

Job Description

Title: Production and Operations Manager

Band: 8B

Staff Group: Additional Scientific and Technical

Reports to: Chief Pharmacist

Job Purpose:

Accountable for all operations within the Pharmacy Manufacturing Unit (PMU), ensuring that safe, effective and efficient operational staff and systems are in place for the purchase, storage, manufacture and shipping of pharmaceutical products; in accordance with the regulatory requirements of the MHRA.

To lead, deliver, develop and evaluate PMU services (i.e. cytotoxic service, aseptic services and non-sterile services) to the Trust and beyond in accordance with objectives set by the Trust.

To be responsible for the strategic development of the PMU to the trust in line with agreed priorities

Anticipating, planning for and responding to changing demands for aseptically-manufactured products to ensure continuity of service to patients.

Key Responsibilities

1. Budgets –

- responsible for a pay budget of £1.4 million
- responsible for a non-pay budget of £700,000
- responsible for a drugs procurement budget of £12 Million

2. Staff – 50

To assume overall responsibility for approximately 50 staff (45 WTE) – comprising of pharmacy technicians, assistants, stores staff, office-based administrative staff – and to maintain a close working relationship with the PMU lead for Quality Assurance.

3. To demonstrate a Pharmacy Department, PHU Trust and whole healthcare system-focused approach.
4. To provide strong leadership and management for the operations staff at PMU, ensuring that responsibilities and decision-making are delegated appropriately.
5. To ensure, on behalf of the licence holder, that Good Manufacturing Practice (GMP) standards expected by the Medicines and Healthcare Regulatory Agency (MHRA) are upheld.

Operational Delivery

- Lead PMU services for patients in accordance with Trust priorities whilst maintaining service levels to non-trust customers, ensuring compliance with current directives, legislation, and external audits to provide an effective and cost-efficient service. This service includes the provision of chemotherapy, TPN supply, aseptically manufactured products
- Responsible for monitoring and critically evaluating the technical services systems to ensure best practice is in operation and to maintain a continuous improvement cycle.
- To take responsibility for the prioritization of tasks, performance analysis and action plans for the manufacture of pharmaceutical products, ensuring all products are delivered in line with customer deadlines or service level agreements, on time and in full.
- Assume overall responsibility for health and safety of unit and staff
- Maintaining a compliant Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) process that ensures all products supplied to hospital services in NHS Trusts both locally and nationally are made in adherence to the required standards and safe for clinical use.
- Assume overall responsibility for the site building and equipment, ensuring it is fit-for-purpose and in accordance with the latest MHRA requirements. Ensure maintenance and servicing contracts are adhered to.
- Assume overall responsibility for technical agreements and contracts of services for PMU, incorporating requirements of customers, liaising with procurement, customers and suppliers to facilitate up-to-date technical agreements with new and old suppliers.
- To liaise continuously with operational managers and clinicians regarding unit capacity and demand to ensure that operational teams provide additional resources where required.
- To efficiently manage on-site resources, scheduling, ordering of raw materials/supplies and participate in feature/functionality trade-off decisions that ensures PMU's ability to maintain output.
- To provide trouble-shooting of deployed processes.
- Ensure all areas have an active capacity plan indicating safe levels of operation and that they operate within this.

Management and Leadership

- To assume overall responsibility for approximately 50 staff comprising of pharmacy technicians, assistants, stores staff, office-based administrative staff and to maintain a close working relationship with the PMU lead for Quality Assurance.
- To demonstrate a Pharmacy Department, PHU Trust and whole healthcare system-focused approach.
- To provide strong leadership and management for the operations staff at PMU, ensuring that responsibilities and decision-making are delegated appropriately.
- To line-manage direct reports to include performance management, appraisals, objective setting and personal development plans.
- To develop and implement systems to monitor performance of line managers and teams to ensure that all staff and teams are managed effectively, remain motivated and perform their roles and responsibilities to a high standard.

