REF CODE:

PORTSMOUTH HOSPITALS NHS TRUST
JOB DESCRIPTION

Job Group:	**FOR OFFICE USE ONLY**
Job Title: Pharmaceutical Quality Assurance Manager	**Position No:**
Directorate/ CSC: *Clinical Support*	**Approved Matching Classification**
Existing Grade: *8b*	**Job Analysis**
Unit: *Pharmacy Manufacturing*	**Job Evaluation**
Base Location: *Railway Triangle, Farlington*	**Pay Band code:**
Reports to: *Director of Pharmacy*	
Accountable to: *Director of Pharmacy*	**Entered By:**

Job Purpose

- To Lead, manage, deliver, evaluate and develop the Pharmaceutical Quality Assurance Service for the Trust.
- To manage and co-ordinate the services and staff of the Quality Assurance/ Quality Control section of the licensed aseptic manufacturing facility and to support income generating service contracts to other departments.
- To be named as the person responsible for quality assurance on the Medicines and Healthcare Products Regulatory Agency (MHRA) Specials manufacturing license.
- To ensure that all requirements for regulatory compliance to this license are adhered to.
- To be responsible for the daily management and control of the quality assurance function within the manufacturing unit.

Duties and Responsibilities

Professional Leadership

To provide a comprehensive and high level Quality Assurance function to support not only Technical Services but also the Pharmacy Directorate to deliver the medicines optimisation and safety agenda.

To demonstrate expert technical knowledge and advanced level of clinical technical reasoning and judgement.

To be recognized as a national expert within Quality Assurance

To perform the role of Head of Quality as nominated on the MHRA specials and IMP manufacturing licenses (MS/ 13142/01)

To perform the role of EU *Qualified Person* on the Manufacturing Licence MS13142/01, issued to the Trust by the MHRA under the provisions of the Medicines for Human Use Regulations

Policy and Planning

To develop Quality Systems to meet the changing needs and demands of the Trust and of external Regulators (eg: MHRA)

To contribute to the planning and design of new and upgraded pharmaceutical manufacturing, preparation and dispensing facilities within the Trust

To ensure that planning, design, building, commissioning of new and upgraded pharmaceutical preparation facilities are carried out in accordance with Good Manufacturing Practice in order to meet regulatory standards eg. New units for Cancer Centre manufacturing facility

To develop, write and present business cases for equipment, staff resources and service developments within Pharmaceutical QA and QC Services

To advise the Chief Pharmacist and Senior Pharmacists in the determination of policy and plans for pharmaceutical technical services

To lead on the risk assessment and documentation of major changes to be made to Pharmacy Technical Services.
Provide quality management advice to the Regional Drug Procurement Centre, and to the Pharmacy Dispensary on resources, policies and procedures required for the provision of an appropriate level of service, conforming to all appropriate legal requirements and professional guidelines to ensure compliance to current GDP regulations to maintain the MHRA WDA license

Work in close relationship with management personnel of Wessex Laboratory Services to ensure that PMU requirements for chemical analysis and environmental monitoring are met

Personnel Management, Training and Development

To manage QA and QC staff, including objective setting, appraisals, and performance monitoring

To be responsible for recruitment of staff to QA and QC Services.

To develop training programmes for QA staff to ensure GMP and GLP compliance of Quality Services

To undertake and manage Trust HR procedures in respect of discipline, grievances and sickness absence

To participate in the training of pharmacists, scientists, pre-registration pharmacy graduates, technicians, and student pharmacy technicians as required in technical services

Resource Management
To assist the budget holder to manage the budgetary allowance allocated to Quality Assurance and Quality Control
To manage all resources within Quality Services in line with trust Standing Financial Instructions

To be responsible for the purchase of new and replacement equipment. To be responsible for the specifications, sourcing, price negotiation, installation, maintenance and repair of such equipment

To be responsible for the suitability and specifications of consumables for Quality Assurance and Quality Control.

Clinical Trials
To undertake and support the development, formulation and validation of new products in response to clinical need and risk management in accordance with objectives set by the Associate Chief Pharmacist (Technical Services).

