Portsmouth Hospitals University NHS Trust

Job Description

Title: Quality Assurance Releasing Pharmacist

Band: 7

Staff Group: Clinical Delivery Division

Reports to: Quality Assurance Manager

Job Purpose:

To perform final product approval (releasing officer) for items produced under the MHRA Manufacturer's Specials Licence and, if appropriate, for items produced under Section 10 of the Medicines Act 1968 and Regulation 37 of The Medicines for Human Use (Clinical Trials) Regulations 2004. To ensure finished products are examined for their compliance with approved specifications and fitness for their intended purpose and to release or reject each batch as appropriate. This will require consideration of all factors relevant to the batch release including facility status, staff training status, production documentation review, and the final product.

Apply specialist technical knowledge of good manufacturing practice and quality systems to ensure development and maintenance of quality control and assurance, including quality monitoring; preparation and review of work instructions; investigating quality deviations, non-conformances', and complaints and reporting to pharmacy management in accordance with procedures.

Key Responsibilities:

Work with the QA Manager and other senior management personnel to ensure good manufacturing practice (GMP) and develop the quality management program to maintain the MHRA license and accredited unlicensed status. This will include providing and receiving complex and sensitive information, analysing and interpreting this information and relaying this information to the appropriate staff or customers

Acting as one of the releasing officers to ensure that finished products are examined for their compliance with approved specifications and fitness for the intended purpose, and to release/reject each batch as appropriate. This will require consideration of all factors relevant to the immediate release including facility status, staff training status, production documentation review. This includes high levels of concentration over long periods of time to ensure each pharmaceutical product complies with a unique hospital specification, which includes dose calculations, precise and total paperwork/ label checking. Due to the nature of the role this will be subject to frequent interruptions to provide advice to staff on immediate resolution of other problems.

Acting as one of the releasing officers requires intense scrutiny of documentation and judgmental skills to interpret information along with the ability to make a reasoned decision, questioning whether a product is fit to be used / released for patient use.

Contribute in particular to those processes demanding higher skills or knowledge e.g. preparation of products for clinical trials. This will involve the receipt and interpretation of complex and sensitive information relating to individual patient care.

To deputize for the Quality Assurance Manager or Accountable Pharmacist when required and line manage other QA staff including workload allocation and performance management.

Operate the internal and external systems for product recall, defect reporting and product return in accordance with PMU work instructions and assess procedures and changes that may be required, liaising / communicating with staff and internal and external customers over specific requirements that may be of a sensitive nature and have financial implications to PMU and the Trust.

Partake in self inspection audits in liaison with production personnel.

Critically evaluate the quality systems in place to ensure best practice is in operation and evaluate new directives and regulatory requirements to ensure compliance with these.

Act as a named person responsible for quality control on the MHRA Specials Manufacturing License (i.e. release or reject starting materials, packaging materials and intermediate, bulk and finished products against quality specifications).

Apply specialist technical knowledge to ensure development and maintenance of quality control and assurance systems, including; investigating complaints, deviation reporting, to identify root cause, approve corrective action, and recommend preventative action to prevent re-occurrence. Reporting to pharmacy management in accordance with procedures.

To undertake a range of project activities which may include but is not limited to: development of new systems of work, validation of new pieces of equipment, validation of new or upgraded computer software, introduction and validation of new products.

Preparation and /or authorisation of documents including work instructions and master production documents.

Review environmental quality monitoring data to ensure adequate completion, documentation, trending and satisfactory resolution of quality exceptions.

Work with the QA Manager and Technical Officers to commission, qualify and validate new and existing facilities, equipment and personnel and to ensure training programs are in place for the safe use of facilities and equipment.

Interpret environmental monitoring data and validation results to ensure unit, equipment and personnel are suitable to start/continue manufacturing on a daily basis, liaising and supervising of junior staff in daily activities to ensure the smooth running of unit.

Review and revise PMU documentation so it complies with current directives on good practice and health & safety. This will include looking at and practicing systems to ensure minimal ULDS.

Monitor suppliers of raw materials and services (e.g. involvement with the purchasing and contracting of manufacturers and suppliers), to ensure compliance with written specifications and requirements of GMP.

