Oxford University Hospitals NHS
NHS Foundation Trust

Pharmacy Department

Clinical Trials Pharmacist

Job Description

Grade Band 7

Based at: Pharmacy Department John Radcliffe and Churchill Hospitals Oxford University Hospitals NHS Foundation Trust

Accountable to: Chief Pharmacist

Managed by: Lead Pharmacist Clinical Trials

Liaison with:

- Clinical Research Associates
- Nursing and Medical staff
- Principal investigators
- Researchers
- Research and Development (R&D)
- R&D Finance Personnel
- Research Ethics Committee personnel
- Dispensary staff
- CTASU and Baxter Aseptic Unit personnel
- CRUK & Research Network personnel
- Specialist Clinical Pharmacists

Overall Objectives

As a Clinical Trials Pharmacist for the Trust:

- Co-ordinate and deliver Pharmacy support to Researchers in the Oxford University Hospitals NHS Foundation Trust
- Work with the dedicated Clinical Trial Team, to strategically plan the workload for Pharmacy Services for the Trust and ensure operational implementation.
- Ensure that Pharmacy procedures relating to clinical trials involving Investigational Medicinal Products (IMP's) are in accordance with appropriate regulations (ICH/GCP, Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019, EMA, FDA, GMP) and with Research Governance Framework.
- Provide highly specialised professional expertise to Researchers in the development of clinical trial protocols involving medication and related substances and to provide advice & information regarding the application for Clinical Trial Authorisation (CTA) certification from the MHRA.
- Interact with and support Clinical Trial Technicians and Senior Technical Officer.
- Provide a ward based clinical pharmacy service according to Trust standards if needed

Key Result Areas

Standards in Clinical Research

1. Ensure compliance with relevant standards for the operation and management of Clinical Trials.

2. Advise and support researchers in complexities and feasibility of trial design and Research Ethics Committee applications, particularly in relation to obtaining a CTA.

3. Professional member of the Oxford Research Ethics Committee.

4. Train medical nursing and pharmacy staff in all aspects of handling drugs in clinical trials.

5. Liaise with other centres for clinical research to ensure common standards of practice.

6. Develop and maintain expertise and knowledge in all aspects of the use of medicines in research.

7. Assist in the development of Pharmacy policies and procedures to support the delivery of clinical trials involving medication and related substances. Oversee the production, implementation and review of detailed written pharmacy guidance and SOP's and liaise with pharmacy teams across the Trust to ensure effective implementation of these SOP's and initiate change if necessary.

8. Where appropriate, co-ordinate purchase of bulk product if required to supervise packing down activities with previously approved batch record documentation and labels (primary and secondary) in accordance with GMP.

Support to individual Clinical Trials

1. Set up the trial specific study file with all necessary essential documentation, in preparation for pharmacy sign off by a trained Pharmacist Reviewer.

2. Complete the training for reviewing and signing off clinical trials set-up once the required competencies and knowledge are gained and then work as part of the reviewing team to review and open studies in accordance with team priorities.

3. Arrange for, and receive investigational medicinal product (IMP) in line with Clinical Trial SOP's and ensure compliance with GMP legislation.

4. Support the clinical trials technicians as required in multidisciplinary team meetings with investigators to initiate, manage and close down trials hence ensuring pharmacy participation.

5. Adhere to the appropriate disposal procedure of unwanted trial materials.

6. Liaise with the Specialist Clinical Pharmacists when assessing, approving or initiating new projects, and update Dispensary staff on newly set up studies.

7. Act as a source of Research expertise to advise on complex issues such as trial design, procurement, randomisation, blinding, and documentation for in-house clinical trials and to defend/justify the opinions or decisions if the advice is challenged.

