

**NHS NATIONAL SERVICES SCOTLAND**

#  JOB DESCRIPTION

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| **1. JOB DETAILS** |
| Job Title | Associate Director, Tissues Cells and Advanced Therapeutics: Manufacturing |
| Immediate Senior Officer | Director, SNBTS. |
| Division | SNBTS  |
| Location | Jack Copland Centre (JCC) |
| CAJE Ref | BTCS519R |
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| **2. JOB PURPOSE** |
| To lead the SNBTS Tissues, Cells and Advanced Therapeutics (TCAT) manufacturing programme to allow the provision of safe and efficacious products for patient care/clinical trials on a timely basis, meeting all appropriate quality and regulatory standards. To manage the Good Manufacturing Practice (GMP) translation, validation and release of multiple novel projects/products across two manufacturing facilities licensed by the Human Tissue Authority (HTA), Human Fertilisation and Embryology Authority (HFEA) and Medicines and Healthcare Regulatory Authority (MHRA). To provide senior management for the MHRA-accredited Quality Control (QC) testing service for TCAT and external customers. |
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| **3. DIMENSIONS**This post will be based at JCC, with specific responsibility for all aspects of TCAT manufacturing and QC across three sites (SCRM, JCC and Pentlands Science Park) compromising a total of 10 clean rooms, Grade B-D and 3 QC laboratories).  |
| Manufacture of TCAT products involves a combination of permanent and grant-funded staff posts, with a total team of >60 staff. This post has overall responsibility for all GMP-related activities pertaining to the manufacture of TCAT products; from initial GMP translation through to routine clinical manufacture, QC and Qualified Person (QP) release. Core budget responsibilities for TCAT manufacture are in the region of £500,000 (Goods & Services), with additional responsibility for expenditure against project grants (usually £500,000 to £1,000,000 for a Phase I/II clinical trial). Specific line management responsibility for the TCAT senior manufacturing and QC management team (Manufacturing Manager(s), Head of TCAT QC and Head of TCAT Operations).  |

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| **4. ORGANISATION CHART**Director, SNBTSManufacturing Managers: TCATHead of TCAT QC **Assoc. Dir. TCAT Manufacturing****(this post)**Head of TCAT Operations |
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| **5. ROLE OF THE DEPARTMENT** |
| The core purpose of the Scottish National Blood Transfusion Service is to meet the transfusion and transplantation 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, development and validation for the delivery of TCAT, 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. SNBTS TCAT is organised into units addressing basic research, translation and manufacturing of cellular and tissue therapies. The department interfaces with the main research intensive Scottish Universities in Edinburgh, Glasgow, Aberdeen and Heriot Watt and with partner organisations such as the Cell and Gene Therapy Catapult.  SNBTS AT also works in partnership with other research-active divisions of NSS, wider NHS Scotland and with other UK Blood Services in order to ensure clinical relevance and efficient use of resources.TCAT products are manufactured to GMP at both the SCRM and JCC. These state of the art clean room facilities are licensed by both the MHRA and HTA for the GMP translation of novel AT for use in clinical trials and routine clinical use. 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.  |

