

JOB DESCRIPTION

1. JOB DETAILS

Job Title:	Pharmacist – Clinical Trials
Band:	Band 8a
Reports to:	Reports to the Principal Pharmacist – Technical Services
Department / Directorate:	Pharmacy Department, Specialist Services

2. JOB PURPOSE

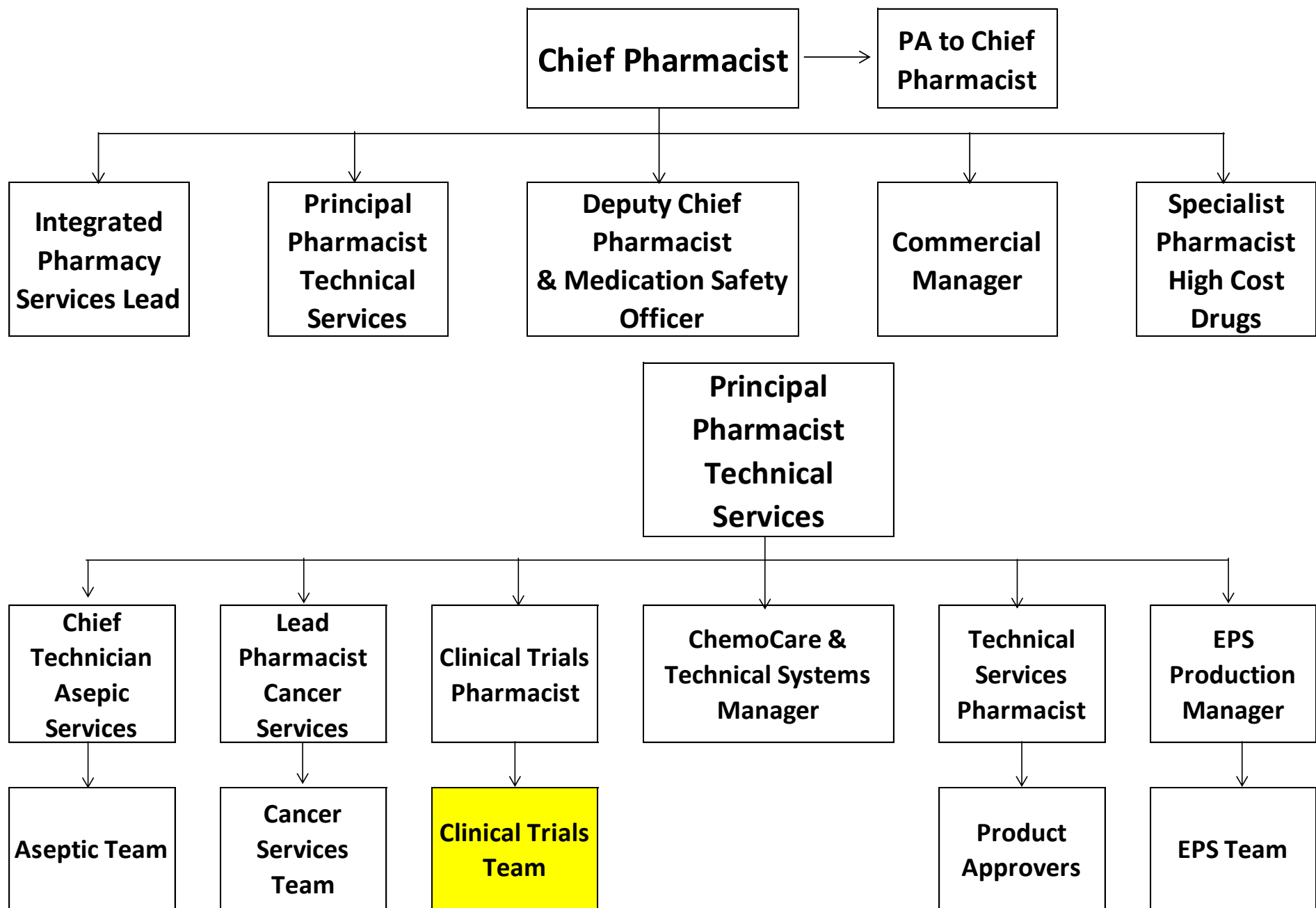
To promote and facilitate the interaction between Research and Development and Pharmacy in order to ensure clinical trials are provided within current medicines legislation and all EU directives.