Support to Clinical Trials Aseptic Services Unit (CTASU) and Advanced Therapy Medicinal Product Unit (ATMP Unit)

1. To act as an Authorised Pharmacist in the CTASU and ATMP Unit. This will involve supervising the aseptic process and releasing products that have been prepared in CTASU and ATMP Unit in accordance with the CTASU Pharmaceutical Quality System and ATMP Unit Pharmaceutical Quality System. For this part of the role you will be professionally responsible to the Accountable Pharmacist for CTASU and ATMP Unit.

Documentation and Finance

1. Help maintain and update Clinical Trial databases on Trust trial activity.

2. Review legislation relating to the conduct of clinical trials involving IMP's and to liaise with R&D of the implications of such legislation.

3. Review and update Pharmacy SOP's with regards implementation of new legislation.

4. Provision of cost quotations for pharmacy activity in Clinical Trials on review of the Protocol.

Clinical Practice Role

1. To provide a ward-based clinical pharmacy service according to Trust agreed standards including:
   - Individual prescription review to optimise therapy
   - Confirmation of the patient's medication history
   - Advise on dosage, side-effects, cautions and monitoring required
   - Advise on administration of medicines
   - Appropriate and clear endorsing of prescriptions to ensure safe practice
   - Monitor the effect and appropriateness of medication
   - Education of patients on their medication

2. To ensure medicines are used appropriately, safely and cost effectively in accordance with Trust policy, standard operating procedures and medicines legislation.

3. To monitor medicines use within the ward area. This includes recording of significant clinical interventions and risk management including:
   - Participation in investigating clinical incidents
   - Recording significant clinical incidents/near misses
   - Ensuring compliance with medicines legislation and local policies

4. To use available information to influence prescribers and ensure the most cost-effective choice of therapy.

5. With the rest of the members of the clinical pharmacy team to support the strategic developments of the service e.g. electronic prescribing, improved discharge processes, accredited technician checking etc.

Professional Role

1. To ensure confidentiality is maintained at all times.

2. To be professionally accountable for actions and advice.

3. To be aware of training and competency assessment of pre-registration pharmacist trainees, diploma pharmacists and student pharmacy technicians and to participate in their training and competency assessment as required.

4. Participate in Continuous Professional Development

5. Conduct Clinical Trial pharmacy screening and dispensing checks within the dispensary according to the rota.

6. To participate in weekend and bank holiday working according to rota

7. To attend Clinical Trial specific training course to maintain and update knowledge including web based learning.

8. Any other reasonable duties as requested by the Chief Pharmacist.

RISK MANAGEMENT

The management of risk is the responsibility of everyone and will be achieved within a progressive, honest and open environment.
Staff will be provided with the necessary education, training and support to enable them to meet this responsibility.
Staff should be familiar with the

- Major Incident Policy
- Fire Policy

and should make themselves familiar with the 'local response' plan and **their** role within that response.

RESPONSIBILITIES FOR HEALTH & SAFETY

The post holder is responsible for ensuring that all duties and responsibilities of this post are carried out in compliance with the Health & Safety at Work Act 1974, Statutory Regulations and Trust Policies and Procedures. This will be supported by the provision of training and specialist advice where required.

INFECTION CONTROL

Infection Control is everyone's responsibility. All staff, both clinical and non clinical, are required to adhere to the Trusts' Infection Prevention and Control Policies and make every

effort to maintain high standards of infection control at all times thereby reducing the burden of Healthcare Associated Infections including MRSA.
All staff employed by the ORH Trust have the following key responsibilities:

- Staff must decontaminate their hands prior to and after direct patient contact or contact with the patient's surroundings.
- Staff members have a duty to attend mandatory infection control training provided for them by the Trust.
- Staff members who develop an infection (other than common colds and illness) that may be transmittable to patients have a duty to contact Occupational Health.

CHILDREN'S RIGHTS

The post holder will endeavour at all times to uphold the rights of children and young people in accordance with the UN Convention Rights of the Child.

SAFEGUARDING CHILDREN AND VULNERABLE ADULTS

The Trust is committed to safeguarding children and vulnerable adults throughout the organisation. As a member of the trust there is a duty to assist in protecting patients and their families from any from of harm when they are vulnerable.

