NHS TAYSIDE

JOB DESCRIPTION

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| 1. JOB IDENTIFICATION
 | Job Title | **Deputy Production Manager**  |
| Department(s)/Location | **NHS Scotland Pharmaceutical ‘Specials’ Service, Ninewells Hospital** |
| Number of job holders | **1** |

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| JOB PURPOSE* To be responsible for the operational management of the production sections of NHS Scotland Pharmaceutical ‘Specials’ Service (PSS).
* To provide advice to staff and customers on aspects of formulation to meet the clinical needs of patient
* To deputise for the Production Manager and to advise on production / formulation issues
* To assist in setting PSS’s annual Trading Account budget and in the overall management of PSS’s Trading Account, ensuring that product prices are set so as to recover all manufacturing and overhead costs.
* To assist in the sourcing of starting materials used in the manufacturing process.
* To assist in ensuring that the principles of Good Pharmaceutical Manufacturing Practice (GMP) and other relevant legislation are followed in accordance with the requirements of the Medicines and Healthcare products Regulatory Agency (MHRA), BSI, and the Home Office licence for Controlled Drugs
* To contribute to national working groups on aspects of GMP
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| ORGANISATIONAL POSITIONSee Appendix 1 – Organisation Chart |

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| SCOPE AND RANGEPSS produces a range of 700 sterile and non-sterile medicines, selling over 1.6 million units annually with a value of over £10 million. These medicines are not commercially available and are supplied to hospital and community pharmacies throughout the UK and to the Scottish Ambulance Service and include the supply of clinical trial materials. In order to undertake this manufacture, PSS is a licensed pharmaceutical manufacturing facility and is subject to external inspection from the Medicines and Healthcare products Regulatory Agency (MHRA) and is accredited to BS EN ISO 9001:2015. In addition, PSS is a registered pharmacy with the General Pharmaceutical Council to allow it to dispense bowel cleaning medication as part of the Scottish Government sponsored ScotCap project.The postholder has the following range of duties:* Manages a team in excess of 30 peoples of Pharmacists, Chief Pharmacy Technician, Pharmacy Technicians, Pharmacy Support Workers
* Ensures that the principles of GMP, GCP, GDP, and other relevant legislation are followed in accordance with the requirements of MHRA, BSI, and the Home Office Licence for Controlled Drugs.
* Deputises for the Production Manager in their absence.
* Assists in the setting of the Trading Account budget and plays a supportive role in managing the Trading Account budget of £10 million per annum.
* Assists with TP’s medicine purchasing policy to the value of £7million per annum.
* Acts as an authorised signatory for purchase orders, travel and SSTS.
* Contributes towards national policy via the National Pharmaceutical Production Committee and other working parties.

NHS Scotland commissioned a new pharmaceutical manufacturing facility which has been built on the Ninewells site and resulted in the activities currently undertaken by TP and PPU being provided from this new build, single site facility. The postholder will support the Production Manager in leading on production-related activities involved in the establishment of this national facility. |

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| MAIN DUTIES/RESPONSIBILITIES**Policy and Planning*** To assist in the development of annual objectives for PSS.
* To assist the Production Manager and other senior managers in the determination of policy and strategic plans for PSS.
* To assist in the development of annual objectives for PSS.
* To assist in the commissioning and validation of new manufacturing equipment and provide adequate staff training to ensure safe operation.

**Operational Management*** To be responsible for the operational management of the production sections within PSS.
* To undertake and manage NHST HR policies such as Grievance, Promoting Attendance at Work and Employee Conduct when required.
* To be responsible for the recruitment and selection of staff within the production sections and to ensure NHST policies on Recruitment and Attendance at Work are adhered to.

**Quality and Evaluation*** To assist in leading the Production services in accordance with national and local legislation and guidance in order to provide a safe, effective and cost efficient service.
* To assist the Production Manager in ensuring that the production facilities and practices meet the standards of GMP required by the MHRA and that the Manufacturers ’Specials’ and Investigational Medicinal Products licences are maintained.
* To ensure that the requirements to maintain the Home Office Controlled Drug licences are met
* To deputise for the Production Manager in their role as Superintendent Pharmacist to ensure the General Pharmaceutical Council standards for a Registered Pharmacy are continually met.
* To critically evaluate quality and production systems to ensure best practice is promoted within all aspects of production services and participate in internal and external audits.
* To ensure that all relevant legislation e.g. Health and Safety at Work, COSHH, risk assessments etc. is applied within the production sections.
* To develop and maintain all control documentation such as worksheets and standard operating procedures in liaison with Quality Control.
* To develop a system that ensures documentation is reviewed on a regular basis and kept up to date.
* To ensure with QA that the resolution of quality exceptions is undertaken and completed in a timely manner and is documented and trended appropriately.
* To review equipment and facilities validation and revalidation data to ensure that equipment and facilities function and continue to function as designed.
* To contribute to the preparation and review of the validation master plan and Site Master File.

