#### **JOB DESCRIPTION**

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| JOB IDENTIFICATION |
|  Job Title: Responsible to: Department: Directorate: Operating Division: Job Reference: No of Job Holders: Last Update:  | Senior Pharmacist – Clinical TrialsHead of Pharmacy- Development & InnovationPharmacyPharmacy and MedicinesCorporate1September 2023 |

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| 2. JOB PURPOSE |
| 1. To lead and co-ordinate the development and maintenance of a clinical trials pharmacy service within a specific research portfolio in line with local and national policies. Thereby ensuring that clinical trials involving medicines are established in accordance with the EU Directives on Clinical Trials, the Research Governance Framework and fulfil requirements of all local, national and internal standards and legislation.
2. To work collaboratively with the multidisciplinary teams (researchers and R&D staff) across the multiple-sites that the research portfolio covers, and interface with pharmacists across NHS Fife.
3. To provide highly specialised advice in all pharmaceutical matters relating to a specific research portfolio and in, relation to individual patients.
4. To deliver a clinical pharmacy service and/or to conduct research within a specified patient group.
5. To co-ordinate the professional pharmaceutical aspects of research and development within the specific research portfolio, including responsibility for the provision of pharmaceutical input into commercial and non commercial clinical trials.
6. To be responsible for the safe and effective procurement, storage and supply of clinical trial medicines within the specific research portfolio. These medicines are predominantly unlicensed and therefore subject to strict legislation. Many are also high risk medicines.
7. To participate in a programme of research, audit and risk assessments in relation to medicines use.
8. To provide and evaluate specialist education and training to pharmacy staff and the wider healthcare team on pharmacy related aspects of clinical trial activities.
9. To provide leadership and be responsible for the planning and organisation of pharmacy activity of clinical trials in NHS Fife in liaison with the clinical trials team.
10. To contribute to ensuring the reimbursement of pharmacy fees and drug costs as a result of work undertaken for commercial clinical trials.
11. To liaise with the Head of Pharmacy – Development & Innovation and relevant members of the pharmacy leadership team in the delivery of operational aspects of clinical trials.
12. To liaise with the Head of Pharmacy – Development & Innovation in the development and maintenance of a clinical trials strategy for pharmacy in NHS Fife.
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| **3. DIMENSIONS** |
| The NHS Fife Pharmacy and Medicines Directorate serves a population of approximately 380,000 people, and is provided by an integrated team of around 300 Pharmacy staff, including Pharmacists, Pharmacy Technicians, Support Workers, Nurses, and Administrators. The team work across Acute and Community hospital sites, General Practices, Mental Health services, and a range of specialist teams. Partnership working is at the core of our values, and we work closely with other members of the multi-disciplinary team, including our Community Pharmacy colleagues, to deliver the highest quality care for everyone in Fife.  |

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| 4. ORGANISATIONAL POSITION |
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| 5. ROLE OF DEPARTMENT |
| The NHS Fife Pharmacy & Medicines Directorate aims to provide the highest quality pharmaceutical care to the people of Fife. The integrated pharmacy team provide person-focussed pharmaceutical care to individuals, and supply medicines through systems that ensure safe, effective and economical use. We strive to ensure patients derive maximum benefit and minimum harm from their medicines, throughout their healthcare journey. We work in partnership with our clinical colleagues, providing high quality care, timely information and advice to deliver the safe and secure use of medicines. By integrating our team across NHS and Health and Social Care Partnership (HSCP) services in Fife, we ensure medicines are purchased, stored, dispensed and prescribed to the highest standards in every care setting. |

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| 6. KEY RESULT AREAS |
| **Organisation and Management**1. To deliver, develop and evaluate a pharmacy clinical trials service in line with local and national strategies.
2. To provide specialised advice relating to the use of medicines in research.
3. To implement and monitor policies and procedures within the pharmacy clinical trials service to ensure service quality and safe working practice in order that the service meets the standards dictated by EU and UK legislation, the General Pharmaceutical Council and, Research Governance.
4. To continually review legislation and practice standards relating to the conduct of clinical trials involving medicines and advise on the implications and implement any updates as required across NHS Fife.
5. To liaise with appropriate members of the Pharmacy team on the likely impact of research involving high-cost medicines and/or studies recruiting substantial patient numbers.
6. To oversee the set-up of clinical trials that involves multiple sites within NHS Fife.
7. Provide advice to other specialist clinical pharmacists regarding proposed and on-going clinical trials within their clinical specialty.
8. Provide expert advice on the processing of unlicensed medicines which will be used in research and in clinical practice when appropriate.
9. To implement processes and systems to ensure that pharmacy input to clinical trials is adequately documented.
10. To participate in local, regional, and where required national groups involved in the pharmaceutical aspects of clinical trials with medicines.
11. To work collaboratively with senior pharmacy and medical staff and the multidisciplinary team ensuring that issues related to pharmaceutical care of patients in clinical trials are appropriately managed.
12. To review adverse clinical incidents and use expert knowledge to advise R&D and the clinical governance group on strategies to minimise risks during the use of medicines within clinical trials.

