

# Pharmacy Department

## Clinical Trials Pharmacist

### Job Description

<b>Grade</b>	Band 7
<b>Based at:</b>	Pharmacy Department John Radcliffe and Churchill Hospitals Oxford University Hospitals NHS Trust
<b>Accountable to:</b>	Chief Pharmacist
<b>Managed by:</b>	Lead Pharmacist Clinical Trials
<b>Liaison with:</b>	<ul style="list-style-type: none"><li>• Clinical Research Associates</li><li>• Nursing and Medical staff</li><li>• Principal investigators</li><li>• Researchers</li><li>• Research and Development (R&amp;D)</li><li>• R&amp;D Finance Personnel</li><li>• Research Ethics Committee personnel</li><li>• Dispensary staff</li><li>• CTASU and Baxter Aseptic Unit personnel</li><li>• CRUK &amp; Research Network personnel</li><li>• Specialist Clinical Pharmacists</li></ul>

### Overall Objectives

As a Clinical Trials Pharmacist for the Trust:

- Co-ordinate and deliver Pharmacy support to Researchers in the Oxford University Hospitals NHS 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, EU Directive 2001/20/EC, 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 the Lead Clinical Trials Pharmacist.
2. Arrange for, and receive investigational medicinal product (IMP) in line with Clinical Trial SOP's and ensure compliance with GMP legislation.
3. Support the clinical trials technicians as required in multidisciplinary team meetings with investigators to initiate, manage and close down trials hence ensuring pharmacy participation.
4. Adhere to the appropriate disposal procedure of unwanted trial materials.
5. Liaise with the Specialist Clinical Pharmacists when assessing, approving or initiating new projects, and update Dispensary staff on newly set up studies.
6. 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)**

1. Maintain knowledge and expertise to provide releasing support and cover to CTASU as per rota.

## **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 form 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.