



MAC Clinical Research

JOB DESCRIPTION

NAME:

JOB TITLE: Senior Pharmacy Technician

REPORTS TO: Pharmacy Manager

FOCUS OF THE JOB:

- Deputise in the absence of the Pharmacy Manager
- Produce Aseptic, Sterile and Non-sterile Investigational Medicinal Products, comparators or nIMP.
- Responsible for training and ongoing competencies and validations of pharmacy staff
- To liaise with Sponsors, vendors and customers for pharmacy and pharmacy queries and guidance.
- To support and host monitoring visits at the pharmacy facility
- To assist and support in responding to quality events

KEY SKILLS, KNOWLEDGE AND QUALIFICATIONS REQUIRED:

- Good knowledge of Good Manufacturing Practice
- Good knowledge of Good Clinical Practice
- Registered Pharmacy technician

RESPONSIBILITIES:

- Ensure compliance of the aseptic units with GCP and environmental requirements.
- To ensure that all processes and procedures are GCP compliant.
- To ensure that study pharmacy documentation is completed to ensure complete accountability of study material.
- To ensure that appropriate measures are taken that Investigational Medicinal Product / commercial and comparator products are kept at the appropriate storage conditions.
- Investigate and report any excursions regarding storage of study drug material.
- To maintain documentation of storage conditions
- Contribute to departmental service review and performance monitoring.
- To assist with internal and external audits, self- inspections, monitoring visits and regulatory inspections as required.
- Assisting with pharmacy procedures; un-blinded and blinded dispensing/assembly or manufacture of medication/IMP/nIMP and supply/resupply.
- Ensure quality events are raised in a timely manner.
- Ensure timely corrective actions are taken in the event of an adverse monitoring report

- Assist with the generation and update of SOP's when necessary.
- Provide support and guidance to the pharmacy assistants.
- Report and take direction from the Pharmacy Manager to ensure service levels are maintained and the unit functions appropriately and safety.
- To ensure all consumables for example bottles, syringes, needles etc are ordered and received in a timely manner.
- To ensure any medication to be used as a comparator or nIMP is ordered and received in a timely manner.
- To ensure all quarterly broth validations and weekly end of session media fills are completed.
- To perform all aspects of validations, performance qualifications and study dry runs.
- To assist with review and update of SOPs to ensure unit runs to compliance and efficiently.

EQUIPMENT:

- To assist in ordering and maintenance of equipment for studies when required.
- Assist with the validation of any new equipment.
- To maintain all environmental standards required for the Pharmacy unit.
- Ensure timely corrective actions are taken in the event of an adverse monitoring report.

DEVELOPMENT & TRAINING:

- Identify areas for self-improvement and progression.
- Identify potential training needs of the department.
- Maintain GPhC requirements of CPD.
- Maintain GPhC registration, providing yearly evidence of registration to the Pharmacy Manager.
- Ensure training folder is updated and maintained.
- Ensure mandatory and necessary training for the role is completed.
- Ensure all departmental SOPs are read in a timely manner.

GENERAL:

- Participate in regular meetings with colleagues and clients.
- Identify priorities; bring issues to the attention of colleagues for the smooth running of the Pharmacy Unit.
- Present a positive image of MAC to all external individuals.
- Set a positive example to all colleagues.
- Share experience and knowledge with colleagues as appropriate and in an appropriate manner.
- Compliance with MAC health and Safety policy.
- Compliance with MAC policy on equality and diversity.
- To work according to MAC SOPs, guidelines and policies

- To work according to current data protection standards and practice good information management. Maintenance of strict confidentiality of patient and business-related data.
- To maintain a high level of initiative and personal responsibility, liaising appropriately with team members and managers to ensure your job role is efficiently carried out
- Implement agreed systems to ensure high standards of customer service are maintained.

PHYSICAL, WORK ENVIRONMENT, TRAVEL DEMANDS:

Required to travel to individual MAC Research sites as appropriate for training, equipment issues, support other MAC Research site and client visits.

LIMITATIONS AND DISCLAIMER

The above job description is meant to describe the general nature and level of work being performed; it is not intended to be construed as an exhaustive list of all responsibilities, duties and skills required for the position.

Employees signature..... Date.....

Head of Department signature..... Date.....