Guy's and St Thomas' NHS
NHS Foundation Trust

JOB DESCRIPTION

1. General Information

JOB TITLE: Advanced Therapy Quality Scientist

GRADE: Band 6

DEPARTMENT: ATMP GMP Unit

HOURS: 37.5

RESPONSIBLE TO: Head of Advanced Therapy Quality

ACCOUNTABLE TO: Head of Advanced Therapy Quality

Guy's and St Thomas' NHS Foundation Trust

Guy's and St Thomas' is one of the largest hospital trusts in the country, with around 12,500 staff; an annual turnover of more than £1 billion; and 1.6 million patient contacts a year. Our hospitals have a long and proud history, dating back almost 900 years, and have been at the forefront of medical progress and innovation since they were founded. We continue to build on these traditions and have a reputation for clinical, teaching and research excellence.

We provide a full range of hospital services for our local communities and - from April 2011 – have integrated community services in Lambeth and Southwark into the Trust. We also provide specialist services for patients from further afield, including cancer, cardiac, kidney, women's and orthopaedic services, and we are home to the Evelina Children's Hospital. See www.guysandstthomas.nhs.uk

As an organisation we are committed to developing our services in ways that best suit the needs of our patients. This means that some staff groups will increasingly be asked to work a more flexible shift pattern so that we can offer services in the evenings or at weekends. We also have a positive approach to corporate social responsibility and are keen to engage our staff in an agenda that ranges from promoting environmental sustainability to the creation of local employment opportunities.

We are part of King's Health Partners Academic Health Sciences Centre (AHSC), a pioneering collaboration between one of the world's leading research-led universities and three of London's most successful NHS Foundation Trusts. Our AHSC is one of only five in the UK and consists of

King's College London and Guy's and St Thomas', King's College Hospital and South London and Maudsley NHS Foundation Trusts.

Across the AHSC we see around 3 million patients a year; have 30,000 staff; 20,000 students; and a combined annual turnover of £2.6 billion. Our AHSC brings together the best of basic and translational research, clinical excellence and world-class teaching to deliver groundbreaking advances in physical and mental healthcare. See www.kingshealthpartners.org

Department Information:
Guy's & St Thomas' NHS Foundation Trust (GSTFT) and King's College London (KCL) have formed an established centre for medical research. The centre has a strong focus on translational research taking advances in basic medical research out of the laboratory and into the clinical setting, forming a key part of the Department of Health's new strategy for research and development in the NHS. The Good Manufacturing Practice (GMP) Unit is co-located with the Clinical Research Facility (CRF) at Guy's Hospital. The GMP Unit is purpose built for the manufacture of somatic cell therapies, gene therapies and proteins for early-phase clinical trials. It is used by staff from different departments within GSTFT and KCL to manufacture products related to trials undertaken in the CRF and at trial sites across the UK.

Organisational Values:

Our **values** help us to define and develop our culture, **what we do** and **how we do it**. It is important that you understand and reflect these values throughout your employment with the Trust.

The post holder will:

- **Put patients first**
- **Take pride in what they do**
- **Respect others**
- **Strive to be the best**
- **Act with integrity**

Our values and behaviours framework describes what it means for every one of us in the Trust to put our values into action. The framework can be found on our Trust careers pages and GTIntranet .

2. Job Summary

Within the United Kingdoms regulatory landscape there are only a few licensed Advanced Therapeutic Medicinal Production Units for the manufacture of somatic cell and gene therapy products. The position on offer allows the applicant a unique opportunity to become involved in cutting edge translational research at the interface between science and clinical medicine.

The post holder will be responsible for the in-process and quality control analysis, and Quality Assurance activities for cell therapy and gene therapy products.

The position includes taking responsibility for developing and implementing independently: Product Specification Files (PSFs), Quality Control Worksheets and Standard Operating Procedures (SOPs) for quality activities in the GMP Unit.

The post-holder will work independently making informed decisions relating to analytical activities as delegated by the Head of Advanced Therapy Quality to create procedures to ensure compliance with government legislation and Trust requirements.

The post-holder will ensure that all products are tested and stored according to appropriate rules and guidelines helping to ensure products are fit for their intended use with respect to safety and quality by undertaking specialist tests to maintain quality standards. The suitability of product specifications will be maintained by the post-holder using Product Quality Review tools in accordance with Quality Risk Management principles.

3. Key Relationships

Head of Advanced Therapy Quality, Head of Advanced Therapy Production, Advanced Therapy Production Scientsts, Trial Investigators, EU Qualified Persons, Consultants and Junior Medical Staff, Nursing Staff, Clinical Nurse Specialists, Allied Health Professionals, Administrative and Clerical Support Staff, Researchers and Healthcare Scientists.

4. Duties and Responsibilities

4.1. Professional / Clinical responsibilities

- Lead in the testing of clinical grade gene and cell therapy products as determined by the clinical need of participants on current clinical trials as delegated by the Head of Advanced Therapy Quality.
- To ensure that the products tested, documented and stored according to product specification and quality standards, and regulatory authorisations.

4.2. Management and Leadership responsibilities

- Attend and lead in presenting research and specialist technical knowledge at: lab meetings, seminars and national or international meetings where deemed appropriate.
- Share with others research and specialist technical knowledge related to the organisation, running and maintenance of the GMP unit.
- Work independently to undertake specialist tests and make informed decisions relating to products manufactured in the GMP Unit.
- Work independently to undertake specialist Validation and Qualification for the GMP Unit and its Equipment as delegated by the Head of Advanced Therapy Quality.