- To be responsible for staff deployment, performance review, sickness absences management, recruitment and selection processes and staff development and training.
- To undertake and manage formal Trust HR policies including disciplinary, sickness and grievance policies.
- To support HR processes in other sections by undertaking formal investigations (such as HR or root cause analysis) or providing informal advice based on personal knowledge and experiences.
- To keep Pharmacy Department and Division management well-informed on a timely basis of progress, status, and concerns for the unit.
- To provide ongoing pastoral support, coaching and mentoring for staff.
- To provide internal consultative leadership and support.
- To appropriately manage difficult and ambiguous problems.
- To demonstrate an advanced level of reasoning and judgement.

Management of Resources

- To manage the staff assigned to PMU and monitor their performance using Trust policies and procedures with local guidelines for performance reviews and that staff motivation and directions are given through appraisal, general communication and specific feedback.
- To manage non-pay budgets, including achieving income targets and controlling expenditure within budget.
- To ensure that orders are raised and invoices are processed for payment within a timely manner in line with Portsmouth Hospitals University NHS Trust's Standing Financial Instructions.
- To ensure ongoing review of processes within production to ensure optimal patient care and value for money.
- To ensure efficient phasing of production to align with acute clinical demand and minimise waste of pharmaceuticals and optimise deployment of staff.
- To work collaboratively with the Pharmacy Department and the Trust to achieve medicines savings and cost improvement opportunities.
- To be aware of national directives and changes to regulatory guidance and lead on local interpretation and implementation in collaboration with the lead for Quality Assurance.
- To have shared responsibility – with the lead for Quality Assurance – for the costing and approval of any new products / customers and the ongoing approval of product prices and customer lines.

Quality, Risk, Governance & Performance Management

- To undertake the role of person responsible for production on the MHRA licence on behalf of PMU
- To act as Home Office controlled drugs licensee on behalf of PMU
- To have shared responsibility – with the lead for Quality Assurance – for PMU Quality Management Systems ensuring updating of SOPs and prompt response to deviations.
- To adhere to all national, regulatory, financial and Trust standards, reporting any exceptions to appropriate stakeholders.
- To prepare documentation on all phases of pharmaceutical aseptic manufacturing processes and modification of existing systems and processes. Specifically, documentation should include policies, procedures, work instructions, and process flow maps that are used to manufacture and distribute pharmaceutical products.
- To assist in the documentation of minimum requirements, designs and specifications for equipment, premises and processes.

- To author complex cross-functional process workflows including the review and approval of risk assessments.
- Develop and implement strategies for risk management within PMU ensuring compliance with current directives, legislation & external audits
- To establish and maintain metrics to monitor and evaluate the performance of specific processes, leading to continuous improvement opportunities.
- To develop a process of self-inspection and internal audit and authorise proposed remedial or improvement actions following audits.
- To be responsible for achieving agreed PMU performance targets in support of Trust performance targets including referral-to-treat targets for oncology.
- To ensure that, where relevant, all staff meet GMP and GCP standards.
- To have shared responsibility with the maintenance of the Validation Master Plan across the Pharmacy Manufacturing Unit to ensure its continuing development and validity.

Strategic Service Development

- To participate as a member of the Pharmacy Board at Portsmouth Hospitals University NHS Trust.
- To develop and improve the aseptic manufacturing service strategy in collaboration with the lead for Quality Assurance and in line with the Pharmacy Department, Division and Trust strategy.
- To support the ongoing development and efficient provision of aseptic services within the Integrated Care System.
- To liaise with the regional procurement team to safeguard supplies of aseptic products, anticipating and responding to shortages of raw material products.
- To contribute to business plans by developing business cases to support requests for financial or other resources associated with strategic development work, including: cost-benefit analyses and financial and operational risk analyses.
- To conduct and/or contribute to relevant clinical and other audits to facilitate clinical governance requirements. To reflect on and interpret the results of audits, address remedial points and implement change as required.
- To be responsible for the formal management of contracts with external customers.

Education, Training and Professional Development

- Run relevant departmental meetings that will enable staff to be brought up to date on current issues and to address staff development needs within the PMU
- To be responsible for the recruitment, training, mentoring and directing of staff, validating the work of the aseptic unit in respect of the new business process deployment
- Responsible for the provision of competency based training to all staff working within the PMU, including authorisation of training documents, that training documents are according to GMP and validation or processes and systems.
- To approve for use all training and on-the-job skills accreditations, including induction training.
- To ensure that all staff in operational areas are fully compliant with statutory and mandatory training.
- To support the development and technical training of all technical staff and assistants working within PMU as well as the releasing officers, rotational pharmacists and pre-registration pharmacists as required.
- To participate in departmental CPD educational sessions.