To act as the EU *Qualified Person* or releasing officer in respect of the Manufacturing Licence MS 13142/01 issued by the MHRA under the provisions of the Medicines for Human Use (Clinical Trials) Regulations 2004

To advise the Trust's R&D Department and Clinical Trial Principal Investigators in respect of all aspects of IMP manufacture, procurement and use and of adherence to associated legislation
To be responsible for QA and QC advice and support necessary for the management of Clinical Trials in the Pharmacy in accordance with the statutory requirements for Good Clinical Practice

Quality Assurance/Quality Control
Ensure that a system is in place in the laboratory ensuring that the requirements of Good Laboratory Practice (GCLP) are met at all times, the quality systems are maintained, equipment is routinely checked and analytical results are recorded correctly and accurately.

To establish, monitor and review QA Standard Operating Procedures

To monitor, review and approve, specifications for starting materials, finished products, packaging materials which have been prepared by the Quality Control Department

To monitor, review and approve manufacturing documents and Standard Operating Procedures which have been prepared by the Production Unit

Ensure that a system is in place such that stability data is established and that relevant files are maintained to support product shelf lives.

To develop and manage Technical Agreements for the provision of services to PHT by external companies

To be nominated as Responsible for Quality Control for products made by the Pharmacy under the terms of the Manufacturing Licence (Specials) ML.13142/01 issued by the MHRA under the Medicines Act

To act as lead Releasing Officer for components, starting materials and finished products used by or prepared with the Trust

To examine components, starting materials and finished products for compliance with specifications and to release or reject each batch as appropriate

To manage and coordinate the response to the remote temperature monitoring system across the Pharmacy department

To generate Certificates of Analysis on request to support the supply of manufactured medicines to external customers of the Trust

Quality System Management
To critically evaluate the Quality Systems across all areas to ensure that best practice is promoted.
To develop and maintain an effective Exception Reporting system within Technical Services. To be responsible for ensuring that Exceptions are fully investigated as to Root Causes and to approve proposed corrective and preventive actions

To develop and manage a Change Control programme for Technical Services, to ensure that equipment and process changes are assessed and implemented in a rigorous manner. To authorise changes and to ensure that they are implemented effectively.

To develop and maintain a document control system as part of the Quality System, in line with GMP and MHRA requirements

To lead on the communication and review of all aspects of the Quality System across the Pharmacy Department

To provide documented evidence/reports to demonstrate that the Quality System is performing to the required standards

Audit
To develop and manage the self-audit programme for the Production Unit according to Regional QA and GMP requirements

To act as Lead Auditor for self-audit programme within the Pharmacy Manufacturing Unit

To provide regulatory audit progress reports to the MHRA, Regional QA and Senior Management as required To represent Quality Assurance at regulatory audits and meet the requirements of the auditor in a clear and concise manner.
To lead on the response to audit deficiencies and ensure these are carried out in a timely manner

Facilities Monitoring
To develop and maintain an efficient facilities monitoring service for the manufacturing areas within the Trust
To establish, authorize and review procedures for the environmental monitoring service

To ensure monitoring takes place in accordance with GMP

To provide training to all staff in the techniques used to monitor the manufacturing environment.

To manage the recording, documentation and review of environmental monitoring results

To manage the exception reporting system for environmental monitoring and implement corrective/preventative actions in a timely manner

To manage the maintenance of results databases, review and provide reports on trended data on a regular basis

To develop and maintain a planned preventive maintenance system for all the manufacturing facilities

To develop and maintain a calibration and validation system for environmental monitoring equipment.

To provide information and advice on any microbiological organisms identified in the manufacturing facilities

To develop.,maintain and review external contracts with companies providing a pharmaceutical microbiological testing service.

Product Safety
To contribute to the patient safety agenda through ensuring the quality assurance of medicines manufactured and prepared by the Trust.

To investigate and report on medicine defects, arising from both commercial and PHT-made products, liaising with the Region and Regulatory Authorities as appropriate

To co-ordinate actions within the Trust on drug recalls

To provide the QA advisory role in the Trust's purchase of medicines

To advise the Trust on the use of unlicensed medicines

To assess the quality of unlicensed medicines supplied from outside the Trust and provide recommendations as to their suitability for use within the Trust

Validation
To provide specialist knowledge and advice to senior technical staff on validation requirements for new equipment, facilities and processes

To manage the commissioning and validation of new pharmaceutical Manufacturing/QC facilities and equipment built within the Trust

To approve Technical Agreements made with external contractors for the (re)validation of equipment, facilities and processes

