East Suffolk and North Essex NHS Foundation Trust

Job Description

Job Title: Pharmacy Clinical Trials Officer	**Band:** 5

Accountable to: Head of Pharmacy Quality Assurance
Responsible to: Senior Pharmacist Clinical Trials
Key Relationships with:- Pharmacy colleagues (both clinical and non-clinical), Pharmacy Technical Services staff, Medicines and Healthcare products Regulatory Agency (MHRA), Consultant colleagues and all members of their clinical teams, Specialist nurses, Site matrons, Allied health professionals, Senior Trust Management, Patients, Parents, Carers and/or other relatives, General Practitioners, Community pharmacy colleagues, Other primary care health professionals, External clients

Purpose of Role:

To act as a Pharmacy Clinical Trials Officer for East Suffolk and North Essex NHS Foundation Trust (ESNEFT), providing GMP and GCP support for all pharmacy clinical trial activities, ensuring compliance with the regulatory requirements for all pharmaceutical licences held by the Trust.

The post holder will work within the pharmacy's clinical trials department and will be required to be a releasing officer for clinical trials named patients doses manufactured under exemption 37. Any or all of the following duties may be undertaken, with specific training and competency-based assessments carried out before working with minimal supervision. Written Standard Operating Procedures (SOPs) are available for work undertaken and these must be adhered to.

Key Responsibilities:

- To work collaboratively with the multidisciplinary team to support the delivery of the pharmaceutical component for clinical trials undertaken within the Trust.
- To assist the Senior Pharmacist Clinical Trials in providing advice and information in relation to the pharmaceutical component of Research and Innovation (R&I) activities including all clinical trials throughout the Trust to ensure compliance with national legislation and guidelines.
- To ensure that all required medication safety and clinical governance issues relating to clinical trials patients are actioned and implemented in a timely manner.
- To be an authorised releasing officer for clinical trials items.

Service Delivery and Improvement

- To learn and understand the principles of Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP) and be able to apply them to own work.
- To assist with the completion of the tasks listed on the daily/weekly/monthly job rota.
- Receive in clinical trial deliveries, including using Sponsors' Interactive Web Response Systems.
- Answer telephone queries from customers both within the Trust and external to the Trust and action appropriately.
- To work with external bodies as and when appropriate to represent the pharmacy service and to promote the profile of services at ESNEFT.
- Follow guidance and instruction from senior staff, questioning when necessary to clarify information.
- Assist in maintaining necessary computer records and other records of work undertaken in compliance with Data integrity principles.
- Complete all paperwork accurately and legibly so that it may be audited as appropriate in compliance with GCP and GMP.
- Follow procedures accurately and efficiently and report any differences between procedures and manufacturers guidelines or the observed practise of other staff.
- Maintain client confidentiality at all times.
- Complete competency based assessments in all relevant Band 5 duties for the Pharmacy Clinical Trials department.
- Prioritise allocated daily tasks effectively and take responsibility for ensuring that allocated tasks are completed within the required time frame and to the required quality standard.

Departmental

- Contributes to the maintenance, implementation and review of all departmental policies and procedures.
- Works closely with staff in the ESNEFT Pharmacy, to ensure cost effective and efficient service delivery and to ensure appropriate clinical trials marketing opportunities are taken.
- Communicates effectively with a range of staff taking into account varying knowledge and skills.
- Ensures that appropriate safe systems of work and security measures are employed in pharmaceutical practice.
- Reads and complies with the departmental Health and Safety policy. Refers to it as necessary to remain familiar with its contents.
- Ensure that the working environment meets all standards set out by the Health and Safety Regulations. Follow Health and safety guidance when completing each task.

Personal

- Complies at all times with the departmental dress code and appropriate use of personal protective equipment (PPE) when undertaking all tasks.
- Ensures that Trust Health and Safety policy and COSHH procedures are read annually.
- Is aware of the location of fire, security and first aid equipment. Be familiar with emergency procedures and in the event of an emergency, summon assistance if necessary.
- Reports all accidents/incidents to senior staff and ensure that an incident form is completed.
- Maintains own professional registration.
- Attends Trust mandatory courses and any other courses identified at performance review. This will include Trust Induction and ESR training modules.
- At all times presents a positive and professional image of the pharmacy department to all service users
- Acts in a way that acknowledges people's beliefs, preferences and choices. Takes into account the effect of your behaviour on others.
- Acts as role model/mentor within the department.
- Maintains client confidentiality at all times.
- Informs senior managers of any observed practice, or behaviour, of a person which could result in a quality standard being compromised.

