

## JOB DESCRIPTION

JOB DETAILS	
Job Title	Product Approver – Aseptic Service
Reports to	Lead Technician – Technical Services
Band	Band 6
Department/Directorate	Pharmacy / Specialist Services

JOB PURPOSE
<ul style="list-style-type: none"> <li>Accredited PIPC checker and product approver to undertake pre-&amp; in-process checks and final approval of medicines.</li> <li>To oversee the production aspects of the Aseptic Unit, ensuring an efficient and legally compliant service</li> <li>Provides specialist Aseptic support to Lead technician Technical Services and the Chief Technician of Aseptic Services.</li> <li>Assist the senior manager in developing Aseptic services in line with Trust and Pharmacy department development policies.</li> <li>To manage the day to day running of relevant Aseptic section.</li> <li>Ensuring service is responsive to need and that staff working within their section are developed to deliver agreed services</li> </ul>

KEY RESULT AREAS/PRINCIPAL DUTIES AND RESPONSIBILITIES
<ul style="list-style-type: none"> <li>To partake in the final approval &amp; release of aseptically prepared products manufactured within the aseptic unit as per rota requirements.</li> <li>To perform pre and in-process checks as part of the production team</li> <li>To lead and oversee aspects of production to ensure efficiency and legal compliance</li> <li>To partake in the production of batch documentation ensuring accuracy</li> <li>To plan workloads ensuring the service is working within its capacity constraints</li> <li>Assist in resolving day to day problems or issues affecting resources or the service provision which require co-operation to achieve standards set out by the NHS standards &amp; Medicinal and HealthCare Regulatory Authority (MHRA).</li> <li>Assisting the development of service provision of Aseptic Services alongside, Senior Pharmacists, Chief and Senior pharmacy technician;</li> <li>To work within the full range of Aseptic pharmacy codes and procedures of aseptic services</li> <li>Assisting the Lead Technician – Technical Services and Chief Technician in Aseptic services in monitoring of all staff to ensure adherence to standard operating procedures as required in the Aseptic production of chemotherapy and TPN.</li> <li>Assisting the Senior Pharmacist, Lead Technician – Technical Services and Chief Technician in managing staff and workload to maximize parenteral nutrition, aseptic and chemotherapy production efficiency.</li> <li>Deputising for the manager when required. Dealing with day-to-day issues, attending meetings, and providing direction and advice when needed. Providing suitable hand over on their return. Support, if needed can be sort from another senior pharmacy manager who is working on site'</li> <li>Responsible for the development, review, and implementation of local Standard operating procedures (SOPs) including ensuring adequate training is provided to ensure staff working within them understand and can adhere to them.</li> </ul>

- Responsible for ensuring maintaining good practice and awareness throughout the work area. Ensuring staff are aware of and can follow written procedures and COSHH guidelines to ensure the safety of the product, patient, and staff.
- Responsible for ensuring maintaining own fitness to practice supporting the delivery of services when required
- Assist in auditing of aseptic services workload and capacity planning in order to maximize capacity. This includes monitoring of amount of chemotherapy doses and parenteral nutrition bags reconstituted by the Aseptic Services
- Resolve aseptic issues for reconstitution of aseptic products and parenteral nutrition.
- Ensure compliance with GMP/medicine legislation in the provision of pharmaceutical care for patients.
- Responsible for management of the supply chain of licensed starting material and consumables
- Co-ordinates ordering processes to ensure appropriate stock levels during weekends and public holidays
- Liaising with the pharmacy procurement team or supplier to ensure adequate supply of cytotoxic, non-cytotoxic, TPN products and consumables for the running of the TPN, aseptic and chemotherapy units. Ensure all resources and supplies are used in an efficient and cost-effective manner.
- To act as a role model and being accountable for your actions and decisions and ensure that you always uphold RDUH Trust values and professional standards