To review periodic equipment, facility and process (re)validations to ensure compliance with Technical Agreements in place and the appropriateness of results. To manage any Exceptions thrown up by the (re)validations

Pharmacy services and Clinical Governance
To provide to all Pharmacy services across the Trust technical advice on Quality Systems, Quality Assurance, Quality Control, medicinal product formulation, storage and stability, and environmental conditions

To provide to external customers of the Trust technical advice on Quality Assurance, Quality Control, medicinal product formulation, storage and stability in relation to products manufactured and supplied by the Trust
To be responsible for ensuring that all clinical incidents, near misses and concerns in Pharmacy Quality Services are reported, investigated, acted upon and learnt from

To be responsible for ensuring that relevant risk management initiatives are taken to minimise all areas of risk within Pharmacy Quality Services

To maintain in conjunction with the Operations Manager a Production/QC Risk Register categorising significant risks

Regional / National Liaison
To participate in national training initiatives for manufacturing, quality assurance and quality control

To be a member of the Regional and National Quality Control Working Group

To be a member of other national groups that regulate and advise on technical services.

External Contracts
To develop and manage Technical Agreements with external NHS Trusts and other bodies for the provision of products and technical services by the Trust to those bodies

To develop and manage other external contracts as appropriate
To prepare business cases and bids in response to regional consortium tenders.

Other Duties
To undertake audit of Pharmacy Services as requested by the Head of Pharmacy

To undertake emergency duties as necessary

To undertake other reasonable duties as requested by the Head of Pharmacy

To participate in on-call duties as rostered

To at all times practice in accordance with the Code of Ethics of the Royal Pharmaceutical Society of Great Britain, whether registered with the RSPGB or not

