Pharmacy Department

Senior Clinical Trials Pharmacy Assistant

Job Description

Grade: Band 3, 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 core support to the Clinical Trials Pharmacy Team

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 order and receive in clinical trial drugs, process receipt paperwork and acknowledge receipt on IVRS (Electronic Medication Supply) systems.

6. To check stock levels and expiry dates of clinical trial drugs and keep balance logs up to date.

7. To assist with the packing down and re-labelling of clinical trial drugs if required.

8. To assist with the preparation for monitoring meetings, audits and inspections,

9. To maintain Clinical Trial files ensuring items can easily be located and are presentable.

10. To process returned clinical trial drugs and ensure the paperwork is kept in order.

11. To participate in the statutory temperature monitoring of clinical trial stock.

12. To assist with the destruction of clinical trial medication.

13. To assist with the closedown and archiving of clinical trial files.

14. To represent the Clinical Trials Team to update the dispensary staff at meetings.

15. To liaise with Research Nurses to update them on trial progress, stock levels etc.

16. To assist in the collection of data as requested by the Senior Clinical Trial Technician or Clinical Trial Pharmacists.

17. To assist in maintaining financial records, including the generation of invoices, checking payments etc.

18. To assist with general administration such as organising set up meetings etc. and be a point of contact within the Clinical Trials Pharmacy Team.

19. To maintain clinical trial filing systems and drug accountability documentation for clinical trials.

20. To use the computer system and other information technology in all areas of Pharmacy.

Clinical Trial Aseptic Unit

1. To participate in the day to day running of the CTASU in line with the rota system.

2. To participate in safe systems of work and documentation of these.

3. To undertake safe and accurate preparation of a wide range of aseptic products on a daily basis, including cytotoxics, epidurals, antibiotics, injectables, novel agents and monoclonal antibodies.

4. To maintain personal expertise, skills and necessary knowledge of the technical aspects of aseptic and non-aseptic dispensing.

5. To ensure products are prepared according to standard operating procedures (SOPs).

6. Assemble drugs and consumables required for preparation of aseptic products, accurately recording batch numbers and expiry dates.

7. To be responsible for the accurate completion of product worksheets and labels, assigning batch numbers to aseptically prepared products.

8. To accurately and safely label aseptically prepared products.

9. To facilitate the quality assurance of products and to notify the Senior Aseptic Technician of any incidents and procedural deficiencies.

10. To be responsible for ensuring finished products are packed prior to distribution to ensure the prompt and safe delivery.

11. To ensure finished products are transported in the appropriate environment taking into account any physical & legal requirements.

12. To be responsible for unpacking and receipt of deliveries.

13. Undertake regular expiry date checking to identify expired or short dated stock.

14. To be responsible for monitoring drug stock and consumable levels and replenishing.

15. To ensure that all equipment within CTASU is in good working order and serviced regularly.

16. To participate in the clean room/isolator cleaning rota.

17. To assist in environmental and physical monitoring of the CTASU.

18. To be involved in the maintenance of departmental records including staff training, environmental monitoring, cleaning, maintenance logs and worksheets.

19. Where applicable to be involved in the delivery of drugs to clinical areas.

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 participate in the training and induction of pre-registration students, technicians and assistants (if required).

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.

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 incidents Policy
- Fire Policy

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

Responsibilities 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 and 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 has the following key responsibilities:

- Staff must wash their hands or use alcohol gel on entry and exit from all clinical areas and/or between each patient contact.
- 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.

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.

Person Specification for
Senior Clinical Trials Pharmacy Assistant

Essential Qualities	Desirable Qualities
NVQ2 in Pharmaceutical Sciences or equivalent	Previous NHS experience
Ability to work in an isolator fully gloved and gowned	Previous aseptic experience
Enthusiastic and responsible attitude	Clinical trials experience
Professional approach	Well organised
Attention to detail	
Good interpersonal and communication skills	
Uses own initiative	Experience of working on own initiative
Team player	Experience of team working
Adaptable to change	Experience of a changing working environment
IT skills e.g. Word processing, spreadsheet	

Produced By: Karolina Joniak **Date:** 28-Feb-2023

Approved by: Alfonso Gonzalez Blas **Date:** 28-Feb-2023