Brighton and Sussex University Hospitals NHS Trust

JOB DESCRIPTION

JOB DETAILS

Job Title: RADIOPHARMACY PRODUCT MANAGER

Grade: Band 8a

Hours: 37.5 (including early shifts starting at 6.15am)

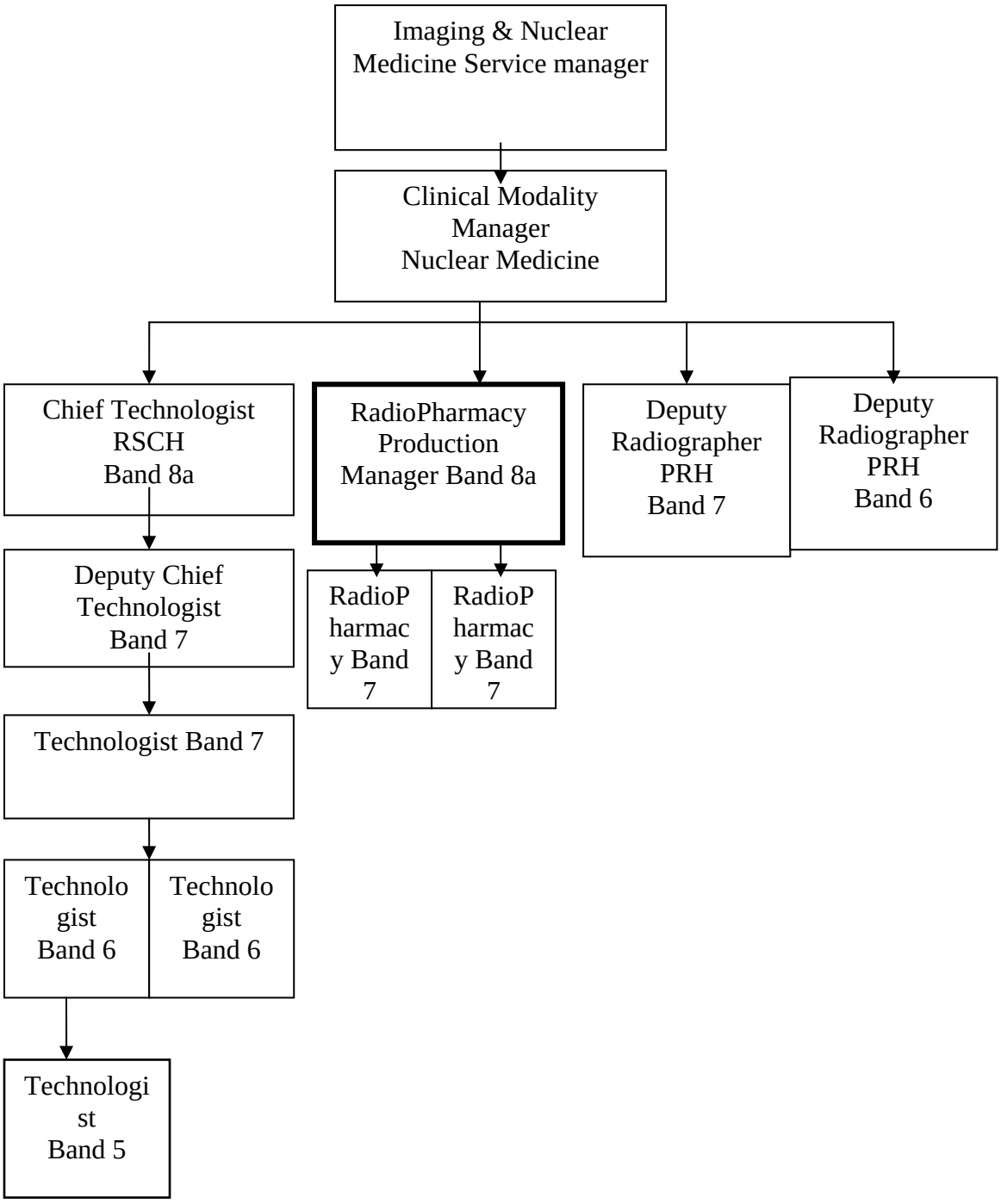
Department / Ward: Nuclear Medicine

Base: RSCH

Directorate: Specialist Division

ORGANISATIONAL ARRANGEMENTS

(You may wish to add a simple organisation chart)