- To maintain an active portfolio of CPD. Undertake and maintain personal CPD to ensure that knowledge is continually updated in the field of pharmacy manufacturing and technical skills are kept current.

Information Management

- To effectively communicate ideas and information with peers, management, and customers.
- To be responsible for effective knowledge transfer to key stakeholders.
- To support the Pharmacy Department and the Division through the provision of appropriate data, analyses, audits and reviews, suitable to inform decision-making and allow evidence-based service planning and provision.
- To maintain patient confidentiality and information governance at all times.

Other duties

- To take part in Saturday, Sunday, Bank Holiday and out-of-hours on-call rotas as necessary.
- To undertake any other duties commensurate with this banding, as required by the Trust.

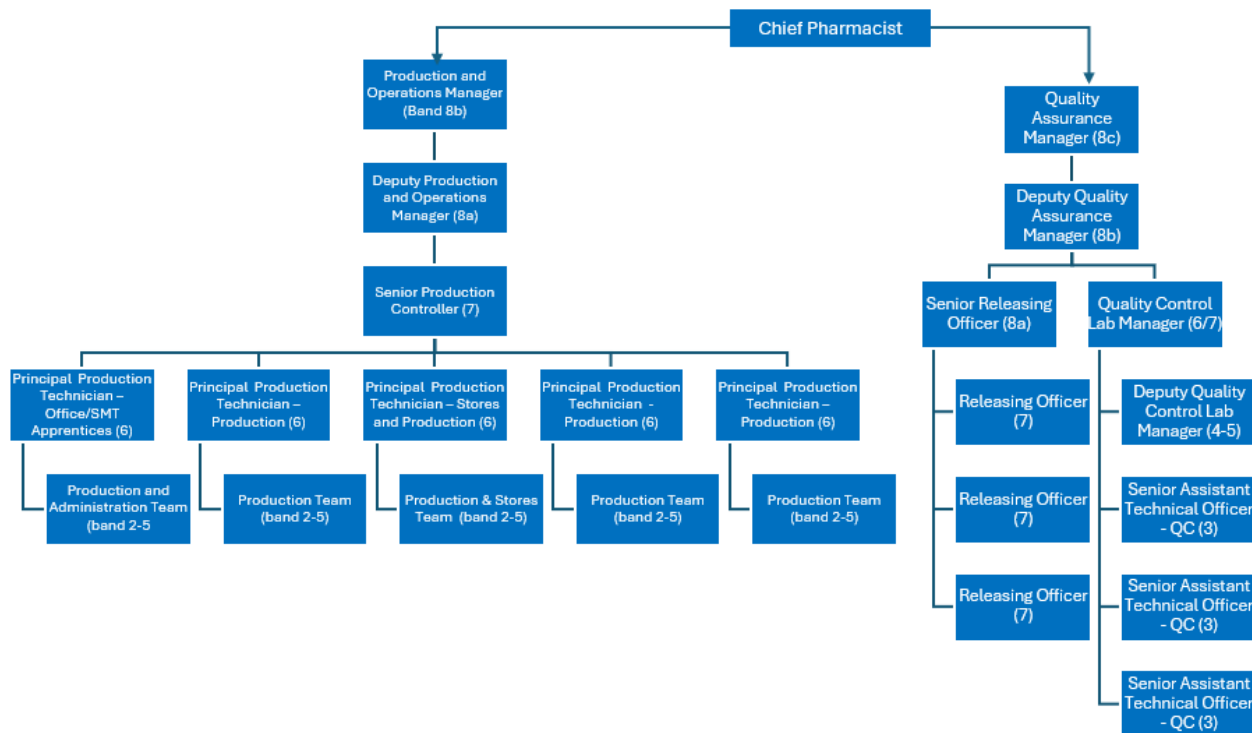
Key relationships

- To build and sustain strong relationships with the PMU QC manager and responsible officers, to ensure the smooth running of quality management systems, providing persuasive communication and working as an advocate for their function.
- To support close working with the wider pharmacy team and multi-disciplinary team to optimise scheduling of chemotherapy and clinical trials products and ensure a seamless service is provided to cancer and trials patients.
- To maintain and further develop, where appropriate, links with relevant professional bodies and organisations e.g. General Pharmaceutical Council, MHRA, Dept. of Health.
- To develop close working relationships with Works and Estates and outside contractors for maintenance of the unit.

