NHS TAYSIDE – AGENDA FOR CHANGE

JOB DESCRIPTION

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| JOB IDENTIFICATION | Job Title | Senior Technician, Quality Assurance |
| Department(s)/Location | Quality Assurance DepartmentNHS Scotland Pharmaceutical ‘Specials’ Service / Tayside Pharmaceuticals |
| Number of job holders | Eight |

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| JOB PURPOSETo perform analytical and microbiological testing to ensure that the medicines manufactured by NHS Scotland Pharmaceutical ‘Specials’ Service (PSS) / Tayside Pharmaceuticals (TP) comply with the required specification. To provide environmental monitoring services to TP and to external NHS Tayside sites in support of manufacturing and aseptic dispensing services.   |

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| ORGANISATIONAL POSITION See Appendix 1- Organisational Chart |

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| SCOPE AND RANGENHSS PSS produces a range of over 700 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. The Quality Assurance Department ensures the quality of these medicines by:* following the principles of Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) and in compliance with BS EN ISO 9001:2015.
* testing the environment where medicines are prepared and personnel carrying out aseptic manufacture
* testing starting materials for use in manufacturing the medicines
* testing the medicines for compliance with approved specifications including sterility of sterile medicines
* carrying out documentation checks on all medicines manufactured

Number of units processed annually:* 450 starting materials
* 1200 batches of medicines analytically tested
* 4000 assays of starting materials and products
* 4600 batches of medicines released by documentation checks only
* 600 sterility tests
* 26000 media plates

 A quality assurance service is provided in support of the Pharmaceutical Services, NHS Tayside. This includes:* monitoring of aseptic dispensing environment and personnel (6 cabinets)
* calibration of thermometers and weights and temperature mapping
* testing of starting materials for use in extemporaneous dispensing
* testing of medical gas pipeline systems

 Testing is also provided to other customers:* Sterile Services Departments: environmental monitoring (NHS Tayside) and steam condensate, washer water testing (NHS Tayside and throughout Scotland via Scottish Healthcare Supplies)

The post holders undertake a range of analytical and microbiology testing and assist in the supervision of three Pharmacy Support Workers. |

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| MAIN DUTIES/RESPONSIBILITIES **Induction Standards and Code of Conduct:*** Your performance must comply with the national Mandatory Induction Standards for Healthcare Support Workers in Scotland 2009 and with the code of Conduct for Healthcare Support Workers.

**Main duties 90% of time.*** Perform chemical analysis of raw materials, in-process products and finished products, requiring technical skill and knowledge and using a wide variety of techniques and analytical instruments.
* Perform testing to Water for Injections BP standard on distilled water produced by PSS / TP’s distillation plant.
* Prepare, and where appropriate analyse, laboratory reagents for use in product and raw material testing.
* Check Production worksheets for all products to ensure they are have been completed fully and accurately. This includes checking label reconciliation, ensuring the correct materials have been used and interpreting autoclave charts to ensure sterile products have been sterilised.
* Document accurate test records for on-going trend analysis and supply results to customers.
* Check emergency drug kits used within NHS Tayside and the Scottish Ambulance Service. This involves checking of paperwork to ensure the correct drugs are present in the kits and that batch details are recorded to provide traceability in the event of a product recall.
* Plan and perform environmental monitoring of aseptic and clean rooms within PSS, TP and other areas within NHS Tayside, using specialised instrumentation and microbiological sampling techniques.
* Document out of specification microbiology results and advise on action to be taken.
* Assess goods returned by customers to confirm they are suitable for return to stock.
* Collect where possible, and test condensed steam samples from porous load autoclaves and washer water and confirm compliance to national standards.
* Carry out calibration and validation of laboratory instrumentation as per PSS / TP’s calibration schedule.
* Calibration of all thermometers used in PSS and TP and the external NHS Tayside sites covered by PSS / TP.
* Review and update existing SOP’s for all practices within the department including use of instrumentation, testing techniques and product/raw material specifications.
* Carry out temperature monitoring and mapping using thermometers or digital data loggers. Interpret data and take action when out of specification.

**Other duties 10% of time.** * Assist the Laboratory Manager in supervising and training PSWs in QA department
* Carry out routine and ad-hoc testing of medical gas pipeline systems in NHS Tayside.
* Undertake product development as assigned, designing new SOP’s to allow accurate and repeatable practice within the department
* Assess laboratory stock levels and order consumables and equipment for the department as required.
* Set up and perform stability studies to provide information on product shelf life and stability.
* Carry out validation of microbiological test methods and study effectiveness of anti-microbial preparations e.g. disinfectants and alcohol hand rubs. This involves the use of live micro-organisms.
* Assist in the training of pre-registration pharmacists, student technicians and new staff.
* In the absence of QA PSWs (see Job description for PSW):
* carry out test for sterility on finished products and bioburden test on non-sterilised samples
* disinfection of materials for sterility testing
* reading of microbiological test results
* cleaning of laboratory glassware
* sampling of raw materials
* delivery and collection of consumables from Ninewells aseptic sites
* Carry out Health and Safety and COSHH risk assessments.
* Carry out calibration of weights and balances for external NHS Tayside sites.
* Contact raw material suppliers to investigate queries regarding missing/inaccurate documentation, doubts over material quality or requests for additional shelf life information.
* Participate in monthly departmental meetings to discuss developments in PSS / TP and QA which may result in changes that will affect current practice.
* Participate in inter-laboratory assessment programme designed to test variation in test methods and results across laboratories nationwide.
* Report faults with equipment or facilities to service contractor/medical physics/estates department.
* Attend appropriate education and training events as required.
* Routine housekeeping to maintain a clean and tidy work area as part of Health and Safety and GLP
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| 6. COMMUNICATIONS AND RELATIONSHIPSThe postholder will communicate with a wide range of people, both within and outwith the organisation including:* staff within the QA team, including providing and receiving complex and technical scientific information regarding analytical interpretation and results
* Sterile/Non-Sterile Production – prioritise testing of raw materials and finished products
* Stores and Office – provide information on raw material testing results and product release schedule.
* Estates - report faults or request access to gas testing areas by phone or email.
* Aseptic units and SSD departments within NHS Tayside:
* to arrange access for environmental monitoring
* to report out of limit monitoring results and action that require to be taken.
* to discuss requirements for monitoring consumables.
* Pharmacy dispensaries and Stores within NHS Tayside - discuss temperature monitoring results and actions that may require to be taken.
* Microbiology – supplies of media and queries over organism identification
* Suppliers – queries over quality of raw materials or documentation
* Domestic services - request for non-routine cleaning requirements
* IT helpdesk - report computer faults or to aid in troubleshooting laboratory PC driven instruments
* Ninewells Supplies Customer Services Department to query orders placed through non-stock requisition

In order to communicate effectively with the above groups, the following are essential:* well developed interpersonal and communication skills, written and verbal, formal and informal.
* ability to use tact, empathy and diplomacy when dealing with departments outwith QA
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| KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOBQualifications* Degree in a relevant scientific discipline (or equivalent experience)

Experience* Previous experience of working in a quality assurance, chemistry or microbiology laboratory environment or previous experience working in a pharmaceutical / aseptic environment
* Previous experience of using analytical instrumentation such as Spectrophotometry
* Previous experience of accurate and precise weighing and measuring
* Computer literacy, familiarity with common software packages such as Microsoft Word and Excel

Knowledge* Knowledge and understanding of GMP and GLP
* Knowledge and understanding of following and developing departmental standard operating procedures
* Knowledge and understanding of Health & Safety Policies and Procedures.
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| 1. SYSTEMS AND EQUIPMENT

Highly complex equipment:* expert knowledge required to set up, operate, calibrate and train staff in the use of highly complex analytical testing equipment including:
* UV spectrophotometer
* IR spectrophotometer
* Fluorescence spectrophotometer
* Ion chromatograph
* HPLC
* Titrators
* Automatic polarimeter
* Particle counter
* Chloride meter
* Medical gas analyser
* learning how to use the above equipment requires two to three months training

**Routine equipment:*** expert knowledge required to set up, operate (if required), calibrate and train staff in the use of routine equipment including:
* electronic weigh scales
* pH meter
* conductivity meter
* burettes
* pipettes
* micrometer
* sterility testing system
* bioburden testing system
* airborne viable count sampler
* airborne particle sampler
* media plates
* data loggers
* incubators and refrigerators
* porous load pack sealer
* learning how to use the above equipment requires three to four weeks training
* basic keyboard skills and knowledge of word processing in order to produce standard worksheets and SOP’s
* operation of computerised stock control system
* operate plant machinery to collect condensed steam at the rear of autoclaves where high temperature steam is condensed to cool water. Requires training and health and safety instruction to operate safely and successfully