Accountable to: **1. (Managerially)** Clinical Modality Manager in Nuclear Medicine
2. (Professionally) Lead Consultant in Nuclear Medicine
3. (Pharmacy) Quality Control Manager – for local supervision of all aspects of quality control.

Responsible for: **1**. Lead specialist in RadioPharmacy

2. Lead specialist in cell labelling

3. Supervises Nuclear Medicine staff when working in RadioPharmacy, Unauthorised personnel (estates, other external staff)

ROLE SUMMARY

The post holder will be the lead person in RadioPharmacy, with overall and ultimate responsibility for operational policies.
To manage a team of staff to enable maintenance and development of all aspects of the RadioPharmacy service (including blood labelling) to ensure compliance with the Medicines Act 1968 and standard provisions for Manufacturer's Licence (Specials) and all other relevant provisions/guides/EC directives, where they apply to licensed activity.

The post holder must be assessed/accepted by the Medicines & Healthcare product Regulatory Agency (MHRA) to act as Product Manager for this licensed facility. (NB. the name of this post holder should appear on the Licence documents. (See Orange guide)

DUTIES AND RESPONSIBILITIES

1. To manage the RadioPharmacy and blood labelling service within Nuclear Medicine to maintain and develop the service, ensuring that radiopharmaceutical products are produced/ inspected/ released/ packaged/ stored and procured of appropriate quality, as required, to achieve the required quality in accordance with Good Manufacturing Practice (GMP), MHRA 'Specials Licence' requirements, DOH Aseptic Dispensing for NHS patients, Radiation Safety Regulations, COSHH (Control of Substances Hazardous to Health) and Trust's Manual Handling Policy. To act as 'Production Manager' working to well defined procedures for release of products as per requirements of MHRA Specials Licence.

2. To prioritise workload, organise, co-ordinate and delegate activities, ensuring appropriate resource allocation, problem solving and initiating the introduction and maintenance of quality systems and processes in the work area. To identify appropriate data bases, for the collection, collation and modification of relevant data to assist service delivery. To work with others to identify and produce plans for the managing and delivery of RadioPharmacy services. Negotiates and agrees with others supporting mechanisms to enable plans to be implemented and projects are managed and delivered effectively. To monitor the delivery, management and assess capacity/future needs, identify trends, evaluate performance against plans for the service.

3. To regularly monitor work areas, staff and practices, and ensure that the relevant risk assessments are undertaken, to identify and resolve any issues of concern, making any necessary recommendations to management. To carry out staff appraisals, inline with trust guidelines for RadioPharmacy staff.

4. To communicate effectively with the Quality Control Manager (EDGH) in relation to the RadioPharmacy QC, to maintain a quality control monitoring program for all radiopharmaceuticals that are produced, with respect to sterility and radiochemical purity. To obtain, collate and evaluate the relevant information on health and wellbeing needs in relation to blood components and products. To evaluate product options and determine those best meet assessed needs. To provide information, advice and support, methods of delivery, benefits and risks. To confirm the validity, accuracy, safety and appropriateness of product request, and to monitor the quantity and quality of supplied products to confirm they meet specified requirements. To obtain feedback on product's effectiveness and take appropriate action in response.

5. To participate/supervise/organise the preparation and supply of radiopharmaceuticals and blood products, complying with Trust policies. To be competent in selecting and using the appropriate techniques, processes and equipment safely and efficiently, to identify, handle and ensure the quality and integrity of products at all stages in the process. To identify any quality

issues in the production process and instigate immediate remedial action. I.e. stopping the use of a product.