**Clinical Trials**1. Review and analyse protocols, and provide expert advice for all proposed clinical trials involving medication.
2. Contribute expert advice to the pharmacy/Research and Development (R&D) review of research projects involving medicines in order to minimise risk to the organisation.
3. Liaise and negotiate with the Principal Investigators, R&D staff and with pharmaceutical companies to ensure that pharmacy is able to support the clinical trial.
4. Assess pharmacy capacity issues as regards clinical trials and highlight any areas of concern to the Pharmacy Operations Manager. The post holder will be involved in the development of any related business case submissions.
5. Responsible for compliance with Good Clinical Practice standards in relation to clinical trials and medication:
6. Clinical trial medication is labelled appropriately
7. Clinical trial medication is stored correctly and securely
8. Clinical trial documentation is completed and filed accordingly
9. Clinical trial medication is dispensed or supplied in strict accordance with protocol
10. Prepare and review all documentation relevant to clinical trials.
11. Ensure that standard operating procedures and documentation completion instructions are in place for each clinical trial.
12. Responsible for pharmacy staff training with regards to standard operating procedures for clinical trials.
13. Provide expert advice to ensure that all reasonable steps are taken to protect patient safety. This may involve working with complex and conflicting information where there is little evidence on which to guide decisions. It will involve protection of patients by ensuring that:
14. only medicines of appropriate quality are used in patients who are participating in research i.e. medicines are manufactured to GMP standards or equivalent.
15. there is sufficient information to support the use of the medicine in the clinical trial. Medicines used in clinical trials are generally used out-with their product license for example at different dosage regimen or in a different patient group. Clinical trials may also involve the use of novel medicines which have not yet been subject to the licensing process and are potentially high risk.
16. through the study design patients at highest risk of adverse effects or in whom the medicine is contra-indicated are excluded.
17. patients are appropriately informed of the risks associated with use of medicines in research.
18. wherever possible, controls are put in place to minimise risk to patients and the organisation.
19. Use expert knowledge to provide expert professional advice and respond to requests from the multidisciplinary team and Clinical Research Associates with regards to clinical trial protocol queries or protocol deviations.
20. Liaise and maintain regular communications with Clinical Research Associates to ensure clinical trial medication is dispensed in accordance with the protocol and that appropriate accountability and documentation is completed
21. Liaise with and provide regular communication and training to the clinical pharmacy team regarding active clinical trials in their areas of practice.
22. Lead, plan, coordinate and participate in internal and external audits as part of the clinical trials team.
23. Establish links with other clinical trials pharmacists to share good practice and coordinate the conduct of multi-centre clinical trials.

**Professional Roles (Clinical)**1. To advise the Lead Clinical Pharmacists of developments in the clinical specialties.
2. Independent Pharmacist Prescribing – responsible and accountable for the assessment of patient with diagnosed and undiagnosed conditions, and for decisions about their clinical management, including prescribing.
3. To ensure that developments in the delivery of the clinical pharmacy service to patients within the clinical specialty are in line with the strategic direction for the development of clinical pharmacy services within the Board.
4. Liaise with nursing and medical staff and directorate managers in all matters relating to medicines management in the clinical specialty.
5. To integrate into the multidisciplinary team and attend consultant ward rounds where possible making proactive interventions in individual patient’s therapy by providing evidence-based information and advice on drug related issues and acting as a pharmacy contact.
6. To provide advice to patients and their relatives, nurses, prescribers, and other healthcare professionals on the correct use of medication and ensure that directions associated with medications are understood.
7. To conduct full medication review on admission including the identification of allergies and drug related admissions and where appropriate follow through with a yellow card report to the Medicines and Healthcare products Regulatory Agency (MHRA).
8. Resolve medicines related problems associated with individual patients between primary and secondary care, including contact with general practitioners, GP prescribing advisers, community nurses, integrated care teams, residential and nursing homes, addiction services/centres, community pharmacists, patient’s families, and carers.
9. To participate in the updating and multidisciplinary audit of treatment guidelines.
10. To provide a Directorate support function to the nominated clinical area, presenting prescribing reports to the appropriate directorate governance and specialty team meetings, reporting to the Lead Clinical Pharmacist.
11. To maintain an up-to-date knowledge of developments in medical and pharmaceutical practice, as part of their own continuing professional development.
12. To participate in regular peer review meetings

 **Supervision, Teaching and Research**1. Participate in local training initiatives to meet CPD requirements in accordance with the departmental strategy.
2. To undertake Educational Supervision and training for rotational pharmacists in the provision of clinical pharmacy services.
3. To undertake a Designated Prescribing Practitioner Role for Pharmacists training in Independent prescribing, where eligible
4. To develop/provide lectures, tutorials and other teaching sessions on medicines related issues for medical, nursing and pharmaceutical staff, including undergraduate MPharm students.
5. To participate in the training programme schedules for experiential learning students, trainee pharmacists, foundation pharmacists, pre-registration trainee pharmacy technicians and other new staff.