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| **6. KEY RESULT AREAS** |
| 1. Responsible for the management of all TCAT manufacturing and QC to ensure that procedures, equipment and facilities are operated according to GMP. The manufacturing and QC group currently comprises >30 staff across three sites.
2. Line management of key senior management team involved in the production and QC of TCAT products .
3. Long term strategic planning (5 years +) of the content and output of the manufacturing programme for TCAT in conjunction with the Director SNBTS. This includes liaising with internal and external colleagues at the highest level
4. Coordinate and implement the manufacturing and QC strategy for a range of TCAT products across both sites to meet the appropriate regulatory standards and the requirements of clinical trials, deploying staff resource as appropriate. The post holder has considerable freedom of action in formulating delivery plans including re-scheduling work to fit with changing priorities.
5. Interpret and evaluate results and assess product quality through the application of legal, scientific and clinical knowledge. Apply outcome of this analysis to allow products to be released for clinical use.
6. Chair and participate in a range of meetings with internal and external colleagues to ensure the effective management of staff, facilities and projects.
7. Be responsible for the continual review and development of manufacturing procedures to incorporate new technology/standards to ensure continued licensing by the MHRA and HTA. Lead on formulating manufacturing policy and improvement in response to regulatory change.
8. Be responsible for ensuring the confidentiality and security of all data relating to donors and recipients is maintained at all times by staff.
9. Maintain a thorough knowledge of EU & UK laws and regulations relating to the GMP manufacture and batch certification of TCAT products, and the complex regulatory pathway required for both clinical trials and proceeding to marketing authorisation.
10. Maintain an awareness of appropriate scientific literature so that work is carried out according to up-to-date knowledge and practice.
11. Manage implementation of NSS policy and implement changes to working practice as appropriate.
12. Be responsible for the implementation and validation of new products/procedures and/or service developments.
13. Responsible for managing the manufacturing and QC budgets from both NSS (circa £500k per year) and grant funds (up to £1 million over the life of the grant). Responsible for directing sourcing, costing & purchase of physical assets. Authorised signatory for payment of on-call / out of hours claims & expenses.
14. Responsible for the compilation of management & activity statistics including regulatory compliance reporting within SNBTS.
15. Senior project management for the manufacturing and QC groups in coordinating the transition of GMP translational projects to ensure the smooth transition of new product manufacture into the facility to the appropriate regulatory standards.
16. Participate in continual personal training and development as the head of a team in a unique area of health care, ensuring up-to-date knowledge and skills.
17. Develop, maintain and use a wide range of GMP documentation which includes writing, reviewing and approving SOPs, forms/worksheets, COSHH/H&S/GxP risk assessments, incident & OOS reports, change controls and validation protocols/reports to ensure a consistent and controlled approach to maintain GMP compliance.
18. Ensure staff 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).
19. Lead for SNBTS TCAT in internal audits and external regulatory authority inspections to ensure inspectors are informed accurately of current practices and procedures.
20. Lead for TCAT manufacturing in the formulation and submission of grant applications and manuscripts for publication to secure external funding for, and disseminate findings from clinical trials of ATs respectively; liaising with colleagues within SNBTS and/or University/NHS as appropriate.
21. Responsibility for the Health and Safety of all staff within the department, ensuring conformance to policy and procedure as appropriate to ensure a safe working environment.
22. Interpret, troubleshoot and advise on relevant test results. Report to and discuss test results with relevant scientists or clinicians.
23. Participate in the teaching and training commitments of the SNBTS and other establishments as appropriate. This will involve the preparation and presentation of lectures/tutorials to SNBTS and other NHS staff, external University students and presentation of work at national and international scientific conferences.
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| **7. ASSIGNMENT AND REVIEW OF WORK**The post holder reports directly to the Director SNBTS with whom high level objectives are agreed each year with formal mid-year and year-end reviews. The post holder will provide expert input on matters of cell culture, regulatory compliance, and process validation. These objectives include deliverables that form part of the SNBTS RDI KPIs and annual business plan. The work of the post holder also has organisation-wide impact, leading on the use and validation of clean room facilities, including the Tissues and Cells function of TCAT.The post holder works autonomously in developing detailed work plans to deliver these objectives. This requires judgement and flexibility in responding to unpredictable and competing demands that have significance for service delivery. The post holder will agree objectives with their direct reports annually and will appraise their performance and personal development plans at mid-year and year-end.The post holder will operate in full compliance with statutory and regulatory requirements including the NSS and CSO Research Governance Policy and Standards, the Health and Safety at Work Act; the Data Protection Act.The post holder will participate in addressing any staff issues that arise, as part of the TCAT senior management group |
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| **8. COMMUNICATIONS AND WORKING RELATIONSHIPS** |
| * Liaise with a range of SNBTS staff and other NHS, University, Commercial and Regulatory Authority staff on a range of issues relating to the manufacture of TCAT products to GMP.
* 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. SNBTS Medical Director, QP(s), Manufacturing Manager(s), Production Manager(s), Head of TCAT QC, QC Manager(s), Head of TCAT Operations, QA/Regulatory Associate Director and Manager(s), senior scientific staff, BMSs, Clinical Scientists, QC analysts, HCSWs etc.
	+ Internal and external medical, nursing and scientific staff to advise end-users on quantity / quality & effective use of TCAT products and to arrange their timely delivery. Modify manufacturing schedule and allocate staff resource in order to accommodate the fluctuating requirements of clinicians pertinent to patient need.
	+ External customers and regulatory authorities regarding complex test results, products, reagents, equipment, inspections and procedures etc.
	+ University colleagues up to and including professorial level, regarding the GMP translation of novel ATs, grant applications, manuscript preparation and teaching as appropriate.
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| **9. MOST CHALLENGING PART OF THE JOB**  |
| Coordinating complex and laborious manufacturing schedule and staff resource across three sites to ensure the provision of safe and effective TCAT products and QC services for patients, and regulatory compliance of manufacturing environments; whilst balancing all the competing priorities of the teams and multiple projects.Although the ultimate objectives of research projects and clinical trials 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 strategic targets. |
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| **10. Systems**The post holder will be expected to be proficient in the use of spreadsheets, databases and presentation packages for the storage, manipulation and presentation of experimental data. Includes creation and maintenance of databases containing records of transplants/infusions, clinical trial data, procedure and facility parameters, materials, products and test results, records of products/cells stored in liquid nitrogen. Will be ultimately responsible for co-ordinating the receipt, storage and reporting of investigations on samples and products for specialist investigation and analysis, including the appropriate storage and maintenance of records.Specifically:* As a delegated budget holder and line manager, use of the NSS Financial Information System (PECOS) for the requisition and receipt of goods/services and HR programs (SSTS, ESS, KSF) respectively.
* The Microsoft Office suite is used extensively throughout the working day and competence in this, especially Word, Excel and Powerpoint is required.
* The Mak TCS database system is used for controlling blood sample testing and the design, testing and validation of new modules for the complete audit trail of TCAT products and services.
* QPulse is used for document control, incident management and other QMS functions on a daily basis.
* TREND 963 and Pharmagraph systems are used on a daily basis as Building Management and Environmental Management systems respectively.
* A range of bespoke software for the control of specific equipment and facilities used in the manufacture of TCAT products.
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| **11. WORKING ENVIRONMENT AND EFFORT****Physical Effort**There is a frequent requirement for prolonged sitting in a restricted position which can include:* At PC workstation on a daily basis.
* At microscopes observing cells in culture.
* At analytical equipment (Flow Cytometer, Sysmex).
* Occasional working within clean room environments with only eyes exposed to the external environment.

Mental Effort* Frequent requirement for intense concentration within the work period. Post holder makes daily decisions relating to a range of staff, facilities, manufacture and release of multiple products for a range of patients.
* There is need to respond to the unpredictable nature of a biological product in a clinical trial and adapting to the many changes in working practice in a rapidly developing speciality.

**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, information pertaining to cadaveric tissue/cell donations.
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| **12. ENVIRONMENTAL / WORKING CONDITIONS & MACHINERY AND EQUIPMENT** |
| * Occasional exposure to hazardous working conditions, including:
	+ Handling samples in cold environments such as -20°C to -80°C freezers
	+ Working with protective gloves handling frozen products and reagents.
	+ Working with dry ice and liquid nitrogen.
	+ Working under class A and B clean room conditions
* Daily use of VDUs.
* Occasional use of microscopes and a variety of specialised manufacturing/QC equipment.
* Occasional contact with untested blood samples and tissues.
* Very occasionally processing samples and disposal of tissues/cells known to be positive for virology markers or microbiological contaminants.
* Very occasionally advising and supporting staff during the night and weekends to cover equipment and manufacturing/QC failures.
* Exposure to a variety of hazards on an occasional basis. These can 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 and an appropriate post-graduate qualification or equivalent expert knowledge base gained from relevant experience.
* Demonstrable substantial experience resulting in specialist knowledge of a range of procedures and processes in the GMP manufacture and QC of TCAT products (tissue, cellular therapy products, ATMPs).
* Demonstrable substantial experience in the QC, QA and regulatory aspects of AT manufacture.
* Extensive experience in supervision/management and the ability to motivate the TCAT manufacturing and QC teams to work efficiently and effectively in order to deliver a complex and novel clinical service.
* Must undertake Continuous Professional Development to maintain knowledge relevant to the requirements of GMP TCAT manufacturing and QC.
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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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