### KEY WORKING RELATIONSHIPS

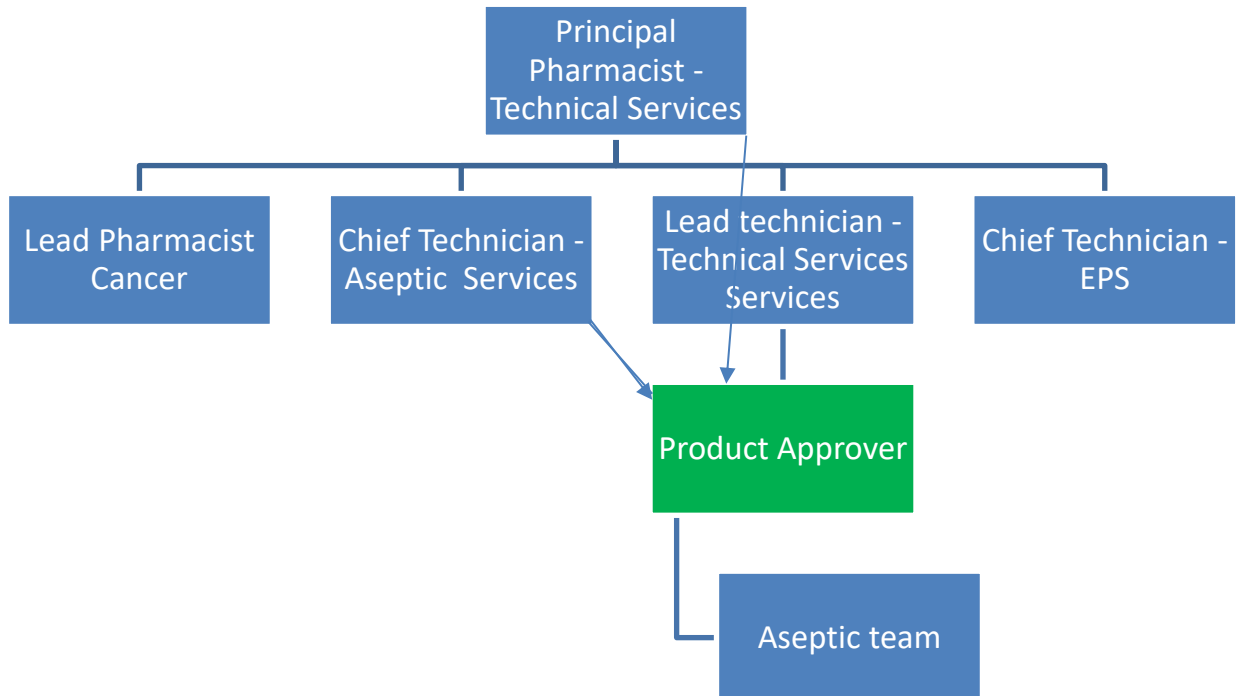
Areas of Responsibility: Product approval & Service delivery

The post holder is required to deal effectively with staff of all levels throughout the Trust as and when they encounter on a day to day basis. In addition, the post holder will deal with the wider healthcare community, external organisations and the public. This will include verbal, written and electronic media.

Of particular importance are working relationships with:

Internal to the Trust	External to the Trust
<ul style="list-style-type: none"> <li>• Principal Pharmacist Technical Services</li> <li>• Lead Technician - Technical Services (East &amp; North)</li> <li>• Chief Technician – Aseptic Services</li> <li>• Aseptic staff</li> <li>• Pharmacy Procurement team</li> <li>• Pharmacy team</li> <li>•</li> </ul>	<ul style="list-style-type: none"> <li>• External commercial suppliers for aseptic products &amp; consumables</li> <li>• Suppliers of aseptic equipment</li> <li>• NHS Pathfinders</li> <li>• Department of Health/NHSE</li> </ul>

## ORGANISATIONAL CHART



## FREEDOM TO ACT

- Works within a range of technical pharmacy procedures to support service delivery within aseptic unit.
- Work is managed and assessed by the Lead Technician – Technical Services.
- Responsible for planning own workload and escalating concerns where support needed.
- Deputise to the Chief Technician – Aseptic Services in their absence
- Deals with complaints & investigations and referring to managers as required and works to clearly defined occupational policies.
- Complies with all legal requirements relating to the prescribing, dispensing, purchase and storage of pharmaceutical products and works to the relevant standard operating procedures at all times and in accordance with criteria set out under COSHH regulations.