**General**1. To participate in a “5 out of 7” working pattern as determined by, and according to, the organisation and pharmacy service needs.
2. To participate in the provision of extended hours of service, including evening working, Saturdays, and Sundays according to formal rota arrangements.
3. To report any suspected or observed defects in drugs, medicinal products and equipment to the Lead Pharmacist – Medicines Safety
4. To be familiar with, and maintain, safe standards of work and adequate records of all processes.
5. To have due regard for, and to always conform with, directives and circulars associated with the provision of pharmaceutical services, including the Medicines Act, the Duthie Report, relevant Controls Assurance requirements and associated Board policies and procedures.
6. To have due regard for all statutory guidance applicable to the pharmacy, including Health and Safety at Work, Manual Handling and the Control of Substances Hazardous to Health (COSHH).
7. To always maintain the rules relating to patient confidentiality and data protection.
8. To have due regard for Board policies on discrimination.
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| 7a. EQUIPMENT AND MACHINERY |
| IT equipment – internet access to medicine information resources, Microsoft office for e-mail, Teams communication, word processing, spreadsheets (management and financial information), PowerPoint (educational presentations, peer review, CPD). |
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| **7b. SYSTEMS** |
| * Hospital Electronic Prescribing Administration system
* Pharmacy Stock Control System
* Common computer packages e.g. Microsoft Office
* Internet – e-libraries
* SCI lab – laboratory results system
* Emergency Care Summary
* Clinical Portal
* Medicines Reconciliation and Immediate Discharge Letter solution
* Specialist R&D software such as the R&D database
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| 8. ASSIGNMENT AND REVIEW OF WORK |
| Workload will be mainly self-generated, influenced by service needs, patient needs and local and national agendas.Plans and organises own workload. Professionally supervises the activities of less experienced pharmacists, pharmacy technicians and assistants. May assign tasks in consultation with their line manager as appropriate to ensure pharmacy clinical trials services are delivered as planned.Works within strategic and policy guidelines established by the pharmacy service and towards objectives agreed jointly on an annual basis with their line manager.Performance appraisal carried out annually by the Pharmacy Operations Manager.Accountable for own professional actions and outcomes – guided by legislation, national and local protocols and local formulary. |
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| **9. DECISIONS AND JUDGEMENTS** |
| The post holder is expected to use his/her own initiative to make professional decisions; advice can be sought from peers or other professionals.The post-holder is an independent practitioner who is responsible for managing their workload and that of the pharmacy clinical trials team without supervision guided only by local and national policies and principles.  As a senior member of the pharmacy profession and an expert in pharmaceutical related aspects of clinical trials, working autonomously within their specialist field, with minimal interaction with their line manager the post holder is required to make decisions based on the evaluation of limited information and to use professional knowledge in order to provide pharmaceutical care to patients.The post holder is expected to help provide expert pharmaceutical advice for this specialist service and make judgements on the operational, clinical, financial and capacity issues relating to clinical trials and deal with problems and incidents as they arise. They will demonstrate and apply highly specialist clinical knowledge with advanced level of clinical reasoning and judgement in the use of medicines, ensuring that their practice is evidence-based and in accordance with current good-practice and local policy.Making clinical and professional decisions based on the evaluation of limited information in particular due to the nature of clinical trials they will anticipate problems and need to be able to independently resolve these.Promote safe, rational, cost effective prescribing of medicines by analysing and interpreting the evidence base and advising on medicine treatment protocols.Interpretation of clinical trial data and conflicting views in review papers required in order to provide medicines information.Manages and reconciles conflicting opinions of professionals (e.g. consultants) to optimise use of medicines. Resource and time constraints will require the postholder to evaluate and prioritise tasks.On occasion the post holder will also be expected to consider the impact of decisions on health care services out with NHS Fife.Evaluating situations which may arise out of hours and deciding how best to deal with them.During absence of the Pharmacy Operations Manager or other team members may need to make decisions and use judgement in areas out with their area of work. |

