HSS REGISTERED

Senior Medical Scientist

Health Salaried Officers Agreement: P-2

Position Number: RP603671

Cell & Tissue Therapies WA / Medical / Surgical Service Division

Royal Perth Hospital / East Metropolitan Health Service (EMHS)

Reporting Relationships

Facility Director
HSO Level G-10
Position Number:105885

⬆

Medical Scientist in Charge
HSO Level P-3
Position Number:600698

⬅ Also reporting to this supervisor:
- Various

⬆

This Position

⬆

Directly reporting to this position:

Title	Classification	FTE
• NIL		

Key Responsibilities

Performs complex and specialised laboratory procedures in the manufacture of diverse medicines for human use that are based on genes, tissues or cells. Develops and manufactures GMP products for clinical use at an advanced level of practice in accordance with TGA, FACT, OGTR and NATA regulatory requirements. Prepares documentation and records for facility accreditation and licences for manufacturing of clinical products.

EMHS Vision and Values

Our Vision

Healthy people, amazing care.
Koorda moort, moorditj kwabadak.

Healthy people refers to the commitment we have as an organisation to ensure our staff, patients and the wider community have access to comprehensive healthcare services, in order to maintain healthy lives.

Amazing care reflects the sentiment of those consumers accessing our healthcare services from feedback provided to us. This common statement resonates with the health service, and reflects our intentions in our practice and work every day.

As a health service which celebrates diversity of culture and languages, it is also important that our vision is shared in the Noongar language.

Our Values

Our Values reflect the qualities that we demonstrate to each other and our community every day. Our staff make a difference every day to the patients, families and consumers they provide care, advice and support to. The EMHS values capture the shared responsibility that we uphold as most important, which are:

- **Kindness** – kindness is represented in the support that we give to one another. This is how we demonstrate genuine care and compassion to each and every person.
- **Excellence** – excellence is the result of always striving to do better. This is represented by constant improvements to the way in which we deliver our services, which results in a high performing health service.
- **Respect** – we demonstrate respect through our actions and behaviours. By showing each other respect, in turn we earn respect.
- **Integrity** – integrity is doing the right thing, knowing it is what we do when people aren't looking that is a true reflection of who we are.
- **Collaboration** – collaboration represents working together in partnership to achieve sustainable health care outcomes for our community with a shared understanding of our priorities.
- **Accountability** – together we have a shared responsibility for ensuring the best health care outcomes for our community. This is a reminder that it is not only our actions, but also the actions we do not do, for which we are accountable.

Royal Perth Hospital staff share a strong sense of pride in the longstanding principles of Servio, Latin for 'to serve' which adorns our historic crest. The principles of this statement, adopted in 1937 bear testimony to the longstanding tradition of excellence in service that we strive to perpetuate into the future.

Brief Summary of Duties (in order of importance)

1. Professional

1.1 Manufactures Advanced Therapy Medicinal Products (ATMP) that is medicines for human use that are based on genes, tissues or cells for clinical use in compliance with regulatory standards.
1.2 Operates Good Manufacturing Practice (GMP) and Office of the Gene Technology Regulator (OGTR) compliant manufacturing cleanroom facility at Cell and Tissue Therapies WA (CTTWA) for the provision of ATMPs for clinical use.
1.3 Develops and validates new GMP processes for the manufacture of ATMPs at CTTWA.
1.4 Authors manufacturing documents, assists with preparing quality documents, and provides written reports to assist management with meeting obligations.
1.5 Prepares and reviews GMP manufacturing batch records for clinical products and prepares records for sign off by CTTWA Facility Director and Quality Manager.
1.6 Investigates, evaluates and reviews existing practices and methodology and implements improvements to ensure current quality standards are maintained, evaluated and improved.
1.7 Prepares and regularly reviews manufacturing Standard Operating Procedures, compiles manufacturing reports, drafts manufacturing and equipment validation protocols and reports.
1.8 Performs tasks required for accreditation and licensing of CTTWA cleanroom facility and clinical products by regulatory bodies, including the Therapeutic Goods Administration (TGA), Foundation for the Accreditation for Cellular Therapy (FACT) and National Association of Testing Authorities (NATA) and the OGTR.
1.9 Adheres to the GMP Quality principles by performing accurate data entry, keeping meticulous records and participating in continuous quality improvements.
1.10 Reports timely non-conformances and identifies opportunities for improvement.
1.11 Provides training in GMP manufacturing procedures for CTTWA staff, and external contractors.
1.12 Maintains ongoing competency in manufacturing and regulations.
1.13 Attends and presents at relevant scientific meetings as required.
1.14 Participates in an out of hours and call back roster on a rotational basis, and as required, to meet manufacturing operational and compliance needs.

2. EMHS Governance, Safety and Quality Requirements

2.1 Participates in the maintenance of a safe work environment.
2.2 Actively participates in the Peak Performance program.
2.3 Supports the delivery of safe patient care and the consumers' experience including participation in continuous quality improvement activities in accordance with the requirements of the National Safety and Quality Health Service Standards and other recognised health standards.
2.4 Completes mandatory training (including safety and quality training) as relevant to role.
2.5 Performs duties in accordance with the EMHS Vision and Values, WA Health Code of Conduct, Occupational Safety and Health legislation, the Disability Services Act and the Equal Opportunity Act and Government, WA Health, EMHS and Departmental / Program specific policies and procedures.

3. Undertakes other duties as directed.

Work Related Requirements

The following criteria should be read together with the Brief Summary of Duties and considered in the context of the EMHS Values.

Essential Selection Criteria

1. Tertiary qualification in Bio medical Science in the field of cell biology, haematology, immunology or molecular biology and eligibility for professional membership of the Australian Institute of Medical Scientists (AIMS).
2. Demonstrated experience with the requirements of the code of GMP and other appropriate accreditation and regulatory authority standards (TGA, FACT, OGTR and NATA).
3. Demonstrated experience in cell processing for transplantation and/or GMP manufacturing of ATMPs in a cleanroom environment.
4. Demonstrated knowledge of Quality Management Systems including audits and management of non-conformances.
5. Demonstrated highly developed written and interpersonal communication skills, including ability to teach and train other staff.
6. Demonstrated proven ability to evaluate, establish and validate new methods, procedures and equipment.
7. Demonstrated ability to work cooperatively and effectively within a multi-disciplinary team.

Desirable Selection Criteria

1. A medical degree or a post graduate qualification in a relevant field.
2. Experience in the processing of therapeutic products including haemopoietic stem cell grafts or cultured expanded products.
3. Current knowledge and commitment to equal opportunity in all aspects of employment and service delivery.

Appointment Prerequisites

Appointment is subject to:

- Evidence of eligibility for or current professional membership of the Australian Institute of Medical Scientists (AIMS) must be provided prior to commencement.
- Completion of 100 Point Identification Check.
- Successful Criminal Record Screening Clearance.
- Successful Pre-Employment Integrity Check.
- Successful Pre-Employment Health Assessment.

Certification

The details contained in this document are an accurate statement of the duties, responsibilities and other requirements of the position.

Manager / Supervisor	**Signature or**	**HE Number**	**Date**
Dept. / Division Head Name	**Signature or**	**HE Number**	**Date**

As Occupant of the position I have noted the statement of duties, responsibilities and other requirements as detailed in this document.

Occupant Name	**Signature or**	**HE Number**	**Date**

Effective Date

HSS Registration Details (to be completed by HSS)

Created on September 2022 **Last Updated on** September 2022