## COMMUNICATION/RELATIONSHIP SKILLS

- The post holder will need to be a skilled communicator, providing and receiving highly complex pricing, order processes and supply route information during interactions with staff, external suppliers, patients and carers on sensitive matters due to the nature of the drugs that are used within technical services including unlicensed, compassionate use and non-commissioned drugs for cancer treatments
- Promotes team working within the Technical Services team
- Addressing comments and concerns from staff in a timely and respectful manner.
- Acts as a professional role model, develops positive relationships with key personnel both internally and externally to the department.
- Presenting complex information to staff at all levels in the departments (written and verbal) and at regional and national meetings

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- Communicate effectively and efficiently with members of the pharmacy clinical team as appropriate to highlight concerns with medication issues (e.g. shortages) which may impact on patient care and provide solutions within scope of clinical competence using tact and persuasive skills
- Respond effectively to informal complaints regarding the service and support pharmacy senior leadership team with investigation of formal complaints concerning medicines supply issues
- Responsible for ensuring clinical pharmacists are consulted in the event of a stock item not being available.
- Liaises with wards and departments regularly to ensure patients treatments are provided in a timely manner when treatment is taken off hold. Gives achievable ETA to ward staff as when treatment will be ready to collect.
- Occasionally requirement for having difficult conversations while striving to develop positive team culture due to non-compliance with standard operating procedures

#### **ANALYTICAL/JUDGEMENTAL SKILLS**

- Analyses, interprets prescription information, resolves service provision problems, reviews supplier data and makes adjustment to stock level ensuring most cost-effective stock holding
- Make judgements which require analysis of several facts and consideration of a variety of options to ensure safe service provision.
- Performs accuracy checks on documentation, including worksheets and labels which may contain complex calculations
- Performs in-process accuracy checks during cleanroom supervision sessions as required.
- Is aware of alert and action limits for environmental monitoring and subsequent measures needed to rectify issues in line with SOPs and policies
- Analyses information or various information sources and guidance relating to medicines and interpret information (e.g. stock supply information, electronic prescribing and administration system).
- Ensuring that EPIC stock levels checked regularly by staff and any inaccuracy is investigated and correct accordingly and ensure that staff are trained and supported to carry out accurate stock adjustments
- Assesses pharmaceutical products returned from clinical areas. Returns to stock items which are fit for reuse or disposes of items unfit for use, in accordance with COSHH regulations and Trust procedures. Processes the returns following departmental procedures.
- Reports and investigates near miss and error data.
- Analyse and interpret data and information concerning medicines inventory and usage, procurement, stock control and financial reports.

#### **PLANNING/ORGANISATIONAL SKILLS**

- Manage and organise complex day to day activities such as preparation, dispensing, distribution and checking ensuring responsibilities are covered; this may require plans to be adjusted in response to workload demand and capacity
- Ensure that activity is handed over, covered or cancelled for any periods of planned absence.
- Assists the Highly Specialised Technician in planning, organising and managing the workload in accordance with the capacity plan, ensuring adequate numbers of appropriately trained staff are available to perform tasks required for a given activity level and feeding back information to managers when breaches and constraints occur.

#### **PATIENT/CLIENT CARE**

- Work collaboratively with clinical pharmacists to provide a specialist clinical technical service, ensuring that all aseptic medications meet the needs of prescribers and patients in all clinical settings and provide information especially with regard to new and specialised medicines used in aseptic service.
- Is trained and named on the intrathecal register to undertake appropriate preparation and documentation tasks relating to intrathecal chemotherapy services following local, trust and national guidance for the safe administration of intrathecal chemotherapy.
- Maintains compliance with Rules and Guidance to Good Manufacturing Practice and any other local, regional and national guidance documents.

- Assists with the maintaining Quality Assurance Standards in accordance with National, Regional and local requirements.
- Ensures that the aseptic service complies with clinical governance strategies, including risk management assessments of working practices, reporting of clinical incidents, pharmacy error reporting schemes, intervention monitoring and risk reduction strategies.
- Conducts regular documented GMP Observations, referring to Chief Technician, Lead Technician and Accountable Pharmacist where non-compliance or deviation identified.
- Undertakes any other duties of a similar nature requested by the Lead Technician, Principal Pharmacist or the Chief Pharmacist.
- Promote medication safety within pharmacy and the wider Trust
- Ensures patients receive drug products as required for administration.

### **POLICY/SERVICE DEVELOPMENT**

- Develops and implements policies and procedures relating to pharmacy provision which may impact wider organisational services
- Develop, review and maintain Standard Operating Procedures for all activities undertaken in technical service areas. These shall be consistent with guidance from the Royal Pharmaceutical Society, MHRA and the Home Office.
- Propose changes to make improvements to working practices concerning medicines stock, supply and procurement management which impact positively on other areas e.g. wards, outreach units
- Have an innovative approach to reviewing and re-evaluating current practices relating to stock management and supply chain. To approach and work with wards/departments to develop alternative supply services where appropriate
- Aim for continuous improvement in the procurement service of aseptic products including staff training, awareness of environment, best operational practice and service provision.
- Work in accordance with all Pharmacy and Trust Standard Operating Procedures and ensure that these are followed by all staff working within Technical Services.
- Establishes and enforces effective communication systems to ensure pharmacy staff are kept informed of all technical operations in line with the change control process
- Ensure that all legal requirements are met for the handling, storage, manufacturing and dispensing of drugs, including controlled drugs, within the aseptic unit.
- Set standards for the service and individuals and monitor performance against these.
- Devise and carry out workplace audits to monitor efficiency of service and to ensure it is appropriate for customer needs.
- Introduce and implement new working practices and products in conjunction with the Senior Technical Service Team, which maximise the skills and potential of SMTs, Pharmacy Technicians and Assistants. These practices and products will contribute to an efficient and effective Technical Service for all users.
- To remain up to date with advances in medicine, aseptic manufacturing and pharmacy attending training courses and maintaining a CPD portfolio.
- Work proactively and collaboratively to improve sustainability through implementation of identified and agreed changes to support the Trust Green Plan.
- Reviews SOPs and worksheets and assist in implementation of any new/changed procedures.
- Ensures compliance with legislation, COSHH Regulations and safe and secure handling of cytostatic and cytotoxic drugs
- Completion of risk assessments to support requirements of the department e.g. COSHH, manual handling and implement appropriate measures to reduce risk

### **FINANCIAL/PHYSICAL RESOURCES**

- Supports medicines security and reduce avoidable medicines waste.
- Maintaining optimum stock holdings and rotation to ensure efficient use of working capital
- Ensure that the aseptic unit and the pharmaceutical products therein, are secure and that all equipment in these areas is maintained and in good working order.

- Responsible for purchase of specialist high-cost medicines from approved suppliers working collaboratively with pharmacy procurement team.
- Ensure quality and integrity of pharmaceutical stock (drug and consumables) within the aseptic unit, including monitoring of shelf life, expiry date checking, temperature controls, standard of cleanliness and integrity of product.
- Utilising staff and physical resources as efficiently as possible to create operational efficiencies through appropriate deployment
- Reviews supplier tender packages when required.
- To be responsible for ensuring the safe storage of stock within pharmacy in line with national guidelines and legislation
- Ensure that there is a robust process in place for the recycling and disposal of returned and expired medication.
- Authorised to write off stock and to amend incorrect stock levels

## **HUMAN RESOURCES**

- Line manager of aseptic staff, involving appraisals, performance and sickness management in line with Trust policies and procedures
- Be responsible for organising rotational systems of work for all aseptic staff through procurement competencies relevant to the Aseptic unit.
- Responsible for recruitment of aseptic staff and act as a member of the interview panel for other staff as requested.
- Co-ordinate and ensure the development and training of Pharmacists, SMT, Pharmacy Technicians and Pharmacy Assistants working within the aseptic unit in relation to procurement aseptic within aseptic service.
- Assess the competency of aseptic staff using approved paperwork.
- Participate in CPD (Continuing Professional Development).

## **INFORMATION RESOURCES**

- Records personally generated clinical details and enters patient details on pharmacy computerised data record systems from prescriptions written by others
- Ensure that all relevant documentation is filed and stored appropriately and securely. Ensure that documentation is archived for the appropriate amount of time.
- Ensures completion of records, worksheets and logs including patient data, adhering to data integrity standards.
- Ensures that systems are in place for the accurate and effective management of the Aseptic Services computer system to record all issues, receipts and returns
- Occasional requirement to produce reports as required
- Demonstrate knowledge and proficiency in the use of the pharmacy and hospital computer systems e.g. EPIC, Ultimate, Chemocare
- Assists in audits and produces written reports and provide statistical information with identified action.

## **RESEARCH AND DEVELOPMENT**

- Completes regular audits as required for role.
- Compiles remedial action plan in response to audits and to the delivery of these plans.
- Pro-actively identifies and initiates improvements and developments to working practices, procedures and documentation.
- Participates in provision of clinical trial's medication and ensures adherence to Good Clinical Practice to all trial's medication supplied by the Aseptic Unit.
- Ensures adherence to environmental monitoring schedules in accordance with departmental procedures.

