed manufacturing facility,working in a Quality Control and Quality Assurance role, including performing final release of products.Post-graduate qualification in Quality Assurance or Radiopharmacy (Post-Graduate Diploma or MSc), such as Pharmaceutical Technology and Quality Assurance (PTQA),**Skills and Experience:**Knowledge, training, and experience relating to the Quality Assurance of Aseptic Preparation Services: Standards issued by the Royal Pharmaceutical Society of Great Britain The post-holder must meet the requirements in qualifications, knowledge and experience stated in the MHRA Guidance for Specials Manufacturers for performing final release of manufactured unlicensed “Specials.”  |
| 14. JOB DESCRIPTION AGREEMENT |
| A separate job description will need to be signed off by each jobholder to whom the job description applies. Job Holder’s Signature: Head of Department Signature: | Date:Date: |

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| **NHS Tayside - PERSON SPECIFICATION** |
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| **Job title** | Senior Quality Assurance Pharmacist  |
| **Base** | Radiopharmacy, Nuclear Medicine Department , Ninewells Hospital |
| **Requirements** | Attribute | Essential (E)**Desirable (D)** |
| **Qualifications** | Pharmacist applicants:Masters degree in Pharmacy (MPharm)Registered as a pharmacist on the General Pharmaceutical Council RegisterCompletion of Scottish Hospital Pharmacists Vocational Training (Stage II) or equivalent experiencePost Graduate qualification in Quality Assurance or Radiopharmacy (Diploma/ MSc) or Scientific Training Programme MSc (STP) | EEED |
| Experience | Experience of working within the specialist area of Aseptic Production in a quality assurance and quality control role, including final product releaseCompletion of competency-based training plan for a pharmacist, working in a Radiopharmacy, Aseptic Unit, Pharmaceutical industry or MHRA licensed manufacturing unit. | EE |
| **Knowledge, skills**  | Knowledge of: |  |
| **and ability** | Rules and Guidance for Pharmaceutical Manufacturers and Distributors issued by the MHRA | D |
|  | Operation of an aseptic suite | E |
|  | Preparation of aseptic pharmaceuticals | E |
|  | Radiation and radiation protection | D |
|  | Aseptic pharmaceutical quality assurance | E |
|  | Dealing with queries relating to the preparation and supply of aseptic pharmaceuticals | E |
|  | Pharmaceutical Quality Systems | E |
|  | Relevant national standards and guidelines | E |
|  | Safe and secure handling of medicines | E |
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|  | Skills: |  |
|  | Aseptic technique | E |
|  | Dispensing and checking skills | E |
|  | Analytical techniques | E |
|  | Critical review of data | E |
|  | Leadership | E |
|  | Supervisory & Appraisal | E |
|  | Computing and keyboard | E |
|  | Management of people and resources | E |
|  | Advanced numeracy | E |
|  | Communication (verbal and written) | E |
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|  | Abilities: |  |
|  | Work within teams | E |
|  | Use and maintain computer databases | E |
|  | Work under time constraints and manage own time | E |
|  | Assign and organise work of others | E |
|  | Lead others | E |
|  | Undertake and record continuing professional development | E |
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| **Other**e.g. personal attributes | Pleasant, kind and respectful mannerFlexible and adaptableAbility to think clearly under pressure | EEEEE |
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