

JOB DESCRIPTION

JOB DETAILS	
Job Title	Pharmacy Quality Assurance SATO
Reports to	Pharmacy QC Laboratory Manager
Band	Band 3 (Subject to formal matching)
Department/Directorate	Pharmacy / Specialist Services

JOB PURPOSE
To support the efficient running of the Quality Control Laboratory by undertaking basic technical and non-technical duties to support environmental monitoring and laboratory testing for Pharmacy Aseptics, Radiopharmacy and the Specials Licensed Manufacturing Unit.

KEY RESULT AREAS/PRINCIPAL DUTIES AND RESPONSIBILITIES
• Perform microbiological and physical monitoring of clean rooms and product storage facilities to ensure the quality of high-risk aseptic products as defined in local procedures. • Complete daily checks of the temperature management system and general laboratory checks used as indicators of Good Manufacturing Practice (GMP). These systems are computer and paper based. • Accurately check and process samples for testing. This includes logging and labelling samples as they are received into the lab using various sample processing mechanisms; both paper based and on the computer. Samples are either processed or incubated in-house, or sent to contract laboratories for testing. • Accurately read microbiological plates and samples i.e. settle plates, contact plates, active air samples, swabs and liquid media and basic laboratory analysis of microbiological cultures. Accurately complete records and identify and report out of specification results in line with laboratory GMP. • Safely control and dispose of test samples including, potentially hazardous laboratory chemicals and biological material (bacteria and fungi) through appropriate waste streams. • Report any non-conformances and out of specification results; assist with investigations where appropriate. • Process non-microbial sample results, accurately complete records and identify out of specification results. Report out of specification results to the Quality Control Manager. • Temperature monitoring and mapping of controlled storage areas within the pharmacy including daily temperature monitoring checks, routine temperature mapping (on an annual rolling basis). • Ordering and stock control of laboratory testing media. Ensuring purchased media is stored and tested appropriately and Certificates of Analysis obtained and reviewed where appropriate • Cleaning of the laboratory area on a rolling daily, weekly and monthly schedule. Handling and cleaning of laboratory equipment, benches and responsibility for general laboratory tidiness in accordance with laboratory GMP standards. The disposal of clinical waste bags, sharps bins, confidential and general waste through appropriate waste stream.

- Enter data in to multiple electronic management systems, including microbiological and analytical results, product details, non-conformances and change controls. These systems involve the use of MS Word, MS Excel, MS Access, Q-Pulse, LIMS and the Pharmacy stock control system.
- Participate in the training of other pharmacy staff e.g. Pharmacy Technicians, Student Pharmacy Technicians and Pre-registration Pharmacists in environmental monitoring techniques.
- Processing of defective medicines and contacting external companies to initiate investigations, where appropriate.
- Resolve immediate problems with stock discrepancies and out of stock medicines, analysing the situation and liaising with colleagues, wards, pharmacists and suppliers where necessary.
- Maintain clean and tidy laboratory facilities and safe systems of work.
- Answer the Quality telephone calls and deal with enquiries in the appropriate manner according to departmental procedures.
- Manage and maintain the QC inbox emails and respond to queries appropriately
- Assist in general house-keeping duties as and when necessary including:
 - Putting away laboratory supplies
 - Replenishing consumable items e.g. bags, cleaning products, syringes, etc.
 - Filing paperwork
 - Cleaning trays, computers and work spaces regularly
- To participate in flexible working arrangements including late duties and bank holidays and as appropriate. Please note that in order to deliver a high standard of care to patients the pharmacy service operates 7 days a week and staff are therefore required to work some weekends as part of their contracted hours.
- The post holder is 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.