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| 10. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB |
| Maintaining consistency in the pharmacy clinical trials service and patient safety in the use of medicines.Prioritisation of clinical trials workload.Maintenance of effective communication to deliver a pharmacy clinical trials service across hospital sites.Working with limited information, to short timescales within stressful environments.Required to work under pressure on a regular and frequent basis, in order to meet deadlines set by senior clinicians and management to provide expert pharmaceutical advice and for the preparation of reports and papers.To keep appraised of all local and national guidance on prescribing as well as current clinical trial data to be able to inform and educate health professionals. Self-motivating and able to balance the demands of various roles within the post in order to deliver of key areas in order to provide advice where opinions may be are divided and/or information is sparse whilst ensuring that patient safety remains paramount working to deliver a high quality clinical trials with limited resources and time constraints.Improving prescribing practice across NHS Fife.Managing, analysing and acting when faced with difficult and ambiguous problems where there is sometimes limited information to guide decisions. Challenging consultant decisions to ensure that prescribing is evidence-based.  |

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| **11. COMMUNICATIONS AND RELATIONSHIPS** |
| The post holder will be required to challenge information and decisions made by other senior staff, which may not be well received, and the post holder will have to negotiate and influence to obtain a satisfactory outcome The post holder requires a highly effective communication skills and excellent interpersonal skills to motivate staff and communicate with a wide range of people. Negotiating and influencing skills are also required to manage change effectively and put forward a best practice agenda to the multi-professional team, challenging the status quo. This may be done on a one to one basis or through group presentation.Provide information to clinical staff to ensure compliance with formulary, ADTC and other pharmacy related strategies. Advising and negotiating with senior members of the medical team requires the ability to communicate extremely complicated, and multi stranded clinical matters and requires well developed persuasion skills.Teaching, presentation and mentoring skills are required when contributing to the education of pharmacy, other healthcare professions and members of the public.The post holder is expected to communicate with consultant medical staff, GPs and nursing on a regular basis, and also with pharmacy management.The post demands a high degree of co-ordination with medical and nursing staff, departmental colleagues both in the Acute Services Division and in Primary CareThe post holder will occasionally provide counselling to patients, who may be frail and elderly, on toxic medication regimens. This requires tact, persuasion and reassurance skills (e.g. while discussing side effects versus benefits) and empathy and motivational skill so maximise patient concordance.The post holder will liaise closely with and attend meetings of relevant national groups.Information received and communicated will often be highly complex, including the need to interpret clinical trial data which may have to be communicated to individuals who may have a limited knowledge in a manner that is easily comprehensible. The post holder will make formal and informal arrangements to discuss and advise the NHS Fife Lead Pharmacist –Medicines &Therapeutics Utilisation on matters of mutual interest.The post holder will make formal and informal arrangements to advise colleagues and staff associated with the care of the identified patients. |

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| **12. PHYSICAL, MENTAL, EMOTIONAL AND ENVIRONMENTAL DEMANDS OF THE JOB** |
| **Physical**Advanced keyboard skillsEffort lifting bags / boxes of pharmaceutical supplies, files, documents weighing 2 – 5kg daily.Prolonged standing while checking products and documentation on wards, for periods of 20 minutes to 2 hours several times daily.**Mental**Work requires a high level of concentration (concentration daily for at least one to two hours at a time) characterised by assessing various strands of sometimes conflicting information and forming a clinical opinion. This is conducted under time management pressures and subject to frequent interruptions some of which may require immediate responses (e.g. responding to an urgent clinical enquiry). High degree of concentration required while checking prescription charts where precision and accuracy is required and is also subject to frequent interruptions**Emotional**Contact with extremely ill patients, dying patients and their relatives**Environmental**Exposure to unpleasant odours at ward level |

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| 13. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB |
| **Qualifications** Masters Degree in Pharmacy or equivalent.Registered with General Pharmaceutical Council.Relevant post graduate qualification (e.g. Diploma or MSc in Clinical Pharmacy) or equivalent experienceIndependent Prescriber (desirable)RPS Core Advanced curriculum credentialed or willing to work towards Qualification achieved / course attended in leadership and / or management ( desirable)**Experience**Significant post registration experience as a pharmacist in a clinical setting.Relevant experience working in clinical trials.Experience of hospital pharmacy service management (desirable)Supervision- Designated Supervisor, Educational Supervisor, Designated Prescribing Practitioner (desirable)Experience of writing reports or business cases (desirable)Leadership and line management experience (desirable)**Knowledge Skills and Ability**Commitment to CPD, ideally including the RPS FacultyTherapeutic and practical skills for dealing with a highly complex range of pharmaceutical interventionsAdvanced keyboard skillsExcellent written, oral and presentation skillsProject Management skillsResource and time management skillsResearch and audit skillsTeam player Flexible and adaptableEmpathetic |

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| **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: |