4.3 Testing Responsibilities:

- Using specialist experience in cell manipulation and processing for clinical use develop testing methods involving: flow cytometry; proliferation methodologies; nucleic-acid techniques; standard phamacopoeial methods for sterility, endotoxin, and mycoplasma detection.
- To work collaboratively with internal and external customers to undertake assay validation work within the GMP Unit to optimise procedures under GMP conditions and provide data for application to the regulatory authorities.
- To work collaboratively with internal and external customers to collate test data within the GMP unit to finalise the analytical procedure under GMP conditions and provide data for application to the regulatory authorities.
- To test cellular therapies under GMP conditions for use in clinical trials or as directed by a commercial organisation as the named contracted manufacturer.
- Maintain, operate, and clean the GMP Unit's Equipment and facilities in compliance with Unit's defined procedures and standards.
- Qualify, process validate and re-validate equipment and GMP procedures successfully and on schedule according to the Unit's Validation Master Plan.
- Monitor and control the GMP Quality Control environment to ensure that standards of cleanliness and hygiene are maintained.
- Ensure all waste generated is subject to appropriate management and disposal.

4.4 Quality Assurance Responsibilities

- Where directed or delegated by the Head of Advanced Therapy Quality assist in Quality Assurance activities relating to allocated projects, including Product Quality Review, and statistical analysis of compiled results.
- Take on delegated responsibility for quality review of Batch Manufacturing Records and other production records in support of certification and release of gene and cell therapy products.
- Lead laboratory investigations relating to out of trend and out of specification results.

- Manage deviations appropriately using quality assurance tools such as planned deviations, change control systems and quality exception reporting and investigations.

4.5 Documentation Responsibilities:

- Using specialist knowledge, write SOPs relating to specific GMP Unit operations. These SOPs must comply with GMP and the Unit's manufacturing licence. Issue documents through the Unit's Q-Pulse document control systems.
- Using specialist knowledge, undertake the development and generation of product specific SOP's and batch specific documentation.
- Using specialist knowledge, undertake the development and generation of Product Specification Files for manufacture.

4.6 Information management responsibilities

- Play a major role in generating data and for the application to the regulatory authorities for Clinical Trial Authorisation.
- Actively interpret data and participate in writing up the results of the project for publication.
- Use specialist knowledge to archive and store appropriately and securely information in accordance with Data Integrity policies and procedures.

The post holder is required to follow Trust policies and procedures which are regularly updated including:

Confidentiality / Data Protection / Freedom of Information

Post holders must maintain the confidentiality of information about patients, staff and other health service business in accordance with the Data Protection Act of 1998. Post holders must not, without prior permission, disclose any information regarding patients or staff. If any member of staff has communicated any such information to an unauthorised person, those staff will be liable to dismissal. Moreover, the Data Protection Act 1998 also renders an individual liable for prosecution in the event of unauthorised disclosure of information.

Following the Freedom of Information Act (FOI) 2005, post holders must apply the Trust's FOI procedure if they receive a written request for information.

Information Governance

All staff must comply with information governance requirements. These includes statutory responsibilities (such as compliance with the Data Protection Act), following national guidance (such as the NHS Confidentiality Code of Practice) and compliance with local policies and procedures (such as the Trust's Confidentiality policy). Staff are responsible for any personal information (belonging to staff or patients) that they access and must ensure it is stored, processed and forwarded in a secure and appropriate manner.

Equal Opportunities

Post holders must at all times fulfil their responsibilities with regard to the Trust's Equal Opportunities Policy and equality laws.

Health and Safety

All post holders have a responsibility, under the Health and Safety at Work Act (1974) and subsequently published regulations, to ensure that the Trust's health and safety policies and procedures are complied with to maintain a safe working environment for patients, visitors and employees.

Infection Control

All post holders have a personal obligation to act to reduce healthcare-associated infections (HCAIs). They must attend mandatory training in Infection Control and be compliant with all measures required by the Trust to reduce HCAIs. **All post holders must comply with Trust infection screening and immunisation policies** as well as be familiar with the Trust's Infection Control Policies, including those that apply to their duties, such as Hand Decontamination Policy, Personal Protective Equipment Policy, safe procedures for using aseptic techniques and safe disposal of sharps.

Risk Management

All post holders have a responsibility to report risks such as clinical and non-clinical accidents or incidents promptly. They are expected to be familiar with the Trust's use of risk assessments to predict and control risk, as well as the incident reporting system for learning from mistakes and near misses in order to improve services. Post holders must also attend training identified by their manager, or stated by the Trust to be mandatory.

Flexible Working

As an organisation we are committed to developing our services in ways that best suit the needs of our patients. This means that some staff groups will increasingly be asked to work a more flexible shift pattern so that we can offer services in the evenings or at weekends.

Safeguarding children and vulnerable adults

Post holders have a general responsibility for safeguarding children and vulnerable adults in the course of their daily duties and for ensuring that they are aware of the specific duties relating to their role.

Sustainability

It is the responsibility of all staff to minimise the Trust's environmental impact by recycling wherever possible, switching off lights, computers monitors and equipment when not in use, minimising water usage and reporting faults promptly.

Smoking Policy

It is the Trust's policy to promote health. Smoking, therefore, is actively discouraged. It is illegal within Trust buildings and vehicles.

Review of this Job Description

This job description is intended as an outline of the general areas of activity and will be amended in the light of the changing needs of the organisation. To be reviewed in conjunction with the post holder.

SG 05 APR 2023