KEY WORKING RELATIONSHIPS

Areas of Responsibility: Pharmacy QC laboratory

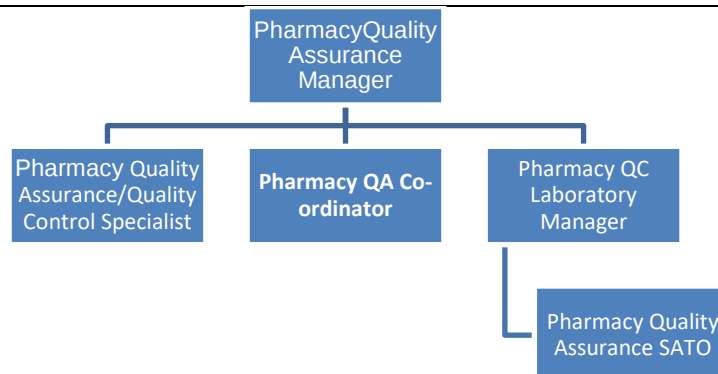
The post holder is required to deal effectively with staff of all levels throughout the Trust as and when they encounter on a day to day basis.

Of particular importance are working relationships with:

Internal to the Trust	External to the Trust
• Accountable Pharmacist and team • QA Manager • QC laboratory Manager	• Regional QC lab

In addition, the post holder will deal with, external organisations to send samples and obtain results

ORGANISATIONAL CHART



FREEDOM TO ACT

- Works within range of Trust policies and pharmacy standards operating procedures (SOPs) to support service delivery.
- Work is overseen by the Pharmacy Quality Assurance Manager, QC lab manager or QA/QC specialist.
- Post holder prioritises how to complete work tasks and in which order e.g. the order in which a queue is processed, answering phone, dealing with queries at aseptic reception, processing aseptic emails.
- To take part in late, weekend and bank holiday rotas to support 7-day pharmacy service.
- Responsible for escalating concerns where support is needed.

COMMUNICATION/RELATIONSHIP SKILLS

- Communication will include provision of and receipt of information from pharmacy colleagues, patients and healthcare professionals from within the Trust and external organisations e.g. receiving enquiries via telephone or face to face, taking messages and ensuring that these are passed on to the appropriate person.
- Communication will typically include factual information but may involve patient sensitive and confidential information.
- May be required to adapt own communication style to overcome communication challenges.
- Communication methods will include verbal, written and electronic.

ANALYTICAL/JUDGEMENTAL SKILLS

- Read plates accurately and record organisms grown, aware of what and when to escalate or further investigation required.
- Communicate with suppliers regarding missing or defective items to ensure timely resolution and prevent financial loss.
- Communicate general issues and those of concern to senior member of staff or pharmacist and use initiative to escalate or resolve straight forward issues in the absence of the manager.

PLANNING/ORGANISATIONAL SKILLS

Responsible for planning own day to day work tasks to meet pharmacy service requirements as directed by line manager/section manager, such as reading of plates, environmental monitoring activities, sending samples in priority order (urgent work first).

PATIENT/CLIENT CARE

- Provides information to healthcare professionals, patients, carers and pharmacy colleagues e.g. signposting patients to outsource outpatient pharmacy.
- Dispenses & prepares medication for Trust patients.

POLICY/SERVICE DEVELOPMENT

Responsible for following department Standard Operating Procedures (SOPs), GMP, COSHH and make suggestions for improvement to practice or to improve pharmacy service provision.