**Product Development*** To undertake and contribute to the formulation and development of unlicensed medicines and clinical trials materials to meet customer requirements.
* To cost new products and provide quotations promptly to customers.
* To take part in the process design and validation of new and existing products.
* To advise clinical and pharmacy staff on pharmaceutical and regulatory aspects of clinical trials and to design, cost and quote for clinical trials supplies.
* To assist in ensuring that clinical trials are managed according to the requirements of GMP and GCP.

Staff Supervision and Training* To manage Production staff and to monitor their performance in accordance with the NHST Employee Appraisal System.
* To identify the training needs of production staff in order to undertake the roles required.
* To identify the training needs for staff within PSS.
* To participate in the training of all grades of staff.
* To ensure with QA that GMP competency based training for all staff is developed and maintained and that individual training records are complete and up to date.
* Supports where required production in the absence of the Specialist Pharmacists.

**Resource Management*** To assist in identifying the production manpower requirements for PSS.
* To assist the Production Manager in forecasting sales and expenditure in order to set the PSS trading account budget and to ensure that income from product sales and services covers all costs. To ensure that new and existing products are priced accordingly.
* To ensure that equipment and plant is adequately maintained and its performance verified.
* To maintain and update the equipment database.
* Participate in the sourcing of starting materials.
* To advise the Production Manager on resource needs for production services.
* To prepare and maintain a capacity plan for the production unit and ensure that resources and demand are managed accordingly.
* Assist with the managing and maintaining of the Syspro Stock Control/ Manufacturing Requirements Planning (MRP)/Pricing system, responsible for MRP & pricing sections, pricing of products and budgetary control. To assist with staff training in the use of Syspro.
* Using the stock control system to monitor stock movements in order to plan production and material purchases. To monitor and adjust the stock control parameters to reflect changing usage of products and raw materials.
* Assist in the management and maintenance of the product labelling system, responsible for policy, design & layout of labels, ensuring that labels meet legal and ethical requirements.
* To assist in developing Business Plans for PSS to generate new sales and services and maintain the existing client base.
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| COMMUNICATIONS AND RELATIONSHIPSThe postholder will communicate with a wide range of people, both within and outwith the organisation including:**Internal*** PSS staff
* Pharmacy
* Estates
* Finance
* Senior professional staff from other NHST departments, IT department, clinicians, nursing staff
* Human Resources

 **External*** Customers including hospital pharmacies, community pharmacies, Scottish Ambulance Service and affiliated services, and staff and patients associated with the ScotCap project
* Medical, nursing and pharmacy staff on pharmaceutical and regulatory aspects of clinical trials
* National Procurement
* Department of Health & Social Care Commercial Medicines Unit
* National Pharmaceutical Production Committee
* Specialist Interest Groups within pharmacy, Royal Colleges, and multi-disciplinary working parties including lay people
* Pharmaceutical wholesalers and the pharmaceutical industry for raw material issues
* Contractors and suppliers of equipment
* MHRA, BSI and other external auditors
* General Pharmaceutical Council inspectors
* Home Office inspectors
* Facilities Management staff within PSS

In order to communicate effectively with the above groups, the following are essential:* highly developed interpersonal and communication skills, written and verbal, formal and informal, and presentation skills
* ability to convey highly complex information in a form readily understood by a variety of target audiences
* ability to motivate staff and influence change
* ability to use diplomacy, tact and empathy when dealing with difficult situations and opposition
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| KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOBQualifications – Essential * Master of Pharmacy degree (MPharm)
* Competency assessed and examined professional registration (GPhC)
* Mandatory CPD to maintain fitness to practice

Qualifications - Desirable * Specialist higher degree (Masters) in technical services such as national course in Pharmaceutical Technology & Quality Assurance or equivalent experience
* Management qualification

Experience - Essential* Extensive post qualification pharmacy practice experience
* Considerable post qualification work in an operational management capacity within a pharmaceutical manufacturing/aseptic unit
* Design, running and audit of clinical trials
* Staff management

Experience - Desirable* Successful budget management
* Experience of the use of Stock Control/Manufacturing Requirements Planning (MRP)/Pricing systems
* Experience of operating under a BS EN ISO 9000 quality system
* The post holder should have a demonstrated ability to:
* deliver and validate staff training
* identify and manage risks
* manage change
* manage the safe handling of hazardous materials

