

**NHS NATIONAL SERVICES SCOTLAND**

#  JOB DESCRIPTION

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| 1. **JOB DETAILS**
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| Job Title | TCAT Quality Control Senior Analyst  |
| Immediate Senior Officer | Quality Control Manager |
| Division | SNBTS Tissues, Cells and Advanced Therapeutics (TCAT) |
| Location | Jack Copland Centre/Scottish Centre for Regenerative Medicine/Pentlands Science Park |
| CAJE Ref | NPBTCS802 |
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| **2. JOB PURPOSE** |
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| The post holder will provide a competent analytical service to permit the monitoring of the quality, sterility, purity and stability of TCAT products and controlled environments, in accordance with Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) using a wide range of complex analytical microbiological and chemical techniques. The post holder will also be expected to develop new processes and assays to support the ongoing development of QC activities and provide support to junior members of staff.  |

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| **3. DIMENSIONS** |
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| This post will be based at either the Jack Copland Centre (JCC), Scottish Centre for Regenerative Medicine (SCRM) or Pentlands Science Park (PSP).  |
| This post is integral to the efficient running of the TCAT Quality Control (QC) service with specific responsibility for all QC-related activities pertaining to products, samples and controlled environments. TCAT is composed of Associate Director, Head of QC, Manufacturing Manager(s), Production Manager(s), QC Manager(s), Production Scientist(s), QC Scientist(s) and MLA(s) in addition to senior Development staff.  |

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| **4. ORGANISATION CHART** |
| Associate Director TCAT GMP Head of QC QC ManagerSenior QC Analyst |

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| **5. ROLE OF THE DEPARTMENT** |
| The core purpose of SNBTS is to meet the transfusion needs of patients in Scotland.  In support of this, the SNBTS TCAT Department is committed to a programme that will enhance the service provided to NHS Scotland in both clinical and operational areas through the provision of various TC in addition to a range of AT.  SNBTS undertakes research, development and validation for the delivery of cellular therapies, which is designed to support the strategic and operational priorities of the organisation, achieve high quality and impact and add value to broader NHS and Governmental objectives. TCAT is the preferred provider of bone and tissue products to NHS Scotland and retrieves and processes a range of tissues from live and cadaveric donors, it also processes haematopoietic progenitor cells and is the provider of pancreatic islet cells to patients in Scotland and the North of England. SNBTS undertakes research, development and validation for the delivery of AT, which is designed to support the strategic and operational priorities of the organisation, achieve high quality and impact whilst adding value to broader NHS and Governmental objectives.   |

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| **6. KEY RESULT AREAS** |
| 1. Coordinate the environmental monitoring requirements of the manufacturing facilities to ensure compliance with Eudralex standards.
2. Perform QC checks, trending of data and QC release of GMP critical consumables required for manufacturing of TCAT products.
3. Assist in the cleaning, maintenance and housekeeping of the cleanroom and associated laboratory areas to ensure that the controlled facilities remain GMP compliant.
4. Ensure that product and environmental samples are processed, recorded and filed in an accurate and traceable manner to maintain the audit trail, transporting as appropriate between sites.
5. Assist in procedures during the QC of a range of products to ensure they are processed and stored in an efficient and safe manner. Plan and undertake the development and validation of new products/procedures and/or service developments, including the surrounding quality documentation.
6. Participate in the on-call rota to cover equipment failure and out of hours QC requirements.
7. Contribute to development projects and/or GMP translational projects as required to ensure the smooth transition of new projects into the facility.
8. Apply computer knowledge and keyboard skills to interface with the software controlling the receipt, tracking and issue of patient medical, processing and product data, ensuring that associated files are GMP compliant, kept orderly and up to date.
9. Participate in continual personal training and development as a member of a small team in a unique area of health care, ensuring up-to-date knowledge and skills.
10. Maintain a working knowledge of UK laws and regulations relating to the GMP manufacturing and QC of TCAT products and understand the requirements for these products and their clinical importance.
11. Ensure the confidentiality and security of all data relating to donors and recipients are maintained at all times.
12. Possess an understanding of the principles of the GMP quality system following appropriate training.

 1. Input of clinical and laboratory data in both paper and electronic form ensuring accuracy and legibility at all times.
2. Perform a wide range of many different, sometimes complex chemical, biochemical and microbiological tests and assays on a wide range of samples. Examples include sterility testing on TCAT product samples, examination & interpretation of environmental monitoring testing, investigation of bacterial contamination where required, flow cytometry and cell enumeration.
3. Develop, maintain and use a wide range of laboratory documentation which includes writing, reviewing and updating SOP’s and associated forms/worksheets, COSHH and risk assessments, incident & OOS reports and validation protocols/reports to ensure a consistent and controlled approach to laboratory activities and maintain GMP compliance.
4. Lead on QMS activities such as incident management, corrective action implementation and change controls, as requested.
5. Train new members of staff following established process and procedures and provide supervision to QC analysts and MLAs.
6. Carry out all duties and responsibilities according to approved SNBTS policies and procedures which are designed to comply with the EU guidelines on GMP (Eudralex Vol. IV).
7. Participate in the development of the department and take responsibility for the validation of new tests, procedures and equipment. All validation work must be fully documented including the generation and completion of change controls, user requirement specifications, validation protocols, reports and SOPs.
8. Continual development and monitoring of assays, test procedures and equipment to ensure compliance with various regulatory guidelines. Continually assess current practices to ensure best practice is used at all times. Keep up to date with regulatory changes that may impact on work performed within the area.
9. Participate in internal audits and external regulatory authority inspections to ensure inspectors are informed accurately of current practices and procedures.
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| **7. ASSIGNMENT AND REVIEW OF WORK** |
| The QC Manager generally assigns work on a weekly basis. The post holder is expected to schedule this work effectively and, if required, to ratify this with both the Head of QC and QC Manager as appropriate. The post holder, after appropriate training is expected to be able to work independently and under their own initiative, managing and prioritising their own workload. They will be expected to manage the response to unscheduled urgent samples within their own QC work schedule. The individual will be expected to QC check the work of others in accordance with current guidelines as well as sign off reports for approval. Work comes from the following sources: * QC Manager
* QC Scientist(s)
* Internal or external customers
* Self-generated