FINANCIAL/PHYSICAL RESOURCES
Responsible for supporting accurate stock levels of laboratory consumables and making sure equipment is well maintained and looked after, including stock rotation.
HUMAN RESOURCES
Responsible for supervising students and trainees during periods in the Quality section.
INFORMATION RESOURCES
- Frequent inputting, storing and using data using Trust computer systems. This may include laboratory data and sample data, managing and amending stock levels, ordering laboratory consumables. - Frequent modifying, maintaining and analysing information using Trust computer systems e.g. EPIC EPR. - Recording information (provided by others) manually into Trust computer software system, inputting, storing and providing information on database or other systems.
RESEARCH AND DEVELOPMENT
Complete and participate in surveys and audits within area of work as appropriate e.g. ward/department satisfaction audit
PHYSICAL SKILLS
- High level of accuracy required for reading plates and data entry - Manual dexterity required to poor environmental monitoring and reading plates.
PHYSICAL EFFORT
- Periods of sitting for data input, frequent standing for dispensing duty. - Repetitive lifting which may include, medicine packs, boxes. - Frequent moving of pharmaceutical goods and products. - Frequent periods of walking within the hospital collecting stock and checking equipment on the wards. - Occasional periods of manual handling of medication stock and cleaning materials which may occur on a weekly basis e.g. 10kg box of medicines being moved from one location to another nearby for dispensing and supply to ward area.
MENTAL EFFORT
- Frequent concentration is required for inputting information into Trust systems (e.g. EPIC), laboratory duties, medication stock management duties, as required to support aseptic medication processes - Frequent planning of workload to respond to urgent requests for information or responding to problems with ward fridges - Frequent planning of preparation workload to consider transport cut-off times and any external demands. - Work pattern is generally predictable
EMOTIONAL EFFORT
Rare exposure to distressing or emotional circumstances such as challenging patient behaviour in ward or dispensary area.
WORKING CONDITIONS
Frequent exposure to unpleasant conditions which may include cytotoxic drugs and cleaning materials. - Ability to understand and empathise with staff and patients in healthcare setting. - Frequent exposure to busy working environment with limited working space at times working in close proximity to colleagues.
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 (DES) if appropriate to role.

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

Job Title	Quality Assurance SATO	
Requirements	Essential	Desirable
QUALIFICATION/ SPECIAL TRAINING. GCSEs Grade (A-C or 9-4) in Maths and English or equivalent. GPhC recognised Level 2 qualification in relevant unit in distribution or dispensing of medicinal products OR laboratory based NVQ. GPhC recognised level 3 qualification or equivalent, or Laboratory based/pathology qualification or equivalent experience.	E E E	
KNOWLEDGE/SKILLS Knowledge of Good Manufacturing Practice guidelines (GMP). Knowledge of QC laboratory procedures. Ability to use computer, basic skills to operate computer systems. Excellent verbal and written communication skills. Ability to deal with telephone enquiries politely and efficiently. Good attention to detail. Knowledge of microbiology. Knowledge of / Quality systems. Ability to problem solve. Ability to manage time and priorities and be able to cope with frequent interruptions.	E E E E E E E	D D D
EXPERIENCE Experience of working within a Pharmacy QC laboratory. Experience of working in a GMP/GCP or GLP environment. Previous Pharmaceutical production or distribution experience. Experience of working with computer system(s).	E E	D D
PERSONAL ATTRIBUTES Enthusiastic and motivated. Good basic organisational skills. Ability to work methodically and prioritise workload. Ability to use own initiative. Excellent interpersonal skills. Ability to work calmly under pressure. Ability to meet deadlines. Able to work as a team member. Understanding own limitations and willingness to ask for assistance. Adaptable and flexible. Able to demonstrate effective learning from experiences. Professional attitude.	E E E E E E E E E E	
OTHER REQUIREMENTS The post holder must demonstrate a positive commitment to uphold diversity and equality policies approved by the Trust. Ability to work effectively and accurately in a busy environment.	E E	

WORKING CONDITIONS/HAZARDS		FREQUENCY (Rare/ Occasional/ Moderate/ Frequent)			
		R	O	M	F
Hazards/ Risks requiring Immunisation Screening					
Laboratory specimens	Y				X
Contact with patients	N				
Exposure Prone Procedures	N				
Blood/body fluids	N				
Laboratory specimens	N				
Hazard/Risks requiring Respiratory Health Surveillance					
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				
Animals	N				
Cytotoxic drugs	Y			X	
Risks requiring Other Health Surveillance					
Radiation (>6mSv)	N				
Laser (Class 3R, 3B, 4)	N				
Dusty environment (>4mg/m3)	N				
Noise (over 80dBA)	N				
Hand held vibration tools (=>2.5 m/s2)	N				
Other General Hazards/ Risks					
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	N				
Working in isolation	N				
Challenging behaviour	N				