Effort

- The work involves prolonged periods of concentration, analyzing data, attending meetings and communicating with large groups of staff.
- The working conditions involve exposure to pressure when responding to fluctuating and unpredictable demands and requirements, including numerous simultaneous and conflicting deadlines and priorities.

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

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
6. Proactively and positively contribute to the successful overall performance of the Trust.
7. Deliver excellent levels of customer service to all patients/visitors and staff at the Trust.
8. 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.

9. Develop an organisational culture that fosters collaborative working among all staff groups, to ensure a focused commitment to delivering quality services and outcomes.
10. 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.
11. Comply with corporate governance structure in keeping with the principles and standards set out by the Trust.
12. 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
13. 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.
14. 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.



Working together
for Patients



Working together
with Compassion



Working together
as One Team



Working together
Always Improving



Management Essentials

We are proud to offer a comprehensive development programme, Management Essentials, designed to equip staff with the skills and knowledge to become effective managers.

This post has been identified as a role that will benefit from this training, and you will be able to enrol in both mandatory and, relevant, optional modules upon commencement with the Trust.

Please click [here](#) for further information on the Management Essentials programme.



Leadership Insights

Additionally, our new leadership development programme, Leadership Insights, aims to help all newly promoted, existing and aspiring leaders, at every level at the Trust, to recognise, reflect and role model the core principles of people-centred leadership.

If, this is of interest to you, you will be able to enrol upon commencement with the Trust.

Please click [here](#) for further information on the Leadership Insights programme.

Person Specification

Qualifications

Essential

- Pharmacist or pharmacy technician registered with the General Pharmaceutical Council, or Science Manufacturing Unit registered with the relevant Professional body
- Up-to-date training in Good Manufacturing Practice, Good Distribution Practice and Good Clinical Practice
- Specialist professional training in aseptic manufacturing (e.g. Diploma or MSc in Pharmaceutical Technology & Quality Assurance) or equivalent experience (minimum 10 years working in aseptic manufacturing)
- Specialist operational management training or equivalent experience

Experience

Essential

- Registered with the General Pharmaceutical Council as a pharmacist or pharmacy technician
- Significant experience of MHRA inspection process for licensed aseptic production unit
- Operational Management pharmacy experience within a large aseptic production unit
- Significant experience of successful working as part of a multi-disciplinary team
- Successful performance as a directorate/team leader at senior level in a previous post
- Successful planning and implementing significant service developments and organisational change
- Experience of successfully managing large groups of staff
- Proven ability to work independently at an advanced level
- Proven ability to deliver innovations within service delivery
- Demonstrated evidence of being able to manage change and improve service quality within Production services

Skills & Knowledge

Essential

- Work across organizational boundaries to document and develop functional and technical specifications and support for the design, development, validation, and maintenance of new processes
- Intimate knowledge of existing processes in pharmacy manufacturing, regulatory compliance with MHRA standards, good documentation and validation practices.
- Strong business analysis skills required
- Excellent knowledge of the relevant business processes
- Ability to work with both technical and non-technical personnel at various levels of the organization
- Excellent analytical and problem-solving skills
- Ability to adapt to a fast and dynamic environment
- Ability to effectively translate between functional and technical teams
- Ability to follow procedures and produce/maintain supporting documentation
- Resolves simple to complex system problems in creative ways
- Excellent written, oral and interpersonal communication skills
- Excellent time management
- Highly self-motivated, self-directed and attentive to detail
- Ability to effectively prioritize and execute tasks in a high-pressure environment
- Extensive experience working in a team-oriented, collaborative environment
- Ability to produce exceptionally high quality outputs
- Ability to communicate effectively with senior management

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: