

**NHS NATIONAL SERVICES SCOTLAND**

#  JOB DESCRIPTION

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| **1. JOB DETAILS** |
| Job Title | **TCAT Production Scientist** |
| Immediate Senior Officer/ Line Manager | Production Manager |
| Department | Tissues, Cells and Advanced Therapeutics |
| SBU | SNBTS |
| Location | Jack Copland Centre/Scottish Centre for Regenerative Medici |
| CAJE Reference | BTCG105 |
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| **2. JOB PURPOSE** |
| To provide the technical and scientific support to the Tissues, Cells and Advanced Therapeutics (TCAT) Jack Copland Centre (JCC) / Scottish Centre for Regenerative Medicine (SCRM) GMP facilities to allow the safe provision of efficacious tissues, cells and advanced therapeutic products on a timely basis, meeting all appropriate quality and regulatory standards. To develop the TCAT GMP manufacturing service in line with future products/clinical trials. |
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| **3. DIMENSIONS** |
| This post will be based at either JCC or SCRM.This post is integral to the efficient running of the TCAT Manufacturing service with specific responsibility for the GMP manufacture of a range of tissues, cells and advanced therapeutic products. The department is composed of Head of Manufacturing, Manufacturing Managers, Production Managers, QC Managers, Production Scientists, QC Scientists and MLAs.  |

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| **4. ORGANISATION CHART** |
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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 use in first in man/Phase I/II clinical trials.  |

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| **6. KEY RESULT AREAS** |
| 1. Manufacture a range of tissues, cells and advanced therapeutics and participate in procurement and aseptic cleanroom procedures as required to provide safe and efficacious products according to GMP, to meet the appropriate regulatory standards and the requirements of clinical trials.
2. Store and dispatch products according to standard operating procedures.
3. Contribute to the cleaning, environmental monitoring, equipment maintenance and housekeeping of the cleanroom and associated laboratory areas to ensure that the facilities remain GMP compliant at all times.
4. Coordinate, through communication with source hospitals/testing laboratories, the receipt and processing of tissues/cells, samples and documentation from donation through to transplant, to ensure the maintenance of the product audit trail.
5. Assist with the continual review of manufacturing procedures, including the maintenance and review of standard operating procedures to incorporate new technology/standards to ensure continued licensing by the HTA and MHRA.
6. Ensure the confidentiality and security of all data relating to donors and recipients is maintained at all times.
7. To be familiar with the aims, policies and future plans for the SNBTS TCAT directorate.
8. Maintain a working knowledge of UK laws and regulations relating to the GMP manufacture of tissues, cells and advanced therapeutic products and understand the requirements for these products and their clinical importance.
9. Maintaining an awareness of appropriate scientific literature so that work is carried out according to up-to-date knowledge and practice.
10. Plan and undertake the development and validation of new products/procedures and/or service developments.
11. Safe use of complex laboratory equipment.
12. Make a positive effort to promote his/her own personal safety and that of others by taking reasonable care at work, by carrying out the requirements of the law or following recognised codes of practice provided or advised by management to ensure safe working.
13. The presentation of data at local, national and international level.
14. Participate in the on-call rota to cover equipment failure and out of hours processing/issue requirements.
15. Contribute to R&D projects and/or GMP translational projects as required to ensure the smooth transition of new projects into the facility.
16. 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.
17. 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.
18. Input of clinical and laboratory data in both paper and electronic form ensuring accuracy and legibility at all times.
19. 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, change controls and validation protocols/reports to ensure a consistent and controlled approach to laboratory activities and maintain GMP compliance.
20. 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).
21. 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** |
| * Weekly meetings with be held and tasks set in discussion with the Production Manager.
* Monthly team meetings will be held with all staff to discuss ongoing workload, setting goals and objectives.
* Following appropriate training, the post holder must be able to work independently and unsupervised.
* **Review:** Production Manager will review success in key result areas. Formal assessment of performance will be reviewed annually.
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| **8. COMMUNICATIONS AND WORKING RELATIONSHIPS** |
| * Liaise with other SNBTS staff regarding the day to day housekeeping of the manufacturing facilities.
* The postholder will provide and receive complex and/or sensitive information. This information will be in the form of oral, written, electronic or face-to-face and come from or be given to:
	+ Other colleagues in SNBTS i.e. TCAT Associate Director, Head of Manufacturing, Production Managers, QC Manager, Quality Manager, senior scientific staff, BMS’s, Clinical Scientists, QC Scientists, MLAs etc.
	+ Internal and external medical, nursing and scientific staff to advise end-users on quantity / quality & effective use of tissues, cells and advanced therapeutic products and to arrange their timely delivery.
	+ External customers and regulatory authorities regarding test results, products, reagents, equipment etc.
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| **9. MOST CHALLENGING PART OF THE JOB**  |
| Participating in complex and laborious manufacturing procedures to ensure safety and efficacy of products and processing environments, while balancing all of the competing priorities of the team and multiple projects.Although the ultimate objectives of research projects are defined at the start, the steps towards achieving these may not be obvious, even to an individual experienced in the field. This requires an ability to think creatively and develop innovative and possibly unconventional approaches to solving specific problems as well as a degree of self-confidence and effective communication with both peers and managers. Working to tight deadlines and budgets is also an important challenge. Therefore it is important that the individual can work to defined targets. |
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| **10. Systems** |
| Experimental data is processed and analysed using statistical packages supplied on the software provided on the PC workstations and on software purchased for specific applications. The post holder will be expected to be proficient in the use of spreadsheets and databases for the storage, manipulation and presentation of experimental data. Includes creation and maintenance of databases containing records of transplants/infusions, stock records of chemicals; records of cells stored in liquid nitrogen. Specifically:* Will be trained to use the NSS Financial Information System (PECOS) for the requisition and receipt of goods/services.
* The Microsoft Office suite is used extensively throughout the working day and competence in this, especially Word and Excel is required.
* The TCSTM database system is used for managing tissue, cells and advanced therapeutics on a weekly basis.
* QPulse is used for document control, incident reporting and asset management on a daily basis.
* TREND 963 and Pharmagraph EnVigil systems are used on a daily basis as Environmental Management and/or Particulate Monitoring systems respectively.
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| **11. WORKING ENVIRONMENT AND EFFORT** |
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| **Physical Effort** |
| There is a frequent requirement for prolonged sitting in a restricted position:* At microscopes observing cells in culture.
* Extended working within cleanroom environments at Microbiological Safety Cabinets maintaining aseptic environment to ensure sterility of final product, with only eyes exposed to the external environment.
* Physical skills include repetitive activities such as pipetting and dissection/processing of human tissue/cells.
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| Mental Effort |
| * Frequent requirement for intense concentration within the work period.
* There is need to respond to the unpredictable nature of a biological product and adapting to the many changes in working practice in a rapidly developing speciality.
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| **Emotional Effort** |
| * Stress may be encountered when dealing with tight manufacturing deadlines. 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, participation in cadaveric tissue procurement.
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| **12. ENVIRONMENTAL / WORKING CONDITIONS & MACHINERY AND EQUIPMENT** |
| * Frequent exposure to hazardous working conditions, including:
	+ Handling samples in cold environments such as -40°C to -80°C freezers.
	+ 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.
* 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/out of hours manufacturing requirements.
* 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 an honours degree in an appropriate biological science or equivalent training.
* Demonstrable experience resulting in specialist knowledge of a range of procedures and processes in the GMP manufacture of tissues, cells and advanced therapeutic products.
* Must undertake Continuous Professional Development to maintain knowledge relevant to the requirements of GMP tissue, cell and advanced therapeutic manufacturing.
* The ability 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 postholder 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 Title: |  |  |
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