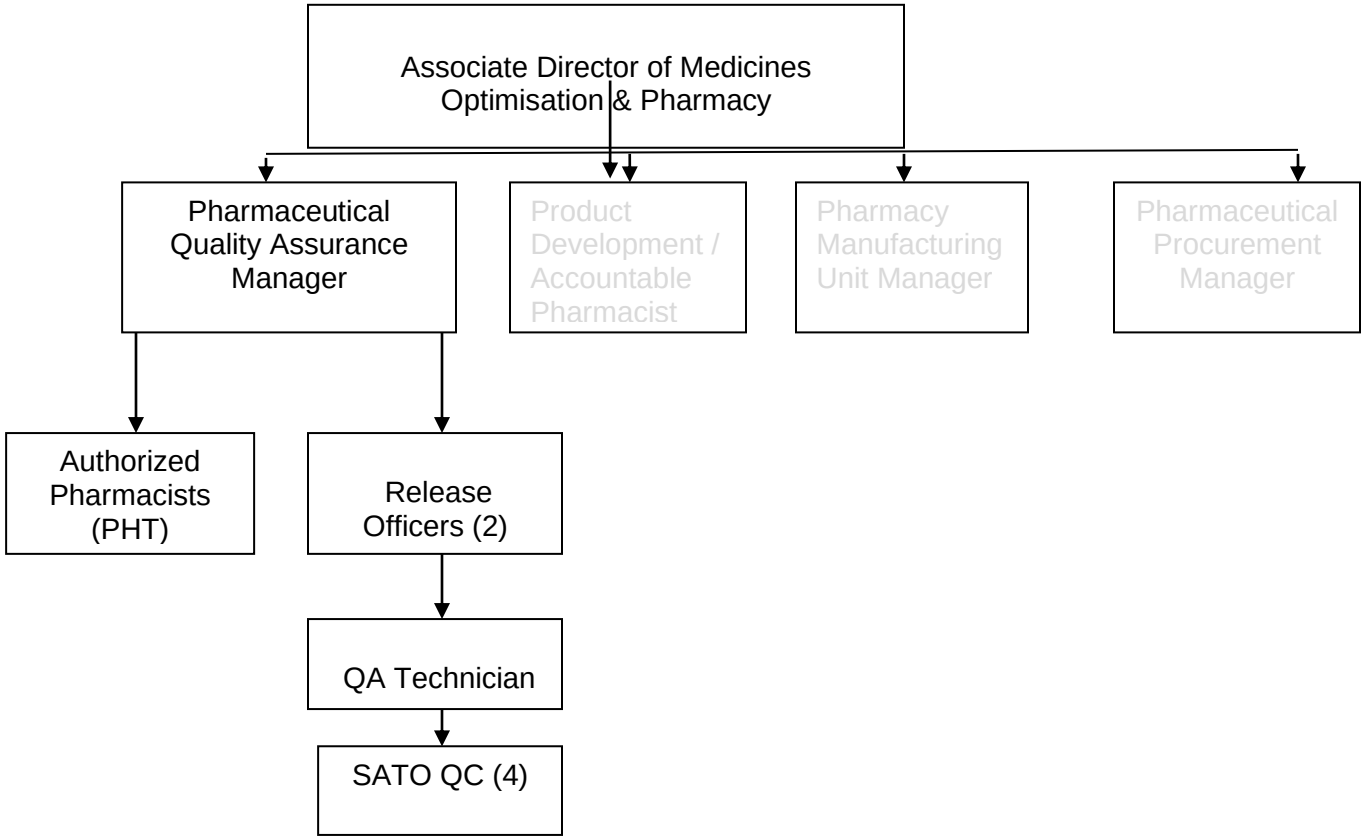
Key Dimensions

a. Capital, Revenue Budgets and Trading Accounts
No direct accountability for budgets but significant influence on risk and potential litigation reduction in association with preparation of products manufactured within the trust under license MS13142 and distributed under WDA (H) 13142.

b. Staff Numbers
QA pharmacist (1wte) Releasing Officer (2 wte),QA Technician (1 wte), Senior QA Assistant (4 wte)
Liaise with Pharmacy Manufacturing, Procurement and Clinical Pharmacy personnel

c. Product Range
TPN (adult, paediatric & neonatal), PCA, CIVA, cytotoxic, biologic, overlabelled and repackaged medicines

ORGANISATIONAL CHART TECHNICAL SERVICES



Trust Organisational Expectations

The post holder will:

1. Proactively and positively contribute to the successful overall performance of the Trust.
2. Deliver excellent levels of customer service to all patients/visitors and staff at the Trust.
3. Develop effective ways of working and create strong partnerships and relationships with all stakeholders to support the implementation of the Government's policies on Health.
4. Develop an organisational culture that fosters collaborative working among all staff groups, to ensure a focused commitment to delivering quality services and outcomes.
5. Act as an advocate for the Trust & its contribution to the Health Service arena through creating effective partnerships and relationships with internal and external stakeholders.
6. Comply with corporate governance structure in keeping with the principles and standards set out by the Trust.
7. Support the Trust culture of collaborative, flexible cross-team working and commitment to delivering quality services and outcomes, which support the Government's policies on public health
8. If your employment is to a post that requires you to be registered with a professional body, the continuation of your employment is conditional upon you continuing to be registered with the appropriate professional body. The Trust will require evidence of current registration.
9. In compliance with the Trust's practices and procedures associated with the control of infection, you are required to:
    - Adhere to Trust Infection Control Policies assuring compliance with all defined infection control standards at all times.
    - Conduct hand hygiene in accordance with Trust policy, challenging those around you that do not.
    - Challenge poor practice that could lead to the transmission of infection.

Proactively, meaningfully and consistently demonstrate the Trust Values in your every day practice, decision making and interactions with patients and colleagues.

Shared Core Functions

1. Proactively and positively contribute to the achievement of deliverables through individual and team effort. Manage the production of the required deliverables and control risks,
2. Support team members to deliver on their functionally relevant objectives through offering advice, guidance and support as appropriate.
3. Ensure that approved budgets are spent effectively and in accordance with agreed procedures
4. Liaison with Senior Professionals and related functions to ensure that work is neither overlooked nor duplicated
5. Build and sustain effective communications with other roles involved in the shared services as required
6. Maintain and continuously improve specialist knowledge in an aspect of Health Service which significantly contributes to the Trust's stated objectives & aims
7. Establish and maintain strategic links with a range of external partners/stakeholders or manage the links made through the team. Engage with external partners/stakeholders to gain their necessary level of contribution & commitment to the successful delivery of your work.
8. Undertake proactive horizon scanning for either developments relating to Trust work or opportunities for Trust involvement around health issues
9. Increase the level of knowledge & skills within the Trust through documenting key learning and supporting others to develop their professional abilities.
10. Dissemination of knowledge through engagement in report writing, and reviewing, taking full responsibility for technical accuracy and reliability and being sensitive to the wider implications of that dissemination.
11. Ensure that expertise is seen as a resource within and outside the Trust and form working partnerships with government departments, national agencies and key stakeholders.
12. Develop structures, systems, ways of working and personal values that will support the Trusts sustainable development objectives with regard to issues such as Carbon reduction and waste minimisation; and to encourage all stakeholders of the Trust to act as enthusiastic agents of change.