6. To communicate effectively with remote sites/customers /manufacturers regarding their orders/supplies/technical queries and service provision issues, using negotiation, persuasion, tact and diplomacy to manage barriers to effective communication and to inform understanding.

7. To provide a comprehensive training and monitoring program for all Nuclear Medicine staff working in RadioPharmacy and Blood Suite to ensure that the standards of quality and accuracy are achieved and to which are adhered and to contribute to developing the work place as a learning environment. To organise/supervise training sessions suitable for: Clinical Scientists, Radiographers, and Technicians on the Nuclear Medicine Diploma course. To actively participate in group teaching sessions, using a variety of teaching methods, evaluating their effectiveness and modifying teaching to meet individual needs. To contribute to/write and present papers/posters at scientific meetings and locally.

8. To be responsible for the management and supervision of staff within the RadioPharmacy and blood suite, providing support, advice and guidance in their professional development. To recruit, select and appraise team members to meet organisation needs being consistent with legislation, policy and procedures. Suggest workforce requirements appropriate to the needs of the trust to enable the trust to carry out its obligation of maintaining adequate staff levels to meet the standards of the MHRA inspectorate. To adhere to the equality and diversity policy, treating everyone with respect, acknowledging others' different perspectives, and reporting any issues of discriminatory behaviour.

9. To supervise/implement cleaning and organising maintenance and servicing of facilities ensuring that they are carried out to required standard. To supervise/implement regular validation of procedures/equipment and premises/staff/environmental monitoring.

10. To be responsible for service development and implementation of RadioPharmacy service. To continuously supervise all written protocols and procedures within the RadioPharmacy and blood labelling unit.

11. To gather and analyse information on environments, assess capacity of and effectiveness to meet future needs of these environments, develops, refines and agrees the design for environments to meet current legislation, policies and procedures.

12. To implement local financial procedures, including managing delegated budget for RadioPharmacy, reporting to budget holder and Clinical Modality Manager. Responsible for purchase of all essential resources to enable service to be provided. Authorised signatory for Non Stock (£200) /Stock supplies (limited by tender), cash, Credit notes/Cheque requests. Responsible for the procurement via contracts/budgets for radiopharmaceuticals with supplies department for term contracts with outside suppliers. Set and agree price structure and review with directorate accountant and provide expected income values for customers to Clinical Modality Manager or the Budget holder. Responsible for further income generation by enlisting new customers as appropriate.

13. Responsible for initiating/co-coordinating R & D program/activities in RadioPharmacy and blood labelling. To participate and promote research within RadioPharmacy in conjunction with the departments active research programme and the medical school.

14. To deputise for the Clinical Modality Manager when required.

Competence

- The jobholder is required to participate in the Trust appraisal process and work towards meeting identified development needs.
- The jobholder is required to demonstrate on-going continuous professional development.
- At no time should the jobholder work outside their defined level of competence. If the post holder has concerns regarding this they should immediately discuss this with their Manager/Supervisor/Consultant. The jobholder has the responsibility to inform those supervising their duties if they are not competent to perform a duty.

Registered Health Professional

Only to be included in the job descriptions for posts where professional registration is required.

All staff who are members of a professional body must comply with standards of professional practice/conduct. It is the post holder's responsibility to ensure they are both familiar with and adhere to these requirements.

Risk Management/Health & Safety

The jobholder has a responsibility to themselves and others in relation to managing risk, health and safety and will be required to work within the policies and procedures laid down by the Trust. All staff have a responsibility to access occupational health, other staff support services and/or any relevant others in times of need and advice.

Infection Control

Infection prevention and control is an essential aspect of patient care. All post holders have a personal obligation to act to reduce Healthcare Associated Infections (HCAIs). They must attend mandatory training in infection prevention and control and be compliant with all measures required by the Trust to reduce HCAIs. Post holders must be familiar with the Trust's Infection Control Policies, including those that apply to their duties, such as Hand Decontamination Policy, The Dress Code and Personal Protective Equipment Policy. Post holders who have clinical responsibilities must incorporate into their clinical activities up-to-date evidence that supports safe infection control practices and procedures, for example the use of aseptic techniques and the safe disposal of sharps.