Knowledge * Demonstrated knowledge of all aspects of GMP, GCP, GDP, and QA and a proven ability to apply this knowledge to maintain, develop and validate a production quality system
* Demonstrated knowledge of the General Pharmaceutical Society standards for a Registered Pharmacy
* Demonstrated expert technical knowledge across a variety of non-sterile and sterile manufacturing and aseptic services
* The post holder must have knowledge of and demonstrate ability to:
* determine the clinical appropriateness of products
* solve difficult and ambiguous problems by advanced reasoning and sound technical judgment
* promote and evaluate best practice within production services
* improve service quality at operational management level
* formulate medicines to meet the clinical needs of patients
* manage out of specification results and incidents and develop and review action plans to resolve these
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| 1. SYSTEMS AND EQUIPMENT
* The postholder has operational responsibility for the systems, facilities and equipment within Sterile and Non-Sterile Production departments.
* Requires knowledge to commission, validate and troubleshoot a wide range of sophisticated pharmaceutical production equipment including purified water systems, steam sterilisers, laminar flow cabinets, bottle washers, ampoule, bag and bottle filling and sealing machines and tablet packing machines.
* Requires knowledge of the design of pharmaceutical production facilities including air handling plant, filtration systems and laminar flow cabinets and their monitoring and testing.
* Basic keyboarding skills, knowledge of standard office software including word processing, spreadsheets and databases. Produces correspondence, reports and standard operating procedures (SOP’s), collects manipulates and presents data on production inputs & outputs, efficiency and costs in order to set product prices and departmental budget.
* Requires knowledge of Q-Pulse CAPA software (or equivalent).
* Use of the internet and e-library to source specialised pharmaceutical and medical information and supplies.
* Requires knowledge of Syspro Stock Control/Manufacturing Requirements Planning (MRP)/Pricing system. Responsible for MRP & pricing sections, pricing of products and budgetary control, Designs and writes reports within Syspro to inform internal and external customers.
* Requires knowledge of product labelling system, responsible for policy, design & layout of labels and ensuring that labels meet legal and ethical requirements.

**Responsibility For Records Management**All records created in the course of the business of NHS Tayside are corporate records and are public records under the terms of the Public Records (Scotland) Act 2011. This includes email messages and other electronic records. It is your responsibility to ensure that you keep appropriate records of your work in NHS Tayside and manage those records in keeping with the NHS Tayside Records Management Policy and with any guidance produced by NHS Tayside specific to your employment. |

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| PHYSICAL DEMANDS OF THE JOB* Mainly seated, long periods of VDU use, walking between locations, occasional need to stand for long periods, occasional need to lift boxes/crates/equipment and move loaded trolleys/pallets, occasional need to work in a clean room environment.
* Daily exposure to unpleasant odours from e.g. coal tar and alcohols, occasional exposure to hazardous chemicals and drugs in and out of containers.

**Mental Effort:*** Intense concentration is required daily for periods of up to 4 hours at a time while analysing data, producing and checking reports and SOP’s, calculating pharmaceutical formulae and pricing products. A high level of accuracy is essential for these activities.
* When representing PSS at NHST or national meetings.
* Subject to frequent interruptions from staff, phone, intercom etc and from urgent and non-urgent requests for advice.
* Operates under the scrutiny of the regulatory authorities.
* Works to tight timescales.
* Operates with limited resources.

**Emotional Effort:*** Empathy and composure required when conducting investigatory and disciplinary hearings and dealing with staff and customer complaints.
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| DECISIONS AND JUDGEMENTS* Expected to act decisively and autonomously in a professional and managerial capacity being accountable for their actions without the need to refer to the Production Manager.
* Required to manage, analyse and act when faced with difficult and ambiguous problems with minimal reference to line manager.
* Required to interpret legislation and national and local protocols for use in production areas.
* Required to be accountable for own professional actions and outcomes.
* Required to assist in making decisions to ensure the Trading Account remains within budget.
* Required to anticipate problems and needs and to be able to independently resolve these.
* Required to manage own time and workload within customer, regulatory body or local management deadlines.
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| MOST CHALLENGING/DIFFICULT PARTS OF THE JOB* Planning the production-related issues for PSS.
* In conjunction with QA ensure that PSS continues to meet the requirements of Good Pharmaceutical Manufacturing Practice and maintains the Manufacturers ‘Specials’ and Investigational Medicinal Products Licences.
* Assist the Production Manager in ensuring along with the Head of NHSS PSS that the Trading Account remains in credit.
* Prioritising allocation of limited resources (staff and financial) against often conflicting requirements of customers, management and regulatory authorities.
* Management and motivation of staff whilst maintaining a team approach within all Production Sections.
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 NHS SCOTLAND PHARMACEUTICAL ‘SPECIALS’ SERVICE – ORGANISATION CHART

 **Appendix 1**

