

 **NHS NATIONAL SERVICES SCOTLAND**

# JOB DESCRIPTION

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| **1. JOB DETAILS** |
| **CAJE Ref. No: BTC G026**  |
| Job Holder |  |
| Job Title | Medical Laboratory Assistant (AFC Band 3) |
| Immediate Senior Officer | Production/QC Manager |
| Division | Tissues, Cells and Advanced Therapeutics (TCAT) |
| Location | Jack Copland Centre (JCC) / Scottish Centre for Regenerative Medicine (SCRM) / Pentlands Science Park (PSP) |
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| **2. JOB PURPOSE** |
| Perform specific procedures and tasks under the supervision of qualified staff to ensure the efficient functioning of the Good Manufacturing Practice (GMP) facility and manufacturing of TCAT products within an agreed time frame.  |
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| **3. DIMENSIONS** |
| 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 TCAT and as such has specific responsibilities for daily housekeeping activities required for the effective operation of the department. TCAT GMP work across several manufacturing and QC facilities and is composed of a variety of Production and QC staff, in addition to senior Development staff.  |
| **4. ORGANISATION CHART** |
| MLAProduction/QC ManagerManufacturing Manager |
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| **5. ROLE OF THE DEPARTMENT** |
| The core purpose of the Scottish National Blood Transfusion Service is to meet the transfusion needs of patients in Scotland.  In support of this, the SNBTS TCAT Directorate is committed to a programme that will enhance the service provided to NHS Scotland in both clinical and operational areas.  SNBTS undertakes research and development 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 manufacture to GMP within the JCC or SCRM. These state of the art cleanroom facilities are licensed by both the HTA and MHRA for the manufacture of tissue, cells and advanced therapeutics for both routine clinical use and first in man/Phase I/II clinical trials. TCAT also performs QC testing at both sites in addition to PSP. |
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| **6. KEY RESULT AREAS** |
| * Assist in the cleaning, maintenance and environmental monitoring of the cleanroom and associated laboratory areas to ensure compliance with Eudralex standards.
* Ensure that tissue/cell and patient samples are processed, recorded and filed in an accurate and traceable manner to maintain the audit trail.
* Assist in aseptic processing, following Standard Operating Procedures (SOPs) during the manufacturing of a range of products to ensure they are processed and stored in an efficient and safe manner.
* Assist in the transport of laboratory samples, consumables, environmental monitoring plates, products and equipment between JCC, SCRM and other hospitals as appropriate.
* Participate in the on-call rota to cover equipment failure and out of hours processing/issue requirements.
* Will be aware of policy and service developments.
* Contribute to R&D projects and/or GMP translational projects as required.
* Computer knowledge and keyboard skills are necessary to interface with the software controlling the receipt, tracking and issue of patient medical, processing and product data and ensuring that associated files are GMP-compliant, kept orderly and up to date.
* Ensure consumables (e.g. reagents, plastics, cleanroom clothing) are maintained at adequate stock levels and prepared for QC release to ensure the smooth operation of manufacturing procedures.
* Ensure laboratory equipment and supplies are kept in a secure area, performing routine QC checks and liaising with the Frontline team as appropriate regarding PPM/calibration.
* Perform daily housekeeping duties associated with a GMP facility, recording critical facility parameters where appropriate.
* Participate in continual personal training and development as a member of a small team in a unique area of health care.
* Have a working knowledge of UK laws and regulations relating to the GMP manufacturing of tissue, cell and advanced therapeutic products and understand the requirements for these products and their clinical importance.
* Ensure the confidentiality and security of all data relating to donors and recipients are maintained at all times.
* Possess an understanding of the principles of the GMP quality system.
* Input of clinical and laboratory data in both paper and electronic form.
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| **7. ASSIGNMENT AND REVIEW OF WORK** |
| * MLAs are guided by SOPs and good practice, and whilst they are supervised by other scientific staff, they may work for long periods without direct supervision.
* Work comes from the following sources:
	+ Line manager or other senior scientific staff
	+ Internal or external customers
	+ Self generated
		- MLAs will take an active role in team meetings where planning will be discussed.

**Review:** Production/QC Manager will review success in key result areas. Formal assessment of performance will be reviewed annually as part of eKSF. |
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| **8. COMMUNICATIONS AND WORKING RELATIONSHIPS** |
| * Liaise with other SNBTS staff on matters affecting their service agreements with TCAT.
* MLAs will provide and receive complex or sensitive information. This information will come from or be given to:
	+ Other colleagues in SNBTS i.e. Production/QC Manager, Quality Manager, senior scientific staff, Production/QC Scientists, Clinical Scientists, MLAs etc.
	+ External medical, nursing and scientific staff.
* 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**  |
| Assisting in TCAT to ensure the efficient functioning of all aspects of manufacturing. Balancing all of the competing processing requirements of multiple projects with tight timescales, whilst performing daily housekeeping requirements within the GMP facilities. |
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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 TraceTM or MAK 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 or Environmental Management systems respectively. |
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| **11. WORKING ENVIRONMENT AND EFFORT** |
| **Physical Effort** |
| * There is a frequent requirement to exert moderate physical effort for extended period’s e.g. lifting and moving boxes to and from vehicles when transferring between sites.
* Working in and maintaining aseptic environment to ensure sterility of final product.
* Extended working within cleanroom environments with only eyes exposed to the external environment.
* Regularly driving to deliver or pick up samples, consumables or equipment from other SNBTS/hospital sites.
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| Mental Effort |
| * There is a frequent requirement for intense concentration within the work period.
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| **Emotional Effort** |
| * Regular 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.
* 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.
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| **13. QUALIFICATIONS AND/OR EXPERIENCE SPECIFIED FOR THE POST** |
| * The post-holder should have an interest in Biomedical Science; experience within this environment would be advantageous although not essential, as full in-house training will be given.
* The post requires base level knowledge and experience of a range of work practices and procedures. This requires on the job training from six months to one year to SVQ/NVQ level 3 equivalence.
* Experience in working in a GMP environment would be advantageous.
* After suitable training they must maintain specialist knowledge across a range of work procedures and practices that must be underpinned by theoretical knowledge of relevant practical experience.
* Must be able to work effectively as part of a small team.
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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. |
| Job Holder’s Signature |  | Date |  |  |
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| Head of Department |  |  |  |  |
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| Signature |  | Date |  |  |
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| Title |  |  |
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| HR Department will check job description format and content and then send the job description to the AfC Team |
| HR Representative’s Signature |  |  |
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| Date Job Description Agreed: |  |  |
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