Oxford University Hospitals NHS
NHS Foundation Trust

Pharmacy Department

Job Description

Job Title	Deputy Aseptic Services Manager for Clinical Trials Aseptic Services Unit
Grade	Band 6
Based at	Churchill Hospital
Accountable to	Clinical Director of Pharmacy and Sterile Services
Responsible to	Aseptic Services Manager for Clinical Trials
Manages	Aseptic Services technical staff

Job Summary

The main responsibilities of this role are to support the management, performance and development of the unlicensed Clinical Trials Aseptic Services Unit (CTASU) which provides injectable Investigational Medicinal Products and selected high risk injectable medicines to all divisions within the Trust. The role will also involve working with the Aseptic Services Manager, Accountable Pharmacist, and Deputy Accountable Pharmacist to ensure the implementation of technical, professional, best practice and regulatory guidance for the preparation and supply of Advanced Therapy Investigational Medicinal Products. A key part of the role will be supporting an ongoing project to build and commission a new CTASU facility to further enable its extensive research portfolio.

Main Tasks and Responsibilities

To lead and manage the day-to-day service provided by CTASU, and ensure that aseptic preparation of medicines is run in accordance with current guidance and best practice, as detailed but not limited to those set out in Quality Assurance of Aseptic Preparation Services Handbook.

To provide cost-effective delivery of high quality aseptic pharmaceuticals, which are fit for their intended purpose to patients of the Trust, and other external customers of the service, and are prepared in a safe, efficient and cost effective manner in accordance with departmental SOPs.

To participate in identifying and implementing initiatives as appropriate to reduce the financial costs and the environmental impact of CTASU service.

To have a good working knowledge of Quality Assurance of Aseptic Preparation Services handbook requirements and the yellow cover guidance documents from SPS. To work with the Aseptic Services Manager, Accountable Pharmacist and Deputy to review the impact of changes to these standards and implementing change where required.

To maintain a comprehensive knowledge of national legislation and recommendations from the Department of Health, MHRA, NHS England, the General Pharmaceutical Council and Royal Pharmaceutical Society relating to aseptic preparation and Good Manufacturing Practice.

To have good working knowledge of the Medicines for Human Use (Clinical Trials) Regulation (EU Directive 2001/20EC), Human Medicines (EU Exit) Regulations 2019 and the International Conference on Harmonisation GCP Guideline (ICH GCP), as applicable to the dispensing of Investigational Medicinal Products for clinical trials or other products eg NIMPs, physiological compounds given to study subjects.

To facilitate NHS QA inspections, MHRA, sponsor audits where required, collaborating and communicating complex regulatory information to ensure that action is undertaken to resolve any findings.

To work with the Aseptic Services Manager, Accountable Pharmacist and Deputy to maintain the Pharmaceutical Quality System (PQS), and ensure staff are working according to the Standard Operating Procedures detailed in the PQS.

Alongside the Aseptic Services Manager and Accountable Pharmacist ensure all staff that work in CTASU are trained and competent to perform daily tasks, and that there is an ongoing validation programme in place to demonstrate ongoing competency.

To ensure the preventative maintenance and environmental monitoring programme is undertaken as per SOPs, paperwork is received and reviewed and that deviations are managed to ensure compliance with the standards.

To monitor and record internal and external errors/near misses, taking corrective and preventative action if necessary, as part of the Trust's Incident Monitoring Programme.

To support in the ongoing recruitment of staff, induction and management, and collaborate with the training team to ensure an effective and competent workforce.

To be aware of Health and Safety regulations, and how these apply to an aseptic unit; such as, but not limited to manual handling, First Aid, COSHH, Biocidal Products Regulation.

To be responsible for accurate financial records, including invoicing, checking of invoices and authorisation of invoices for payment.

To be responsible for ensuring that Drug Alerts received from the Medicines and Healthcare Regulatory Authority (MHRA) are processed and any actions taken within a required time frame.

To ensure the CTASU and its staff operate to standards of excellence in customer care and with a strong patient focus.

Technical role:

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

To provide specialist technical advice to service users as necessary e.g. suitability of diluents, volume of diluents, administration routes and stability data.

To partake in the rota where required, and perform specific tasks related to the preparation of an aseptic product such as completion of product worksheets, assembly of medicines and consumables, aseptic dispensing, packing prepared medicines for transport.

To perform pre and in-process checks of aseptically prepared products having undergone the appropriate accreditation.

To ensure finished products are transported appropriately according to any physical and regulatory requirements.

To ensure clean room and isolator cleaning standards, and to participate in the clean room/isolator cleaning rota as required.

To be responsible for ensuring that expiry date and stock level checks are carried out.

To ensure maintenance of departmental records including staff training, environmental monitoring, cleaning, maintenance logs and worksheets.

To work collaboratively with Pharmacy Purchasing and Distribution Unit (PPDU) and OUH procurement team to oversee purchasing and distribution for the CTASU.

To liaise with external and internal suppliers of stock, consumables, equipment etc.

To be responsible for the preparation of rotas for CTASU staff and collaborate with other operational managers to always ensure the most effective deployment of staff.

To identify and monitor the needs of service users and CTASU, and effectively plan and implement changes and improvements to the CTASU.

To support the development and commissioning of new equipment, processes or facilities through agreed SOPs and Change Control procedures.

Management:

To be responsible for the supervision and day to day management of staff within the CTASU.

To line manage technical CTASU staff.