Undertake administrator role for specialist computer systems such as Episys, Ascribe

Help provide training and development to PMU personnel and Pre-Registration pharmacy graduates in the area of quality assurance and control using competency based training packages.

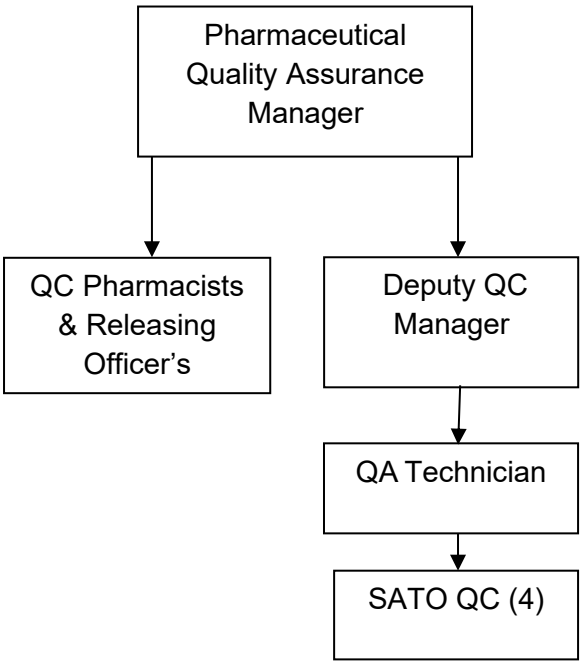
Work with senior personnel to develop competency based training packages, monitoring and validation systems in the areas of quality assurance and control for PMU and support personnel and Pre-Registration pharmacy graduates.

Contribute with the Pharmacy preparation workforce through participation in weekend and Bank Holiday working as required.

Training Requirement for Releasing Officers

As part of the pathway to becoming a Releasing Officer, the postholder is required to undertake structured training within the Production to gain a full understanding of all manufacturing processes. This includes hands-on experience of aseptic activities, as well as comprehensive learning of all associated documentation and workflow systems. Following this, the postholder must complete competency-based training in the final checking of all products. Successful completion of all production training and final-check competencies is an essential prerequisite before independently undertaking batch release responsibilities.

Organisational Chart



Other

This job description does not purport to cover all aspects of the job holder's duties but is intended to be indicative of the main areas of responsibility.

Person Specification

Qualifications

Essential

- Degree in Pharmacy, registered with the general pharmaceutical council.

Experience

Essential

- Thorough understanding of GMP and the requirements of the MHRA
- A good understanding of current microbiological or chemical methods and instruments used in QA/QC
- An excellent understanding of equipment and techniques used in aseptic manufacturing or compounding
- Working experience as a Releasing Officer

Desirable

- Previous work experience within the NHS aseptic services is desirable

Skills & Knowledge

Essential

- Ability to think strategically, develop services and manage change
- Ability to identify risk and carry our risk assessments
- Ability to analyse and solve problems
- Ability to set targets and meet deadlines
- Ability to appropriately recommend, substantiate and communicate decisions and influence senior staff
- Ability to promote & develop a quality work environment and ethos
- Good personal organization, time management and meeting skills
- Good computer literacy for report writing and presentations
- Able to work in clean room environments and operate precision equipment

Working Together For Patients with Compassion as One Team Always Improving

Strategic approach (clarity on objectives, clear on expectations)

Relationship building (communicate effectively, be open and willing to help, courtesy, nurtures partnerships)

Personal credibility (visibility, approachable, back bone, courage, resilience, confidence, role model, challenge bad behaviour, manage poor performance, act with honesty and integrity)

Passion to succeed (patient centred, positive attitude, take action, take pride, take responsibility, aspire for excellence)

Harness performance through teams (champion positive change, develop staff, create a culture without fear of retribution, actively listen and value contribution, feedback and empower staff , respect diversity)

Job holders are required to act in such a way that at all times the health and well being of children and vulnerable adults is safeguarded. Familiarisation with and adherence to the Safeguarding Policies of the Trust is an essential requirement for all employees. In addition all staff are expected to complete essential/mandatory training in this area.

Print Name:

Date:

Signature: