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#### **JOB DESCRIPTION**

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| JOB IDENTIFICATION | |
| Job Title: Trainee Clinical Scientist  Responsible to: Lead Pharmacist, Radiopharmacy  Department(s): Pharmacy  Directorate: Pharmacy  Operating Division: Corporate  Job Reference: 152844  No of Job Holders: 1  Last Update (insert date): 28 Mar 2023 | |
| 2. JOB PURPOSE | |
| The Trainee Clinical Scientist will contribute to the maintenance and development of the Pharmaceutical Quality System of NHS Lothian, which presides over four “Section 10” Aseptic units, a Radiopharmacy that operates under a Manufacturer’s “Specials” Licence and a Clinical Trials Unit regulated by the Medicines and Healthcare products Regulatory Agency (MHRA). The trainee’s role will be to develop competency in and perform Quality System tasks such as: writing and review of procedures; investigation of product and process deviations; performing risk assessments; writing validation reports (for processes, equipment, operators and products); undertaking trend analysis of data and the quality control checks associated with medicines manufacture. All activities will be performed under the direct supervision of the principal supervisor responsible for the post-holder’s training.  To undertake a formal postgraduate training programme in Clinical Pharmaceutical Science, specialising in Quality Assurance roles in Radiopharmacy, Aseptic, Clinical Trials and the Quality, Risk and Governance (QRGS) department.  Opportunities to undertake research and development activities in pharmaceutical science applied to the provision of medicines supply, manufacture and quality assurance will also be prioritised. | |
| 3. DIMENSIONS | |
| The responsibility for the delivery of the training programme (3 years formal training) is held by NHS Lothian on behalf of NHS Education Scotland (NES), with the trainee being employed by NHS Lothian. The programme matches closely with the other funded Clinical Scientist training programmes managed by other Health Boards.  Trainees are generally based in a specific hospital site where there is a senior pharmacist who acts as principal supervisor. Placements are agreed ahead of starting training and trainees can expect short term placements in any of NHS Lothian’s Acute Hospital sites, with the potential for short visits to external Health Boards for the purpose of meeting specific training requirements.  The unique remit of the Clinical Scientist in pharmacy is to apply up-to-date, highly-specialised knowledge of Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) to all aspects of the provision of medicines to NHS Lothian patients. This post provides a comprehensive and varied training programme in Clinical Trials, Quality Assurance and sterile pharmaceutical manufacture to diversify the pharmacy workforce and provide access to a wider selection of candidates for specialised pharmacy services for the National Health Service of the future in Scotland.  The programme includes training in Quality Assurance, Radiopharmacy, Aseptic Services, Medicines Manufacture and Clinical Trials. Applied research methodology is an important part of the programme and trainees will contribute to research and development projects across the pharmacy service. An integral part of the post is attendance at, and successful completion of an MSc course in Clinical Pharmaceutical Sciences.  The trainee will be expected to complete all work-based training and assessment alongside the academic master’s course to exit the programme with eligibility for registration with the Health and Care Professions Council (HCPC), to use the protected title of Clinical Scientist. In addition, they will be expected to undertake work-based experiential learning to enable them to communicate complex technical, scientific and potentially sensitive information to colleagues within their department in both verbal and written forms. It is a requirement for healthcare professionals working in these roles to be registered with the HCPC and must therefore meet the HCPC's standards for training, professional skills and behaviour | |
| 4. ORGANISATIONAL POSITION | |
| Associate Director of Pharmacy:  Acute Services  Lead Pharmacist, Radiopharmacy  Radiopharmacy  Production Manager  Senior QA Pharmacist, Radiopharmacy Assurance Specialist **this post** (2.0 wte)  Trainee Clinical Scientist  (this post)  Lead Pharmacist, Clinical Trials  Lead Pharmacist, Aseptic Services  Accountable Pharmacists for Aseptic Units |  |
| 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 NHS Lothian Acute Pharmacy Service achieves these objectives through the provision of the Pharmaceutical Quality System, which is certified by the British Standards Institution (BSI) and regularly inspected by the Medicine and Healthcare Products Regulatory Agency (MHRA) in both Radiopharmacy and Clinical Trials.  The Clinical Scientist Trainee is a member of the NHS Lothian Pharmacy team and, as such, there may be a requirement to work flexibly across NHS Lothian’s Acute Hospital sites to meet service demands and training requirements.  The Department of Pharmacy provides services to primary and secondary centres throughout Lothian. Services include dispensing, aseptic, clinical, radiopharmacy, procurement and distribution, medicines information, medicines management and quality assurance. These services are currently delivered across 4 Health and Social Care Partnerships and 7 hospital sites: the Western General Hospital (WGH), the Royal Infirmary of Edinburgh (RIE), the Royal Hospital for Children and Young People (RHCYP), St John’s Hospital (SJH), Royal Edinburgh Hospital (REH), East Lothian Community Hospital (ELCH) and Liberton Hospital (LIB). | |

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| 6. KEY RESULT AREAS |
| **Main duties and responsibilities**   1. The trainee will undertake the full training programme in order to progress through the modules of the training scheme including:  * to perform and interpret clinical and specialist scientific processes underpinned by theoretical and applied knowledge and practical experience, * how to carry out complex scientific and technical roles, including the preparation and quality control testing of medicines for administration to patients; * to analyse, interpret and compare investigative tests, specifications and procedures; make analytical and differential judgements, involving complicated data or situations that impact patients; * to initiate and undertake innovation, improvement, research and development, * to be involved in the education of pharmacy staff, students and other healthcare workers.  1. Under supervision, undertake a range of technical and scientific investigations as appropriate to the role. These may include the quality control testing of locally manufactured medicinal products (radiochemical purity, endotoxin, pH and filter integrity testing); analysis of microbiological samples from sterility testing and environmental monitoring and review of QC results on certificates of analysis for materials used in aseptic preparation or medicines procured for patient use in clinical trials. 2. Whilst in training, develop competency in the safe use of complex scientific and medical equipment, including recording all maintenance and calibration procedures performed and any corrective actions undertaken. Assist in the provision of advice to other healthcare staff on the optimal and safe use of scientific procedures and highly complex equipment. 3. Participate in the aseptic manufacture and preparation of sterile medicinal products, which involves exposure to ionising radiation and cytotoxic medicinal products. This requires validation and maintenance of competency as an aseptic operator in the NHS Lothian Pharmacy service. 4. Under supervision, perform quality control and acceptance tests on active pharmaceutical ingredients, medicines and consumables used for administration to patients. 5. Participate in quality risk management procedures including risk assessment and the investigation and reporting of errors and deviations. The quality risk management role will include raising, investigating and reviewing deviation investigations; performing root cause analysis and other quality risk management investigations in response to internal and external errors; developing and participating in the corrective action plans arising from deviation investigations; and active participation in change control, including the writing of change control forms, the performing of change control actions and investigations into the impact of change through trend analysis of data. 6. Participate in internal and external audit processes, including regulatory inspections by the MHRA, the Office of Nuclear Regulation, the Scottish Environmental Protection Agency, the Health and Safety Executive and the British Standards Institution. Acquire and develop the relevant skills to undertake internal audits of Radiopharmacy and Pharmacy Aseptic Units relating to accreditation and regulation. 7. Writing and review of standard operating procedures, change control reports, risk assessments, worksheets and other approved documentation under the supervision of the principal supervisor in order to contribute to the assurance of the quality, safety and efficacy of the medicinal products manufactured and purchased by NHS Lothian Pharmacy 8. Comply with and contribute to the promotion of quality, risk and governance procedures within the pharmacy departments of NHS Lothian including risk management and risk mitigation. Maintain standards for health & safety procedures and maintain high standards of professional and personal conduct, in line with NHS Lothian’s values 9. 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 medicines and procedures. 10. Successfully complete the training and assessment programme in conjunction with the local Training Coordinator and National School of Healthcare Science to achieve certified competence awarded by the Academy of Healthcare Science. Undertake suitable training within the host department and other placements to successfully acquire core competencies and thereafter maintain the required standards of competence when undertaking duties. 11. Take responsibility for own learning and development by recognising and taking advantage of all opportunities to learn, including appraisal, supervision, the academic course, problem-based learning and maintenance of a personal portfolio of learning. Ensure that own learning needs, identified with the Training Coordinator, reflect the requirements of the curriculum and may require:  * Sufficient flexibility and adaptability in learning in order to ensure full contribution to improving services in response to changing health care needs * Maintenance of knowledge of recent scientific developments, which in turn could require supplementary training to develop both knowledge and skills * Attendance at and completion of mandatory training (both vocational and academic) * Participation in internal and external assessment processes.  1. Communication and interpretation of complex scientific and technical information to a wide range of people including clinicians, pharmacy staff, managers, patients and the public. 2. Liaise with senior pharmacists, scientists and clinical users of the service on appropriateness of investigations, quality control tests, certificates of analysis and microbiological results. 3. Communicate research and development findings in written and oral formats to pharmacy staff, senior managers and external contacts, including communication of findings from scientific innovation and service redesign. 4. Meet clinical scientist training competencies by contributing to the training of pharmacy staff in the principles of Good Manufacturing Practice and Good Clinical Practice by undertaking in-house training for pharmacy staff. |

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| 7a. EQUIPMENT AND MACHINERY |
| The post-holder requires specialist knowledge and experience of the principles of operation of the equipment and instrumentation in the areas of Quality Risk and Governance, Radiopharmacy and Aseptic Services. This involves practical use, quality control and first-line diagnosis of faults in equipment such as: radionuclide generators; laminar air-flow cabinets and safety cabinets; negative pressure isolators; radionuclide calibrators; laboratory quality control instruments (high performance liquid chromatograph; thin-layer radiochromatogram scanner); radiation monitors; and instruments for testing the quality of clean room air, such as particle samplers; active air samplers; balometers and anemometers.  An understanding of the operation of the air handing plant that supplies sterile air to the aseptic suite is also required.  **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:  A range of software programmes and databases to generate worksheets, labels, delivery notes and transport documentation in Aseptic and Radiopharmacy.  Software systems: Pharmacy stock control and dispensing system (CMM); PECOS.  Pharmacy management information reporting system.  Microsoft Office for word processing, spreadsheets, e-mail, internet access.  Medicines Information database.  Patient administration system.  Datix incident management system.  Turas personal development and review system.  The Radiopharmacy Pharmaceutical Quality System.  The NHS Lothian Pharmaceutical Quality System (BS EN ISO 9001:2015).  Environmental Monitoring Systems.  **Note:** New systems may be introduced as the organisation and technology develops, however training will be provided. |
| 8. ASSIGNMENT AND REVIEW OF WORK |
| The trainee is directly responsible to their Principal Supervisor, but, while on placement in other departments, will have local supervisors to whom they will be responsible.  The University of Manchester provides a structured curriculum covering the necessary educational and training requirements to complete the Scientific Training Programme and this, together with a jointly agreed three-year training plan, will be used as a framework for training. It is the responsibility of the trainee, together with the supervisor, to ensure adequate coverage of all the prescribed areas.  Work is supervised and is subject to continuous assessment, with annual review in accordance with professional guidelines.  Progress is audited through regular meetings with the Principal Supervisor and local placement supervisors.  Review of performance is carried out by the Senior Quality Assurance Pharmacist in Radiopharmacy in accordance with the principles of personal development and the Knowledge & Skills Framework.  Agree objectives with the Senior Quality Assurance Pharmacist in Radiopharmacy, with three monthly review and annual appraisal. |
| 9. DECISIONS AND JUDGEMENTS |
| Contributes to minimising all risks to the patient attributable to sterile manufacture of 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 aseptic clean rooms (environmental monitoring results, air pressure differentials, air change rates and microbiological results) and the necessary actions based on critical risks to patient safety.  Provides information and advice on the quality of manufactured licensed and unlicensed medicinal products by performing or assessing in-process and final product quality control checks. Critically appraise quality control test data to inform decisions on product quality assessment and facility compliance with Good Manufacturing Practice standards. Escalate identified out of specification results to senior Quality Assurance staff when performing testing of medicinal products for patient use. Plan and organise own workload and education.Act independently within appropriate guidance and consult line manager or local supervisor when necessary. During training the post-holder will have access to confidential material about patients, members of staff or other health service business. They must understand the need for confidentiality and that information relating to identifiable patients must not be divulged to anyone other than authorised persons, as appropriate. |
| 10. MOST CHALLENGING / DIFFICULT PARTS OF THE JOB |
| Accepting the role of observer in the early months and managing the varied areas of training, including placements multiple hospital sites within NHS Lothian.  To work safely in an environment where the post holder will be exposed to challenging working conditions, including exposure to ionizing radiation, volatile chemicals and carcinogenic substances; and contributing to the safety, quality and efficacy of unlicensed medicinal products (“Specials”) manufactured, by analysis of data obtained within a Quality Control laboratory with limited staffing and instrumental resources.  Working with pharmacy teams to strive to meet the increasing quality standards of EU Good Manufacturing Practice and the Medicines and Healthcare products Regulatory Agency (MHRA) Guidance for Specials Manufacturers. |

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| 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 by NHS Lothian’s Pharmacy services. This communication may be highly complex, sensitive or contentious where it challenges others’ clinical or technical judgement.  Provide advice to healthcare professionals (pharmacy staff, radiographers, nurses, medical physics technicians) about the quality of medicinal products.  Communicate with suppliers and resolve resulting issues concerning the quality of raw materials and medicinal products, following guidance from senior Quality Assurance staff or supervisors.  Communicate with Quality Risk and Governance staff, Aseptic teams and Microbiology concerning the microbiological monitoring results of the clean room suites and aseptic process tests.  Participate in the pharmacy 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 professional operation of the department.  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 and cytotoxic materials using needles, syringes and small vials requires great care to avoid contamination and rapid working to avoid radiation exposure. Aseptic manipulation skills are essential and will be regularly validated.  Mental:  Apply high levels of concentration, precision and accuracy during aseptic manipulation of precise volumes and when performing quality control checks of medicinal products within strict time constraints.  Emotional:  Conduct investigations, under supervision, customer complaints relating to product quality issues with potentially serious consequences.  Environmental:  Exposure to ionising radiation and cytotoxic or carcinogenic chemicals. Working regularly in laboratory or aseptic clean room environments. |

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| 13. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB | |
| **Essential**  A First, or Upper Second Class (2:1) honours degree in a physical, biological or other suitable science subject, or pharmacy.  Excellent communication skills.  An underpinning knowledge of general physiology, physics, chemistry and biology.  Acquiring specialist knowledge across a wide range of procedures and a sound understanding of professional, clinical and scientific principles through formal teaching and professional supervision to Masters level.  Able to prioritise and manage own work and take responsibility for own learning and development.  **Skills and Experience:**  Knowledge, training or equivalent post-graduate experience relating to Good Manufacturing Practice or Good Clinical Practice | |
| 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: |