Safeguarding Children and Vulnerable Adults

Post holders have a general responsibility for safeguarding children and vulnerable adults in the course of their daily duties and for ensuring that they are aware of the specific duties relating to their role.

Smoking Policy

It is the Trust's policy to promote health. Smoking, therefore, is actively discouraged. It is illegal within the Trust's buildings and vehicles.

Flexibility Statement

This job description is not inflexible but is an outline and account of the main duties. Other duties may be required to be performed from time to time in line with the jobholder's grade, experience and job role. The job description will be reviewed periodically and at the time of the employee's appraisal, to take into account changes and developments in service requirements. Any significant changes that are proposed will be discussed fully and agreed with the post holder in advance.

Confidentiality

As an employee of this Trust you may gain privileged knowledge of a highly confidential nature relating to private affairs, diagnosis and treatment of patients, information affecting members of the public, personal matters concerning staff, commercial confidences of third parties, and details of items under consideration by this Trust. Such information should not be divulged or passed to any unauthorised person or persons, and the requirements of the Trust's Code of Conduct for Employees in Respect of Confidentiality, a copy of which is available from your Head of Department, must be adhered to with particular regard to the responsibilities of individuals and the Trust under appropriate legislation, notably the Data Protection Act. **Failure to comply with this requirement may constitute gross misconduct under the Trust's Disciplinary Policy which may lead to summary dismissal.**

Date Reviewed: ……

Agreed by:

Signed by Post holder…… Date ……

Signed by line manager …… Date ……

Brighton and Sussex NHS
University Hospitals
NHS Trust

Date of next review: ……

PERSON SPECIFICATION

JOB TITLE: _____ RadioPharmacy Product Manager_____

Department: _____Nuclear Medicine, RSCH_____

Area	Requirements	
Qualifications	Essential	Desirable
(Use categories e.g. Nursing, Scientific, Technical as/where appropriate)	1. First Degree in a suitable Science subject. 2. MSc qualification in related subject or equivalent knowledge/experience gained through evidence of special study or presented papers). 3. Experience in RadioPharmacy or Aseptic Pharmacy services or other similar environments.	Diploma in Pharmaceutical Technology and Quality Assurance(or Equivalent) Leeds Course in Aseptic Dispensing and Preparation of Medicines in Health Care (4 day specialist course).
Registration (where applicable)	Registered Member of VRCT, Association of Pharmacy Technicians, or Royal College of Pharmacy/Chemistry. Professional requirement to maintain CPD.	Health Professions Council
Knowledge & Experience		
Non-clinical (e.g. Scientific, Technical, Administrative, Managerial – use one or more categories as/where appropriate)	1. Highly developed specialist experience in RadioPharmacy or Pharmacy / Aseptic Dispensing or Chemistry and labelling techniques: 2. Supervisory capacity of staff using complex highly specialised equipment; 3. Specialist knowledge in documentation and technical services procedures. 4. Ability to discuss/analyse and solve complex problems related to use of radiopharmaceuticals in patient diagnostic studies. 5. Interview skills for specialised unit. 6. Full understanding of legal requirements in all areas and ability to interpret those into working practice. Project management skills. 7. Highly specialised knowledge of Purity Control techniques and other quality control methods. 8. Understanding of, and use of,	5 years + in RadioPharmacy / Aseptic Pharmacy Dispensing. Isolator course. Management course or experience Have a good knowledge of general nuclear medicine studies and Radiopharmaceuticals used.

	audit for ensuring the continued compliance with legislation. 9. Good knowledge of GMP, licensed facilities requirement (MHRA), DOH Aseptic dispensing for patients, Radioactive Substances Act, Transport of Dangerous Goods (2009), Local Rules, COSHH and manual handling policy. 10. Knowledge of Health and Safety policy and awareness to alert local officer of risks.	Working knowledge of Trust risk assessment policy and procedures
Clinical (where relevant)	Specialist knowledge in Chemistry and/or Pharmacy.	Specialist knowledge on the use of Radiopharmaceuticals used in Nuclear Medicine for diagnosis and Therapy procedures.