Senior QC Analysts will take an active role in team meetings where planning will be discussed. **Review:** QC Manager will review success in key result areas. Formal assessment of performance will be reviewed annually as part of TURAS. In relation to Policy and Service Development, the post holder will need to be aware of policy and service developments particularly those relating to GMP manufacturing/QC activities and Quality Management Systems.  |
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| **8. COMMUNICATIONS AND WORKING RELATIONSHIPS** |
| * Liaise with other SNBTS staff and external staff on matters affecting QC within TCAT.
* Senior QC analysts will provide and receive complex or sensitive information. This information will come from or be given to:
* Other colleagues in SNBTS i.e. QC Manager, QC Scientists, Quality Manager, QC Analysts, senior scientific staff, BMS’s, Clinical Scientists, MLAs etc.
* Medical, nursing and scientific staff receiving test results.
* External customers regarding test results, reagents, equipment etc.

The communication will be in the form of oral, written, electronically or face-to-face. |

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| **9. MOST CHALLENGING PART OF THE JOB** |
| Coordinating QC requirements within TCAT to ensure safety and efficacy of products and processing environments, while balancing all of the competing priorities of the team and multiple projects. Acting as point of contact for QC analysts and MLAs. Performing a wide range of standard analytical and microbiological tests to the required standard of control and reproducibility in a small multi-functional laboratory with relatively few other analytical staff, whilst ensuring the highest standards of reliability and performance.  |

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| **10. Systems** |
| The Microsoft Office suite is used extensively throughout the working day and competence in this, especially Word and Excel is required. The Tissue Trace/TCSTM database system used for controlling blood sample donations and is used on a weekly basis. QPulse is used for document control, incident reporting and asset management. TREND 963 and Pharmagraph systems are used on a daily basis as Building Management and Environmental Management systems respectively. Use of a Laboratory Information Management System (LIMS) for registration and management of samples received. Flow cytometry and other analyser software.  |
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| **11. WORKING ENVIRONMENT AND EFFORT** |
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| **Physical Effort**  |
| * There is a frequent requirement to exert moderate physical effort for extended periods e.g. lifting and moving boxes to and from vehicles when transferring samples between sites.
* Working in and maintaining aseptic environment to ensure sterility of final product.
* Extended working within cleanroom environments during environmental monitoring with only eyes exposed to the external environment.
* Physical skills include repetitive activities such as pipetting and colony counting of bacteria.
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| **Mental Effort**  |
| * Frequent requirement for intense concentration within the work period. Post holder is involved in making decisions relating to GMP manufacturing, reporting results of environmental monitoring and QC assays all of which will have a bearing on final product outcome.
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| **Emotional Effort** |
| * Stress may be encountered when dealing with tight QC deadlines, particularly when sample analysis is required to facilitate product release within a finite time period to patients. There may also be confrontational issues when discrepant or erroneous results occur.
* Occasional exposure to distressing or emotional circumstances e.g. receiving information on patient medical conditions, information pertaining to cadaveric tissue/cell donations.
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| **12. ENVIRONMENTAL / WORKING CONDITIONS & MACHINERY AND EQUIPMENT** |
| * Frequent exposure to hazardous working conditions, including:

- Working for periods in cold environments -40°C to -80°C. - Working with protective gloves handling frozen products and reagents. - Working with dry ice and liquid nitrogen. - Working for long periods under class A and B clean room conditions * Frequent use of VDUs, microscopes and a variety of specialised laboratory equipment on a daily basis.
* Direct contact with untested blood samples and tissues.
* Handling blood samples and tissues known to be HIV, Hepatitis B or Hepatitis C positive.
* Processing and disposal of tissues/cells known to be positive for virology markers or microbiological contaminants.
* Responding to call outs during the night and weekends to cover equipment failures.
* Working in an analytical environment necessitates exposure to a variety of hazards on a daily basis. These include chemicals (corrosive, poisons, flammable, toxic and harmful) and gases (flammable, compressed, explosive and asphyxiating).
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| **13. QUALIFICATIONS AND/OR EXPERIENCE SPECIFIED FOR THE POST** |
| * Required to hold as a minimum a degree or equivalent in a relevant scientific discipline.
* Demonstrable experience resulting in specialist knowledge of a range of procedures and processes in either an analytical chemistry or biological analysis laboratory working to GMP and/or GLP standards.
* Must undertake Continuous Professional Development within this specialism to maintain knowledge relevant to the requirements of analytical techniques.
* A clear understanding of how to operate under the constraints of GMP and GLP.
* Must be able to work effectively as part of a small team.
* Computer literacy and standard keyboard skills.
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| **14. JOB DESCRIPTION AGREEMENT** |
| A separate job description will need to be signed off by each jobholder to whom the job description applies. |
| Postholder Signature |  | Date |  |  |
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| Postholder Print |  |  |  |  |
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| Manager Signature |  | Date |  |  |
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| Manager Print |  |  |
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| Manager Title |  |  |
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