- Employs non-discriminatory behaviour and a courteous, sympathetic approach to all co-workers and the public are expected at all times.
- Treats everyone with respect and dignity and recognise that people are different and have differing perspectives.
- Reports behaviour that undermines equality and diversity to senior staff.
- Undertakes such other duties as may be required to ensure the continuing provision of a high standard of pharmaceutical care.
- To participate in regular review meetings with the Senior Pharmacist Clinical Trials (or another suitably appropriate senior manager). To discuss current practice and assess objectives set at previous meetings and at appraisal.
- To commit to Continuing Professional Development (CPD) and training, reflecting the needs and interests of the individual, the post and the department as identified through performance appraisal.
- Liaise with the team and line managers to report problems, share information and improve the working of the team and as an individual.
- Personally implement agreed changes for improving the service, and take an active role in assisting the clinical trials team to both understand and to also implement agreed changes.
- Seek feedback from colleagues and line managers on own work to assist in the self-assessment of continuing personal development needs.
- To identify own progress, areas for future development and recognise positive learning experiences, in preparation for appraisal.
- Have annual performance appraisals that will be reviewed against the KSF outlines for the post, contributing identified learning and development needs and ideas on how to address them. Interim appraisals may take place if felt necessary.
- Produce a personal development plan from the identified learning and development needs and participate in all learning and training opportunities. Ensure that training records are kept up to date.
- Evaluate the effectiveness of all learning and training participated in, with particular reference to the needs of the post, the department and the possible value to colleagues.
- Provide constructive feedback to colleagues to assist in their ongoing development and the demands of the department.
- Ensure that you have read and comply with the departmental Health and Safety policy. Refer to it as necessary to remain familiar with its contents.
- To be aware of the potential hazards relating to medications used in clinical trials and act accordingly to reduce the risks.
- Assist in the safe disposal and re-cycling of Pharmacy waste as per Trust procedure.
- Assist in the management and safe storage and disposal of clinical trial products and items as per Trust and departmental procedures.
- To act as an independent practitioner. To prioritise own workload effectively and in a manner that maintains quality. Delegate when appropriate.
- To know limits of own knowledge and authority and refer to senior staff appropriately.
- To aid in the recruitment of staff and participate in interviewing potential candidates as deemed necessary.
- To deputise for more senior colleagues in their absence and make decisions necessary for the provision of high quality pharmaceutical service.

General

- To be responsible for complying with Trust and local Safeguarding policies and procedures.
- To be responsible for the quality of data recorded. The data should be accurate, legible (if hand written), recorded in a timely manner, kept up to date and appropriately filed.
- All employees must comply with the East Suffolk and North Essex NHS Foundation Trust's Equality and Diversity Policy and must not discriminate on the grounds of sex, colour, race, ethnic or national origins, marital status, age, gender reassignment, disability, sexual orientation or religious belief.
- Employees have a responsibility to themselves and others in relation to managing risk and health and safety, and will be required to work within the policies and procedures laid down by East Suffolk and North Essex NHS Foundation Trust. The Trust seeks to establish a safe and healthy working environment for its employees and operates a non-smoking policy.

- All employees have the right to work in an environment which is safe and to be protected from all forms of abuse, violence, harassment and undue stress. All employees are responsible for helping to ensure that individuals do not suffer harassment or bullying in any form. All employees will be personally accountable for their actions and behaviour in cases of complaint of harassment or bullying.
- All staff have a responsibility to contribute to a reduction in the Trust's carbon footprint and should pro-actively reduce and encourage others through own actions to reduce their contribution to carbon emissions. This includes switching off electrical appliances that are not in use, turning down heating, closing windows, switching off lights and reporting carbon waste etc.

Prepared By:	Nicola Guiver	Date:	April 2024

NHS
East Suffolk and North Essex
NHS Foundation Trust

Person Specification

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Criteria	Essential	Desirable
Experience	• Previous GCP experience within NHS or pharmaceutical industry or equivalent professional environment • Previous experience of working within a clinical environment • Demonstrated experience of multi-disciplinary working	• Previous clinical trials experience • Previous experience of Aseptic/sterile/GMP manufacturing • Previous prescription dispensing and checking experience
Qualifications	• Degree in Pharmaceutical Science, Pharmacy, Biotechnology or equivalent or B-Tech in Pharmaceutical Science or equivalent	• Registered Pharmacy Technician with the GPhC • Accredited Checking Technician Qualification • Current Good Clinical Practice certificate
Knowledge	• Computer Literacy (Microsoft Office-365) • Pharmacy structure (local and national) • Relationship (specifically to pharmacy) between secondary and primary care • Good pharmaceutical knowledge	• Structure of the modern NHS • Awareness of current national issues affecting pharmacy, especially relating to Medication Safety • Awareness of the Principles of Good Clinical Practice relating to Clinical Trials activity
Personal Skills	• Commitment to further training and self-development • Demonstrated ability to communicate information effectively using clear written and spoken English • Proven organisational skills and time management • Ability to meet the standards of the Trust code of conduct at all times • Self-motivated with a good attendance record • Understanding of hygiene standards in the preparation of medicines • Able to work in cleanrooms with the appropriate gowning and PPEs • Appreciation of confidentiality issues	

	• Ability to meet objectives and targets • Accurate, flexible and adaptable • Demonstrated ability to concentrate for prolonged periods of time • Accurate, flexible and adaptable • Lifting and carrying duties	