		Provide specialist knowledge of blood labelling techniques and develop new methods.
Skills		
Communication/ relationship	1. Have good English language/ understanding skills to: a. Communicate effectively with remote sites/customers /manufacturers regarding their orders/supplies/technical queries and service provision issues, using negotiation, persuasion, tact and diplomacy to manage barriers to effective communication and to inform understanding. b. Understand and use various methods of communication (e.g. email/text/documents/fax) to train/inform/alert other staff of any important issues related to service provision. 2. Presenting complex information to large groups, e.g. presenting scientific papers/poster at international meetings.	
Analytical/ judgmental	Uses skills to analyse/interpret/dispense accurately RadioPharmacy production and Blood labelling; problem solve service provision issues. Recommend to trust changes to working practice/ policies/ equipment to improve quality/ safety of service	
Planning/ organisational	1. Responsible for policies implementation and service development for RadioPharmacy service. 2. Co-ordinating day to day provision of RadioPharmacy and Blood Labelling services; planning training/ meetings/ presentations/ lectures and CPD within the RadioPharmacy Service and Trust 3. Use experience and knowledge to take major role in planning for updating/new facilities. Planning and management of project	

	programs, e.g. design, procure and commission RadioPharmacy clean room and blood labelling suite.	
IT	Computer Literate to basic level, including internet search techniques Use of presentation software and equipment	
Physical	Capable of accurately dispensing hazardous products with a narrow margin of error; dexterity/safety/precision/speed/co-ordination of hand and eye; manual handling of generators (weighing 17Kg)	
Abilities		
Physical	Capable of Bending/ stretching/ lifting/ handling/ manipulation of hazardous products; long periods of standing in production session	
Mental	Able to concentrate in: calculation, supply, production; packaging of products; checking and releasing of products. Able to assess risks to products in manufacture and indirectly Patients receiving doses from products produced in RadioPharmacy.	
Emotional	Need to be able to assess carefully and objectively conditions relating to production and make difficult decisions, e.g. closure of production/ labelling facilities affecting many patients across several trusts.	
Working conditions	Handling hazardous material (Radioactivity /Blood) in a restricted area; exposure to noxious chemicals; required to use VDU frequently	
Other		
Research/Development	Initiates/co-ordinates and participates in R & D program and produce presentations/papers; participate in clinical trials in Nuclear Medicine also initiate and monitor development work in RadioPharmacy or blood labelling	

SUPPLEMENTARY JOB DESCRIPTION INFORMATION

Post Title: **Radiopharmacy Product Manager**

Ward/Dept and Site: **Nuclear Medicine, RSCH**

Date Completed: **31/01/2005** **updated: 02nd Oct 2009**

Working Conditions	Yes	No	Details
Inclement weather			
Excessive temperatures	√		1 to 2 times a month
Unpleasant smells/odours	√		At least 3 times a month
Noxious fumes	√		At least 3 times a month
Excessive noise &/or vibration			
Use of VDU more or less continuously	√		Several occurrences each working day
Unpleasant substances/non-household waste	√		Several occurrences each working day
Infectious Material/Foul Linen	√		Several times a week
Body fluids, faeces, vomit	√		Several times a week
Dust/dirt			
Humidity	√		Very rarely
Contaminated equipment or work areas	√		Occasionally need to de-contaminate equipment
Driving/being driven in normal situations			
Driving/being driven in emergency situations			
Fleas or lice			
Exposure to dangerous chemicals/ substances in/not in containers	√		Daily, including: Radiation, Chemicals (noxious) for RCP.
Exposure to aggressive verbal behaviour where there is little/no support			
Exposure to aggressive physical behaviour where there is little/no support			
Comments:			
Required to work in a clean room environment, using specialist equipment (Isolator Cabinets), handling radioactive sources and intricate handling of vials/syringes/needles shielded with lead/tungsten, to strict time schedule.			