 **Systems the post holder will be required to operate / oversee include:** * NHS Tayside Health and Safety policies
* Departmental Standard Operating Procedures
* NHS Tayside Data Protection and Information Security Policy
* Control of Substances Hazardous to Health (COSHH)

**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 JOBPhysical Effort* Standing while carrying out a variety chemical test methods for up to 2 hours.
* Good eye sight (corrected if necessary) required in making accurate measurements repeatedly over the course of the day. To be able to determine colour changes and differentiate between small increments in colour.
* Holding arms outstretched for extended periods while pipetting accurate volumes.
* Bending and lifting heavy raw materials or equipment (once or twice a week).
* Move and negotiate heavy trolleys/pallets (a few times a week).
* Climb ladders to access gas sampling points (a few times a year).

Mental Effort* Regular demand to interpret and calculate data. This may involve arithmetic equations to calculate test results, make or check worksheet formulation changes.
* Specialised effort required to participate in development of analytical techniques and new practices throughout the department.
* Understanding the processes involved in the department and when appropriate use initiative to solve problems.

Working Conditions* Product and raw material testing involves working with a variety of chemical substances in liquid and powder form. These range from being harmless through irritant, harmful, toxic and corrosive.
* While testing product/raw materials nitrile gloves and disposable masks are requires dependant on COSHH guidelines. Special safety glasses are required at all times.
* Occasional use of computer for prolonged periods.
* While performing sterility testing or environmental monitoring in aseptic or clean rooms, non-breathable suits, hoods, gloves and close fitting mask must be worn resulting in warm uncomfortable conditions. These may be worn for up to 3 hours.
* While working in isolators in external sites tight gloves may be worn resulting constriction of the hands and awkward manipulations.
* During environmental monitoring outwith NHSS PSS, working in areas where cytotoxic and radioactive medicines have been prepared.
* While performing bioburden testing hat, mask, disposable gown and close fitting mask must be worn resulting in warm uncomfortable conditions.
* While sanitising equipment and consumables for sterility testing hat, gloves, gown and heavy, uncomfortable organic vapour mask must be worn for up to 2 hours. This is to protect form the toxic isopropyl alcohol vapour generated in the process.
* Working with distilled water at 80oC at least weekly.
* Working behind autoclaves in plant machinery area.
* Working with compressed and pipeline gases.
* Handling live cultures of micro-organisms.
* Laboratory temperatures may be high in the summer, enhanced by incubators.

Physical Skills* Manual dexterity and good hand to eye co-ordination are required when operating analytical balances for weighing materials, using pipettes and burettes to dispense accurate volumes and in using the micrometer for accurate measurements.
* Manipulate syringe, needle and proprietary kits with aseptic technique to avoid contamination with micro-organisms which would invalidate the test
* PC and keyboard skills required to interact with instrumentation and office software packages.
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ESSENTIAL ADDITIONAL INFORMATION

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| DECISIONS AND JUDGEMENTS* Follows SOPs in carrying out work in the department.
* Prioritise own workload following the product release schedule for products and productions’ demand for raw materials. Adapt to sudden priority demands and reallocate work accordingly.
* Analyse environmental results and decide on action for results out with limits.
* Make visual identification on common micro-organism isolates.
* Assess whether emergency drug kits comply with specification and whether they can be released to stock without further checks.
* Assess need for re-assay process following SOP.
* Check the work of the QA PSW’s relating to raw material acceptance before passing to QA Pharmacist.
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| MOST CHALLENGING/DIFFICULT PARTS OF THE JOB* Maintaining necessary concentration to carry out critical specialised techniques.
* Using initiative in non-routine tasks, such as developing new SOP’s and worksheets.
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|  JOB DESCRIPTION AGREEMENT * A separate job description will need to be signed off by each postholder to whom the job description applies.
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| **Job Holder’s Signature:** | **Date:** |
| **Head of Department’s Signature:** | **Date:** |

**Tayside Pharmaceuticals / NHS Scotland Pharmaceutical ‘Specials’ Service**

**Appendix 1 Organisation Chart**