INFORMATION GOVERNANCE

All staff must complete annual information governance training. If you have a Trust email account this can be completed on-line, otherwise you must attend a classroom session. For further details, go to the Information Governance intranet site.

SERIOUS UNTOWARD INCIDENTS

All staff must report incidents and near misses so that the Trust can reduce the risk of harm by investigating and incorporating risk reducing measures to safe guard patients, visitors and staff, in accordance with the Trust Incident Reporting Policy.

Note

1) This Post is subject to appraisal, which is a two way process.
2) This job description is not definitive or restrictive in any way and should be regarded only as a guide to the duties required, and also it will be understood that at a time of rapid change within the Health Service other responsibilities may be added, as determined by the Chief Pharmacist. The job description does not form part of the contract of employment.
3) The post-holder will be expected to participate in flexible working if introduced.
4) Out of hours working may be included and participation in such arrangements will be required.
5) Pharmacists will be required to participate in on-call arrangements according to site and experience.
6) Individual's continuous Professional Development needs will be identified and supported.

Pharmacy Department

Person Specification:
Clinical Trials Pharmacist Band 7

	Essential	Desirable
Qualifications	• MPharm Qualified to master's degree level (4 year MPharm) or equivalent Pharmacy degree. • Registered Pharmacist with General Pharmaceutical Council (GPhC). • Postgraduate clinical pharmacy certificate or GPhC registered independent prescriber.	• Diploma/MSc in Clinical/Hospital Pharmacy or appropriate Research Qualification. • RPS Membership. • Good Clinical Practice (GCP) trained.
Experience	• Experience of practicing as a registered pharmacist including but not limited to a hospital (band 6 or above), community, Primary Care Networks (PCN) setting. • Broad based clinical experience. • Completed clinical audit / practice research. • Experience of supervising, training, and assessing staff. • Evidence of proposing and implementing service changes.	• Previous Clinical Trials or Research experience. • Aseptic Unit experience. • Research Ethics experience / training. • Experience of managing others.
Personal Skills	• Strong interpersonal skills • Good written and verbal communication skills, with proficiency in communicating complex information to diverse stakeholders. • Competent in influencing and persuading others • Excellent organisational and time management skills with	• Experience in presenting to a group.

	the ability to prioritize tasks and manage multiple projects simultaneously. • Detail orientated with a commitment to accuracy and precision. • Ability to review, process and present complex information in a clear and concise manner. • Adaptable and flexible, with the ability to deal effectively with unpredictable demands.	
Behavioral Skills	• Will uphold trust values and demonstrate kindness in action. • Proactive and self-motivated, with a passion for advancing and improving patient. • Collaborative team player who values teamwork, diversity, and inclusivity • Demonstrated ability to exercise discretion, maintain confidentiality, and adhere to ethical standards in all aspects of work. • Resilient and able to handle challenges and setbacks with professionalism and a positive attitude. • Continuous learner with a commitment to professional development and staying updated on advancements in clinical pharmacy and research methodologies. • Applying critical thinking skills to assess complex situations and make informed decisions. • Independently managing complex situations while adhering to regulatory frameworks and best practices. • Maintain composure and ability to remain calm when	

	faced with tight deadlines, interruptions or high-stress situations.	
Technical Skills	• Computer literate with experience of working with the Microsoft Office package. • Proficient in pharmaceutical calculations, ability to check aseptically dispensed medicines or be willing to be trained. • Critically review and extract relevant information from sponsor-provided documents. • Familiar with electronic patient records and screening prescriptions.	• Experience in project management. • In-depth knowledge of Good Clinical Practice (GCP) guidelines, regulatory requirements, and ethical considerations governing clinical trials • Familiarity with electronic data capture systems and pharmacy management software used in clinical research settings.
General	• Flexible working across sites. • Ability to work on 1 in 6 week-end rota. • Ability to start work at 08:00 depending on the rota.	