## **PHYSICAL SKILLS**

- Participates in the production of all types of aseptically prepared products demonstrating the necessary high standard of dexterity, accuracy and precision required for aseptic manipulations
- Advanced keyboard skills required for speed and high degree of accuracy for stock management

### PHYSICAL EFFORT

- Moves pharmaceutical goods of up to 10kg using trolleys
- Standing for long periods for supervision of manufacturing process in isolator rooms and product approval within the clean rooms.

### MENTAL EFFORT

- Frequent requirement to concentrate for periods while manufacturing aseptic products, supervising, calculating doses and final product approval
- Frequent interruptions to provide advice to staff, clinical colleagues and solve service provision issues.
- Responding to the demands of an unpredictable work pattern to support medication supply provision in different locations within the hospital and frequently changing priorities
- Frequent periods of concentration performing accuracy checks.

### EMOTIONAL EFFORT

- Occasional exposure to distressing and emotional circumstances while preparing medicines for patients or dealing with incidents involving medicines e.g. distressed patients
- Regular preparing medication to patients including urgently required orders and orders delayed due to stock issues and capacity. Explaining to dissatisfied customers why stock is delayed.
- Line management of Aseptic staff

### WORKING CONDITIONS

- Frequent use of VDU throughout day
- Dispense & Manufacture medicines in accordance with COSHH regulations.
- Frequent handling of medicines including cytotoxic drugs.
- Frequent handling of potentially hazardous materials that have been returned to the aseptic unit
- Frequent exposure to cleanroom environment including restricted cleanroom clothing
- Working within a clean room setting. Unable to leave the environment for a prolonged period (up to 4 hours) due to the required changing procedures

### OTHER RESPONSIBILITIES

Take part in regular performance appraisal.

Undertake any training required in order to maintain competency including mandatory training, e.g. Manual Handling

Contribute to and work within a safe working environment

You are expected to comply with Trust Infection Control Policies and conduct him/herself at all times in such a manner as to minimise the risk of healthcare associated infection

As an employee of the Trust, it is a contractual duty that you abide by any relevant code of professional conduct and/or practice applicable to you. A breach of this requirement may result in action being taken against you (in accordance with the Trust's disciplinary policy) up to and including dismissal.

You must also take responsibility for your workplace health and wellbeing:

- When required, gain support from Occupational Health, Human Resources or other sources.

- Familiarise yourself with the health and wellbeing support available from policies and/or Occupational Health.
- Follow the Trust's health and wellbeing vision of healthy body, healthy mind, healthy you.
- Undertake a Display Screen Equipment assessment (DSE) if appropriate to role.

#### **APPLICABLE TO MANAGERS ONLY**

Leading the team effectively and supporting their wellbeing by:

- Championing health and wellbeing.
- Encouraging and support staff engagement in delivery of the service.
- Encouraging staff to comment on development and delivery of the service.
- Ensuring during 1:1's / supervision with employees you always check how they are.

#### **DISCLOSURE AND BARRING SERVICE CHECKS**

This post has been identified as involving access to vulnerable adults and/or children and in line with Trust policy successful applicants will be required to undertake a Disclosure & Barring Service Disclosure Check.

#### **GENERAL**

This is a description of the job as it is now. We periodically examine employees' job descriptions and update them to ensure that they reflect the job as it is then being performed, or to incorporate any changes being proposed. This procedure is conducted by the manager in consultation with the jobholder. You will, therefore, be expected to participate fully in such discussions. We aim to reach agreement on reasonable changes, but if agreement is not possible, we reserve the right to insist on changes to your job description after consultation with you.

Everyone within the Trust has a responsibility for, and is committed to, safeguarding and promoting the welfare of vulnerable adults, children and young people and for ensuring that they are protected from harm, ensuring that the Trusts Child Protection and Safeguarding Adult policies and procedures are promoted and adhered to by all members of staff.

At the Royal Devon, we are committed to reducing our carbon emissions and minimising the impact of healthcare on the environment, as outlined in our Green Plan available on our website. We actively promote sustainable practices and encourage colleagues to explore and implement greener ways of working within their roles.