To ensure all staff in the CTASU are appraised at least annually in line with OUH policy, and personal development plan and participate in Continuous Professional Development, including competency frameworks as appropriate.

To ensure staff maintain statutory and mandatory training to meet Trust requirements.

To work with the Lead Pharmacist for Education and Training and other senior staff to ensure individual training and educational needs of staff are identified and met through a programme of Continuous Professional Development; including the use of competency frameworks where appropriate.

Clinical Trials

To ensure all CTASU staff are in compliance with relevant standards for the operation and management of Clinical Trials, including ICH-GCP and GMP.

To ensure all members of the CTASU staff have appropriate ICH-GCP training.

To work within the Medicines for Human Use (Clinical Trial) Regulations 2004 and EU directive relating to Clinical Trials.

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.

To oversee the production, implementation and review of detailed written pharmacy guidance and SOP's for each clinical trial in accordance regulatory standards and each trial's protocol.

To ensure clinical trial protocols are followed during dispensing of clinical trial investigational medicinal products and other drugs included in the protocol.

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

To support the training of medical, nursing and pharmacy staff in all aspects of handling drugs in clinical trials.

To liaise with other centres for clinical research to ensure common standards of practice.

To assist in the development of Pharmacy policies and procedures to support the delivery of clinical trials involving medication and related substances.

Teaching and Training

To be an accredited Pre and In Process Checker

To support in the planning, writing and delivery of training programmes for staff in CTASU, ensuring that training folders are up to date and valid.

To support the Pre and In Process checking programme for pharmacy technicians in the CTASU, in liaison with the Pharmacy Education and Training Team.

To co-ordinate the training for rotational staff such as clinical trial team, cancer team, pre-registration technician and pre-registration pharmacists.

To work closely with the Pharmacy Education and Development team to ensure all CTASU staff are trained and competent and comply with mandatory training requirements.

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

To work with the technician training team to ensure all CTASU staff are released for mandatory training, and CTASU staff contribute as required to training and competency assessment of pharmacy staff as required.

General responsibilities

To maintain registration with General Pharmaceutical Council and uphold the professional standards

To ensure confidentiality is maintained at all times.

To use experience and clinical judgment to assist in problem solving and trouble-shooting.

To be professionally accountable for actions and advice.

To collect evidence to deal with complaints in accordance with the Trust's complaints policy.

To be first point of contact for operational issues, queries and concerns.

To represent CTASU at departmental and Trust meetings.

To participate in week day service starting at 07:00, weekend, evening and bank holiday working according to rota.

Any other reasonable duties as requested by the Clinical Director of Pharmacy and Sterile Services or line manager.

Liaises with:

- Pharmacy Clinical Trials team
- Pharmacy Operational Managers for all sites
- Clinical Pharmacists
- Clinical Staff
- Dispensary staff
- Estates and Portering Managers
- Clinical Research Associates
- Principal Investigators and Researchers
- Research and Development (R&D) staff

- OUH procurement
- R&D Finance Personnel
- CRUK & Research Network personnel
- Quality assurance and quality control personnel
- External suppliers & contractors

General Conditions

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
- Information governance

and 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 & 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 OUH have 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.

Child Protection

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.

Data Quality

Data quality is a vital element of every member of staff's job role. Oxford University Hospitals recognises the importance of information in the provision of patient care and in reporting on its performance. Data quality is therefore crucial in ensuring complete, timely and accurate information is available in support of patient care, clinical governance, performance management, service planning, and financial and resource planning and performance. All staff should ensure that they have read and understood the Trust's Data Quality Policy

Personal Specification

Deputy Aseptic Services Manager Clinical Trials Aseptic Services Unit (CTASU)

	Essential	Desirable
Qualification	Qualified Pharmacy Technician holding an NVQ Level 3 or equivalent qualification, plus underpinning knowledge (BTEC in Pharmaceutical Sciences) allowing registration with GPhC Current Registration with GPhC as a Pharmacy Technician Pre and In Process Checking Qualification	Evidence of further post qualification training in aseptic services Management qualification or significant experience and willingness to work towards
Knowledge and Experience	Experience of working in an aseptic unit Proven in depth technical ability and knowledge in cytotoxic and aseptic reconstitution Experience of training and supervision of staff Knowledge of and ability to apply GMP, QA and regulations and legislation relevant to aseptic services Knowledge and awareness of the risks of working in an environment where there is a risk of exposure to novel compounds and cytotoxics Experience of managing change or implement new ways of working	Experience of working with clinical trials Knowledge of and ability to apply GCP regulations and legislation to aseptic services Experience of working with Advanced Therapy Medicinal Products Evidence of successfully project managing a significant change in a department Experience in undertaking risk assessments, and develop and implement action plans
Personal and Behavioural Skills	Passion for your field of excellence Excellent interpersonal skills Able to deal with sensitive issues and deal with and resolve conflict	Ability to liaise, explain and convey difficult information and messages to senior colleagues including research consultants and sponsors

	Ability to set targets and meet deadlines and prioritise own workload & across teams Ability to work under pressure Problem identification and solving skills Be assertive Uphold the values of the Trust and act to support the welfare of others	
Technical Skills	Ability to work in an isolator fully gloved and gowned for 4 hours in a session Good manual dexterity and ability to maintain concentration Good written and oral skills to be able to communicate complex and specialised information within the department, the Trust and to external/regulatory agencies Methodical with high attention to detail Ability to devise new processes, SOPs or assessments IT literacy, including word processing, use of excel, email and use of internet	

Prepared by: Laura Rodden Jan 2022

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