Other

Job Holders are required to:

1. Maintain personal and professional development to meet the changing demands of the job, participate in appropriate training activities and encourage and support staff development and training.
2. Always keep requirements in mind and seek out to improve, including achieving customer service performance targets.
3. Adhere to Trust policies and procedures, e.g. Health and Safety at Work, Equal Opportunities, and No Smoking.
4. 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.
5. Respect the confidentiality of all matters that they may learn relating to their employment and other members of staff. All staff are expected to respect conform to the requirements of the Data Protection Act 1998, including the responsibility to ensure that personal data is accurate and kept up to date

Job Description Agreement

Job Holders name:
(print)

Job Holders signature: Date:

Senior Officer/ Chief of Service

Name (print)

Signature: Date:

Title:

PERSON SPECIFICATION

CRITERIA	***How criteria will be assessed:*** ***Application*** ***Interview*** ***Assessment*** ***Reference***
Qualifications Degree in Pharmacy, registered with the general pharmaceutical council. OR Other qualification that supports eligibility to be named as a Qualified Person e.g. PTQA qualifacation or with formal qualification in Chemistry or Biology registered with the Royal society of Chemistry or Biology	*Application form/CV:*
Experience Comprehensive working experience of at least 5 years in a Quality Assurance managerial capacity in a licensed aseptic manufacturing GMP facility. Previous work experience within the NHS is desirable. But experience in a commercial aspetic facility would be acceptable Thorough understanding of GMP, GCP, WDL 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 Knowledge of QA requirements of the NHS	*Application form/CV:*
Skills and Knowledge 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 organisation, time management and meeting skills Good computer literacy for report writing and presentations Able to work in clean room environments and operate precision equipment	*Application form/CV:*
Quality of Care (Trust Value) Demonstrate an understanding of the importance of quality of care Accountable	
Respect and Dignity (Trust Value) Respects the privacy and dignity of individuals Demonstrate an understanding of equal opportunities	
Working together (Trust Value) Ability to work efficiently, effectively and professionally in a multidisciplinary team Demonstrate that you value everyone's contribution	
Efficiency (Trust Value) Understanding and experience of improving efficiency and reducing waste Demonstrate that you will be open to improving everything you do	

Values based behaviours for leaders

In discussion with its leaders The Trust has developed a Leadership Framework, based on its Values. As a result the following expected standards for leadership have been identified, which all leaders will be required to demonstrate.

Strategic approach (clarity on objectives, clear on expectations)

- Plans and takes initiative in the best interest of the patient
- Makes decisions based on organisation strategic direction
- Makes success criteria clear to others and focuses them on what matters most
- Avoids major problems through anticipation and contingency planning

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

- Consistently seeks to understand and meet the needs and interests of patients
- Asks open questions and listens to other ideas to develop joint solutions
- Involves key stakeholder and staff in planning organisational change

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

- Articulates a compelling vision of how things could be and might be
- Consistently delivers on promises
- Consistently acts in accordance with, and champions PHTs values
- Displays sensitivity to the needs and feelings of others
- Has a zero tolerance to, and challenges bad behaviour
- Actively manages poor performance

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

- Motivates others through infectious enthusiasm and 'can do' attitude
- Maintains optimism and sense of humour in stressful situations
- Emphasises the positive side of difficulties, portraying them as opportunities
- Finds ways around seemingly insurmountable obstacles, not easily defeated
- Infuse pride and joy in work
- Lead by example by taking responsibility, being compassionate and aspiring 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)

- Takes proactive steps to develop team members using a variety of approaches
- Involves team members in planning and delivering change
- Stimulates and communicates cross disciplinary communication
- Recognises and rewards effort, not just achievement
- Matches the needs of activity to available resources
- Seeks out and listens to team members and stakeholders, welcoming warnings or problems