# PERSON SPECIFICATION

<b>Job Title</b>	<b>Product Approver – Aseptic Procurement</b>
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REQUIREMENTS	Essential	Desirable
<b>QUALIFICATIONS / TRAINING</b>		
<ul style="list-style-type: none"> <li>• Knowledge of pharmaceutical technical procedures for specialist area to degree or equivalent level acquired through training, NVQ3, BTEC in pharmaceutical science or equivalent level (including Level 3 Apprenticeship Standard for Science Manufacturing Technicians) or equivalent experience</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Registered Science Manufacturing Technician or Registered Pharmacy Technician with the GPhC</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Accredited Pre-&amp; In-process and/or Product Approver for aseptic products</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Leadership Qualification</li> </ul>		D
<b>KNOWLEDGE / SKILLS</b>		
<ul style="list-style-type: none"> <li>• Substantial post qualification hospital experience in pharmacy services</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Knowledge of pharmacy procurement</li> </ul>		D
<ul style="list-style-type: none"> <li>• Confident to work independently and as part of a team</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Excellent interpersonal and communication skills (oral and written) and ability to convey information in clear and concise manner</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Relevant knowledge of GMP</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Influencing / negotiation skills</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Understanding of hospital pharmacy systems</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Effective staff management and leadership skills</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Auditing and analysis skills</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Ability to motivate and engage other members of staff</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Experience of training delivery</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Excellent written, oral and presentation skills to communicate effectively with a variety of stakeholders</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Excellent IT skills and ability to use information systems confidently including ability to use Microsoft Office packages e.g. Word, Excel, Outlook</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Experience of training and mentoring students, trainee pharmacists and non-registered staff</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Proven ability to problem solves and prioritise workload</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Demonstrate people management ability</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Ability to lead and drive change</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Demonstrate excellent professional standards</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Ability to work under pressure</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Awareness of health and safety issues</li> </ul>	E	
<b>EXPERIENCE</b>		
<ul style="list-style-type: none"> <li>• Substantial experience at pharmacy technician Band 5 or above Previous experience of line-managing direct reports</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Experience of audit or quality improvement</li> </ul>	E	
<ul style="list-style-type: none"> <li>• Experience of training pharmacy staff</li> </ul>		D
<ul style="list-style-type: none"> <li>• Up to date knowledge of legislation relevant to pharmacy practice e.g. unlicensed medicine</li> </ul>	E	

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• Experience of developing, reviewing and maintaining Standard Operating Procedures	E	
• Experience of implementing change	E	
• Experience of quality improvement	E	
<b>PERSONAL ATTRIBUTES</b>		
• Able to work as a team member and organise work of others	E	
• Professional attitude and role model – honest, trustworthy, reliable, respectful	E	
• Commitment to improving the quality of care for patients	E	
• Commitment to Continuous professional development	E	
• Responds positively to service deadlines	E	
• Able to plan and manage own workload	E	
• Possesses good verbal and written communication skills	E	
• Able to work under pressure	E	
• Self-motivated, enthusiastic and flexible	E	
• Display an understanding of and ability to deal with patient confidential and sensitive information on a daily basis	E	
• Ability to communicate complex medication issues to staff, patients and carers	E	
• Compassionate	E	
• Flexible and willing to adapt approach if required to support change	E	
• Demonstrate understanding and ability to communicate and deal with all patients and/or carers	E	
<b>OTHER REQUIREMENTS</b>		
• The post holder must demonstrate a positive commitment to uphold diversity and equality policies approved by the Trust	E	

		FREQUENCY			
		(Rare/ Occasional/ Moderate/ Frequent)			
WORKING CONDITIONS/HAZARDS		R	O	M	F
<b>Hazards/ Risks requiring Immunisation Screening</b>					
Laboratory specimens	N				
Contact with patients	Y		x		
Exposure Prone Procedures	N				
Blood/body fluids	N				
<b>Hazard/Risks requiring Respiratory Health Surveillance</b>					
Solvents (e.g. toluene, xylene, white spirit, acetone, formaldehyde and ethyl acetate)	N				
Respiratory sensitisers (e.g isocyanates)	N				
Chlorine based cleaning solutions (e.g. Chlorclean, Actichlor, Tristel)	Y				X
Animals	N				
Cytotoxic drugs	Y				X
<b>Risks requiring Other Health Surveillance</b>					
Radiation (>6mSv)	N				
Laser (Class 3R, 3B, 4)	N				
Dusty environment (>4mg/m3)	N				
Noise (over 80dBA)	Y	X			
Hand held vibration tools (=>2.5 m/s2)	N				
<b>Other General Hazards/ Risks</b>					
VDU use (> 1 hour daily)	Y				X
Heavy manual handling (>10kg)	Y	X			
Driving	N				
Food handling	N				
Night working	N				
Electrical work	N				
Physical Effort	Y			X	
Mental Effort	Y				X
Emotional Effort	Y			X	
Working in isolation	N				
Challenging behaviour	Y		X		

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