3. DIMENSIONS/ KEY WORKING RELATIONS

Lead Pharmacist – Clinical Trials
Chief Technician - Clinical Trials, Pharmacy Services
Research & Development Manager
Principal Pharmacist Technical Services
Principal Pharmacist Medicines Management
Oncology/Haematology Pharmacists
Pharmacy Staff and R&D Staff

4. ORGANISATIONAL CHART:

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KEY RESULT AREAS/PRINCIPAL DUTIES AND RESPONSIBILITIES:

- To ensure that the Pharmacy Clinical Trials Department provides safe and efficient services in accordance with relevant regulations and guidance such as the Royal Pharmaceutical Society of Great Britain's 'Professional Guidance on Pharmacy Services for Clinical Trials'
- To ensure that the documentation, processes and procedures for the handling of Investigational Medicines Products (IMPs) within the pharmacy department meet the current relevant UK and European legislation, ICH GCP guidelines and GMP principles required by the Medicines and Healthcare Regulatory Authority (MHRA), National Patient Safety Alerting System (NPSAS), Regional Pharmaceutical Quality Assurance Services and relevant clinical trial sponsors
- To promote the Clinical Trials Service within the RD&E and to service users provided under service level agreements to ensure all clinical trials are appropriately considered by pharmacy prior to their approval by Research & Development (R&D)
- To participate in R&D planning meetings in order to provide guidance at an early stage, on trial design and pharmacy processes for any clinical trial under consideration, ensuring pharmacy capacity has been considered
- To participate in sponsor led site selection and initiation visits
- To be responsible for co-ordinating the pharmaceutical input into the setting-up, design and running of clinical trials at the RD+E. This will involve close liaison with pharmacy, nursing, medical staff and R&D
- To be responsible for the sign off of pharmacy clinical trial and R&D agreements on behalf of the pharmacy department
- To critically review clinical trial protocols on their impact on pharmacy – operation and capacity, e.g. packaging, labelling and documentation, incorporating further comments from appropriate specialist clinical and technical pharmacists where required
- To liaise with all research delivery teams across the Trust to facilitate smooth set-up and running of all clinical trials
- To ensure processes are in place to assess the impact of all proposed clinical trials on pharmacy including aseptic services, considering capacity and technical aspects of any related dispensing processes
- To approve all pharmacy related departmental or Trust clinical trial SOPs, policies, procedures and documents
- To approve all commercial, non-commercial and in-house clinical trials and associated paperwork e.g. prescriptions and labels, liaising as necessary with the Principal Pharmacist Technical Services
- To provide advice and guidance to R+D and investigating teams on the planning and execution of in-house clinical trials
- To liaise with finance to ensure that all pharmacy generated income is invoiced and received into the pharmacy R&D budget
- To liaise with the Cancer Services Pharmacy team and ChemoCare and Technical Services Systems Manager to prioritise, facilitate and support the set-up and validation of new SACT protocols on the live ChemoCare system prior to trial initiation.
- To promote research and development in pharmacy practice to colleagues in the pharmacy department
- To take charge of the Pharmacy investigations into study issues and incidents involving IMP, ensuring appropriate documentation and completion of any actions
- To lead MHRA, Sponsor and in-house GCP inspections for the pharmacy trials service
- To establish and maintain a good working relationship with sponsors, monitors, the R&D department, auditors and regulatory authorities.
- To ensure that the confidentiality and security of information and data about study subjects and clinical trial studies are maintained and respected.

- To provide considered highly specialised and complex advice on medicines including IMPs where information is lacking or when there are conflicting opinions and the client may be enquiring about potential contentious issues.
- To manage the raising, completion and implementation of all relevant IMP and non-IMP documents, controlled procedures, risk assessments, feasibility assessments, prescriptions, dispensing protocols, accountability logs, and stock management records.
- To be responsible for the oversight and maintenance of dispensing procedures for all clinical trials
- To assess each trial for the need for a pharmacist clinical screen in conjunction with the Chief Technician - Clinical Trials, Pharmacy Services
- To ensure that safe dispensing practices are applied and adhered to at all times when dispensing and preparing Clinical Trial IMPs (CTIMPs).
- To accurately screen, dispense, check and counsel patients regarding their medication as required in accordance with the particular study protocol
- To ensure that health and safety and COSHH guidelines are managed within the clinical trials team
- To ensure all staff involved in clinical and final checking, dispensing and preparation and supply of IMPs have sufficient training and up to date knowledge in order to carry out their functions safely, effectively and in a timely manner. This includes supporting the Cancer Services Pharmacy team in clinical checking SACT trial prescriptions.
- To act as the main contact with clinicians and sponsors in the event of an adverse event linked to a clinical trial
- To ensure all pharmacy on-call staff can provide details for out of hours trial support as agreed with R&D
- To drive, plan and implement developments in the clinical trials service, in order to meet the needs of service users.
- To represent the pharmacy clinical trials department on appropriate governance and trial steering meetings
- To represent the Trust at clinical trial or research networks at all levels. To use these networks to share best practice and to bring information and new ideas back to the Trust.

Training and Education

- To provide training and education to rotational pharmacists, pre-registration pharmacists, on-call pharmacists, R+D, nursing and medical staff on all aspects of clinical trials as required.

Other Responsibilities:

To undertake any other duties as required by the Chief Pharmacist or Deputy which are regarded as being within the scope of this post.

Will carry out activities in an orderly and well-structured way, working within appropriate policy and procedures.

Can perform role without unnecessary support in all situations taking personal responsibility for own actions. Will refer any problem outside the post's responsibility to the appropriate person(s).

To participate in flexible working arrangements including late duties, weekends, bank holidays and on-call as appropriate.

To take part in regular performance appraisal

To undertake any training required in order to maintain competency including mandatory training, e.g. Manual Handling

To contribute to and work within a safe working environment

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

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.

THE TRUST – Vision and Values

Our vision is to provide safe, high quality seamless services delivered with courtesy and respect. To achieve our vision we expect all our staff to uphold our Trust values. Our Trust values are:

Honesty, Openness & Integrity
Fairness,
Inclusion & Collaboration
Respect & Dignity

We recruit competent staff that we support in maintaining and extending their skills in accordance with the needs of the people we serve. We will pay staff fairly and recognise the whole staff's commitment to meeting the needs of our patients.

We are committed to equal opportunity for all and encourage flexible working arrangements including job sharing.

We are committed to recruiting and supporting a diverse workforce and welcome applications from all sections of the community, regardless of age, disability, gender, race, religion, sexual orientation, maternity/pregnancy, marriage/civil partnership or transgender status. We expect all staff to behave in a way which recognises and respects this diversity, in line with the appropriate standards.

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.

The RD&E is a totally smoke-free Trust. Smoking is not permitted anywhere on Trust property, including all buildings, grounds and car parks. For help to quit call: 01392 207462.

POST: Clinical Trials Pharmacist

BAND: 8A

REQUIREMENTS	At Recruitment	At 2 nd KSF Gateway
<u>QUALIFICATIONS / TRAINING</u>		
Degree in Pharmacy	E	E
Post-graduate clinical qualification	E	E
Registration with GPhC	E	E
Management Training	D	E
Qualification in Clinical Research	D	E
<u>KNOWLEDGE / SKILLS</u>		
Understanding of hospital pharmacy systems	D	E
Knowledge of all aspects of clinical trial management	D	E
Knowledge of medicines legislation associated with clinical trials	D	E
Knowledge of Good Clinical Practice and Good Manufacturing Practice	E	E
Knowledge of quality assurance and systems for error reduction	D	E
Excellent interpersonal skills	E	E
Effective oral and written communication	E	E
Effective influencing and negotiating skills	E	E
Excellent mentoring skills	D	E
Leadership skills	D	E
<u>EXPERIENCE</u>		
Recent pharmacy experience in hospital or industry sectors	E	E
Experience in clinical trials procedures, commercial and non-commercial	D	E
Experience of managing a staff group	D	E
Evidence of practice research	D	D
Experience of budget management	D	E
<u>PERSONAL ATTRIBUTES</u>		
Commitment to CPD of self and others	E	E
Creative thinker	E	E
Resourceful	E	E
Flexible	E	E
Self-motivated and motivator of others	E	E
Ability to think clearly and work effectively under pressure	E	E
<u>OTHER REQUIREMENTS:</u>		
Computer literate	E	E

* Essential/Desirable

HAZARDS IDENTIFIED (<i>tick as appropriate</i>):					
Laboratory specimens		Clinical contact with patients		Performing Exposure Prone Invasive Procedures	
Proteinacious Dusts					
Blood / Body Fluids		Dusty environment		VDU use	√
Radiation		Challenging Behaviour		Manual handling	√
Solvents		Driving		Noise	
Respiratory Sensitisers		Food handling		Working in isolation	
Handling Cytotoxic Drugs	√				

(NB – Above hazards shown is not an exhaustive list)