MAC Clinical Research

JOB DESCRIPTION

NAME:

JOB TITLE: Production Manager

REPORTS TO: Vice President of Clinical Operations

FOCUS OF THE JOB:

- Named as the "Production Manager" on the MHRA MIA (IMP) licence.
- To be responsible for the leading, delivery and evaluation of comprehensive production services including aseptic services.
- Responsible for training of production staff.
- To liaise with staff including the Medical Director, PI (Principal Investigator), Sub-Investigators, Site Directors, Project Managers and CTAs, regarding requirements for studies of Investigational Medicinal Product (IMP) / commercial and comparator
- To liaise with sponsors, vendors and customers for pharmacy production queries and guidance.

KEY SKILLS, KNOWLEDGE AND QUALIFICATIONS REQUIRED:

- Good knowledge of Good Manufacturing Practice
- Good knowledge of Good Clinical Practice

RESPONSIBILITIES (including staff):

- Ensure compliance of Manufacturing Unit with EU GMP
- Ensure that products are produced and stored according to the appropriate documentation so that they reach the appropriate standards of quality
- Approving the instructions relating to production operations and ensure their strict implementation
- Ensuring that the production records are evaluated and signed by an authorised person before they are sent to Quality Control (QC) Department
- Checking the maintenance of their department, premises and equipment
- Ensuring that the appropriate equipment and process validations are carried out to GMP standards
- Ensuring that the required initial and continuing training of their department personnel is carried out and adapted according to need
- Authorisation of written procedures and other documents, including amendments

- The monitoring and control of the manufacturing environment,
- Ensure plant hygiene standards are maintained
- The approval and monitoring of suppliers of materials
- The approval and monitoring of contract manufacturers and providers of other GMP related outsourced activates
- The designation and monitoring of storage condition of materials and products
- Responsible for paper documentation and electronic record retention
- The monitoring of compliance with the requirements of good manufacturing practice
- The inspection, investigation, and taking of samples, in order to monitor factors which may affect product quality
- Participation in management reviews of processes performance, product quality and of the quality management system and advocating continual improvement
- Ensuring that a timely and effective communication and escalation process exists to raise quality issues to the appropriate levels of management
- Compliance with MAC health and Safety policy
- Compliance with MAC policy on equality and diversity
- To maintain professional qualifications required for the role, including continuous personal development
- To work to the requirements of SI 2004 no 1031 and amendments thereof, which includes Good Clinical Practice
- 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
- To support the aims of MAC and to represent MAC appropriately in a professional way to all our customers

PHYSICAL, WORK ENVIRONMENT, TRAVEL DEMANDS:

- Required to travel to individual MAC Research sites as appropriate for training, equipment issues and client visits.
- Required to work in aseptic environment.

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…….