Emotional Effort	Yes	No	Details
Processing (e.g. typing/transmitting) news of highly distressing events			
Giving unwelcome news to patients/ clients/carers/staff			
Caring for the terminally ill			
Dealing with difficult situations/ circumstances	√		Responsible for decision to close RadioPharmacy, under adverse conditions, i.e. out of spec. Equipment, lack of trained staff, etc. this can lead to 4-5 Nuclear Medicine depts closing temporarily (at least a day)
Designated to provide emotional support to front line staff			
Communicating life changing events			
Dealing with people with challenging behaviour			
Arriving at the scene of an accident			
Comments:			

Physical Effort	Yes	No	Details
Working in uncomfortable/ unpleasant physical conditions	√		At least once a week on average for periods over 20 minutes
Working in physically cramped conditions	√		Several occurrences each working day
Lifting weights, equipment or patients with mechanical aids			
Lifting or weights/equipment without mechanical aids	√		At least once a week on average for periods under 20 minutes
Moving patients without mechanical aids			
Making repetitive movements	√		Several times a day for periods over 20 minutes
Climbing or crawling			
Manipulating objects	√		On average once a day for periods over 20 minutes
Manual digging			
Running			
Standing/sitting with limited scope for movement for long periods	√		Several occurrences each working day
Kneeling, crouching, twisting, bending or stretching	√		At least once a week on average for periods over 20 minutes each
Standing/walking for substantial periods of time	√		On average once a day for periods over 20 minutes each
Heavy duty cleaning			
Pushing/pulling trolleys or similar			
Working at heights	√		Less than once a month on average
Controlled restraint i.e. jobs requiring training/certification in this			

Comments:			
Operating in clean rooms standing at Isolator cabinets, dressed in clean room garments, for periods of at least 2 hours, daily, handling heavy shields carrying out intricate operations.			

Mental Effort	**Yes**	**No**	**Details**
Carry out formal student/trainee assessments	√		Less than once a week
Carry out clinical/social care interventions			
Analyse statistics	√		On average once a day for several short periods less than 30 minutes
Operate equipment/machinery	√		Several times a day for several short periods less than 30 minutes
Give evidence in a court/tribunal/ formal hearings			
Attend meetings (describe role):	√		At least once a week as active participant
Carry out screening tests/ microscope work			
Prepare detailed reports	√		On average once a week
Check documents	√		On average once a day for several long periods over 30 minutes
Drive a vehicle			
Carry out calculations	√		Several times a day for several short periods less than 30 minutes
Carry out clinical diagnosis			
Carry out non-clinical fault finding	√		Less than once a week
Comments:			
Sterility Tests Radiochemical Purity Tests(precision, dexterity)			

Freedom to Act	**Yes**	**No**	**Details**
Does the post holder generally work with the supervisor/manager close by/available		√	See below
Does the post holder generally work with the supervisor/manager contactable by telephone or bleep		√	
Is the post holder the lead specialist in their field	√		Lead specialist takes ultimate responsibility for RadioPharmacy operational policies
			Less frequent *(state how often)*
How often on average is guidance/advice given	√		On average once a month by QC manager
How often is your work checked/monitored/assessed	√		Every 2 years MHRA inspection. Monthly internal audit.
Comments:			
This post requires 'adequate authority to carry out their responsibilities' see sect 2.2, page 61 Orange Guide.(copy enclosed) **Acts independently but to strict guidelines enforceable by Medicines and Healthcare Products Regulatory Agency (MHRA) (subject to regular inspection visits to ensure compliance)** **Post holder is assessed by MHRA as suitable for role of Production Manager.** **NB. 'Orange guide' the MHRA's Rules and Guidance for Pharmaceutical Manufacturers and**			

Distributors 2002.

Please attach any additional information on a separate sheet.

Signed by post holder: _____ **Date** _____

Signed by line manager: _____ **Date** _____