

# Pharmacy Department

## Senior Clinical Trials Pharmacy Technician

### Job Description

**Grade:** Band 5, 37.5 hours per week  
**Based at:** Cross site (Churchill, John Radcliffe and Horton Hospitals)  
**Accountable to:** Chief Pharmacist  
**Managed by:** Lead Pharmacy Technician, Clinical Trials

### Overall Objectives

- To provide comprehensive technical support to the Clinical Trials Services at OUH Trust.
- To ensure the effective and efficient supply of medicines and advice to service users including staff and patients. To ensure these services are delivered in accordance with National and local standards of Good Clinical Practice (GCP) and EU directive relating to Clinical trials.
- To deputise for the Lead Technician as appropriate across the Oxford University Hospitals NHS Trust.

### Key Result Areas

#### Core Role - Clinical Trials

1. To obtain and maintain Good Clinical Practice (GCP) training.
2. To apply principles of GCP in the management of clinical trials and work within the Medicines for Human Use (Clinical Trial) Regulations 2004 and EU directive relating to Clinical Trials.
3. To communicate with Investigators, Research Nurses, Trust R&D, Sponsors, Clinical Research Associates and Pharmacy staff during the set-up and running of a clinical trial.
4. To ensure clinical trial protocols and SOPs are followed during dispensing of clinical trial investigational medicinal products and other drugs included in the protocol.
5. To implement and maintain clear and accurate SOPs, and ensure they are followed for dispensing for each clinical trial in accordance with regulatory standards and each trial's protocol.
6. To order and receive in clinical trial drugs, process receipt paperwork and acknowledge receipt on IVRS/IWRS (Electronic Medication Supply) systems.
7. Deputise and be a point of contact in the absence of the Lead Clinical Trial Pharmacy Technician.
8. To check stock levels and expiry dates of clinical trial drugs and keep balance logs up to date.
9. To assist with the packing down and re-labelling of clinical trial drugs if required.

**Created by:** Carley Merritt

**Date:** 24 August 2016

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10. To assist with the preparation for monitoring meetings, audits and inspections, and carry out any necessary work prior to this.
11. To maintain Clinical Trial files ensuring items can easily be located and are presentable.
12. To process returned clinical trial drugs and ensure the paperwork is kept in order.
13. To participate in the statutory temperature monitoring of clinical trial stocks.
14. To assist with the destruction of clinical trial medication.
15. To assist with the closedown and archiving of clinical trial files.
16. To represent the Clinical Trials Team to update the dispensary staff at meetings and deputise for Lead Pharmacy Technician at requested meetings.
17. To liaise with Research Nurses to update them on trial progress, stock levels etc.
18. To assist in the collection of data as requested by the Lead Clinical Trial Technician or Clinical Trial Pharmacists.
19. To assist in maintaining financial records, including the generation of invoices, checking payments etc.
20. To assist with general administration such as organising set up meetings etc and is a point of contact within the Clinical Trials Pharmacy Team.
21. To maintain clinical trial filing systems and drug accountability documentation for clinical trials.
22. To use the computer system and other information technology in all areas of Pharmacy.

#### **Clinical Trial Aseptic Services Unit**

1. To participate and contribute in the day to day running of the CTASU in line with the Rota system.
2. To undertake safe and accurate preparation of a wide range of aseptic products on a daily basis, including cytotoxic, epidurals, antibiotics, injectables, novel agents and monoclonal antibodies.
3. To maintain personal expertise, skills and necessary knowledge of the technical aspects of aseptic and non-aseptic dispensing.
4. To ensure products are prepared according to standard operating procedures (SOPs).
5. Assemble drugs and consumables required for preparation of aseptic products, accurately recording batch numbers and expiry dates.
6. To be responsible for the accurate completion of product worksheets and labels, assigning batch numbers to aseptically prepared products.
7. To accurately and safely label aseptically prepared products.
8. To facilitate the quality assurance of products and to notify the Senior Aseptic Technician of any incidents and procedural deficiencies.
9. To ensure finished products are transported in the appropriate environment taking into account any physical & legal requirements.
10. To participate in the clean room/isolator cleaning rota.
11. To assist in environmental and physical monitoring of the CTASU.
12. To be involved in the maintenance of departmental records including staff training, environmental monitoring, cleaning, maintenance logs and worksheets.
13. Where applicable to be involved in the delivery of drugs to clinical areas.

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### **Regulatory**

1. To assist in aseptic and non-aseptic preparation and dispensing of clinical trial medication in accordance with the RPSGB code of ethics and current legislation and guidance including Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), Guidance on Aseptic Dispensing for NHS Patients, Health and Safety, Medicines Act, Misuse of Drugs Act, Control of Substances Hazardous to Health (COSHH) and Departmental Procedures.
2. To ensure you are familiar with and adhere to Pharmacy, CTASU and Trust standard operating procedures (SOPs).
3. To ensure the disposal or recycling of medicinal products is carried out in a safe and efficient manner, in accordance with Health & Safety, COSHH regulations and Departmental Standard Operating Procedure.

### **Teaching and Training**

1. To participate in a programme of work based training, development and appraisal.
2. To be an accredited checking Technician having undertaken the relevant training package according to departmental/national guidelines.
3. To be or become accredited as an NVQ A1/A2 Assessor having undertaken the relevant training according to national guidelines.
4. To participate in the induction of Clinical Trials Staff from the Trust including supervise and be involved in the training of junior staff.
5. To participate in the training and induction of pre-registration students, technicians and assistants (if required).
6. To complete regular rotated slot in CTASU to maintain necessary skill set, if required.
7. To participate in and be responsible for completing a programme of Continuing Professional Development.

### **General responsibilities**

1. To ensure confidentiality is maintained at all times.
2. To be aware of and be involved in good customer service.
3. To assist in audit programme.
4. To participate in weekend, evening and bank holiday working according to rota.
5. To complete regular rotated slot in the Clinical Trials Aseptic Services Unit and dispensary to maintain skill set, if required.
6. 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.

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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.

### **Responsibility for Health and 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 endeavor 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.

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### **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.

### **Special Working Conditions**

The post holder must adhere to associated hygiene and clothing requirements of individual work areas. This may involve: absence of make-up, removal of jewellery, wearing of protective clothing, working in a confined space for up to periods of 3 hours at a time.

### **Please 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.

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## Person Specification

### Senior Clinical Trials Pharmacy Technician

Essential Qualities	Desirable Qualities
Qualified Pharmacy Technician holding an NVQ Level 3 (Pharmaceutical Sciences) or other relevant qualification	Previous NHS experience
At least 2 years' experience as a Pharmacy technician either in hospital or community	Clinical trials experience
Previous experience of training/supervision of other/junior staff	A1 Assessor's Qualification
Ability to show attention to detail in work	A role model that demonstrates a professional attitude at all times
Good interpersonal skills with all levels of staff	Ability to interact with all team members and demonstrates good communication skills at all times inside and outside of the dept.
Accredited Checking Technician or commitment to undertake course	Previous aseptic experience including ability to work at an isolator fully gloved and gowned
Professional approach and experience of team working	Awareness of legislation and standards relating to Good Clinical Practice
Enthusiastic and responsible attitude towards work	Able to acknowledge, appreciate and conform to change that occurs
Good organisational skills and prioritisation of work	Experience of working on own initiative
Able to work alone and able to use own initiative	
Demonstrate an on-going commitment to CPD and PDP as per GPhC requirements	Understands the changing roles of the Pharmacy Technician and what GPhC registration involves.
Basic all round knowledge of Pharmacy department and its services.	
IT skills e.g. Word processing, spreadsheet	

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