Queensland Institute of Medical Research

# POSITION DESCRIPTION

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| **POSITION TITLE:** | Quality Control Leader |
| **CLASSIFICATION:** | STO-3 |
| **GROUP:** | Q-Gen Cell Therapeutics |
| **DEPARTMENT:** | Scientific Services |
| **DIVISION:** | Support |

## POSITION OBJECTIVES

Lead the day-to-day quality control function for Q-Gen Cell Therapeutics. This includes co-ordinating and performing the quality control and environmental monitoring for the manufacture of therapeutic products and complete documentation or reporting requirements, in accordance with Q-Gen quality systems.

## ORGANISATION CONTEXT

QIMR Berghofer is a statutory body under the QIMR Act (1945). The mission of QIMR Berghofer is to promote the wellbeing of humankind through medical research, to maintain within the State of Queensland an internationally recognised Centre for Medical Research, to develop that Centre as the primary focus of Medical Research within the State and to co-operate with, and where possible assist the work of other medical research establishments within the State and throughout the world.

Q-Gen Cell Therapeutics is part of the Scientific Services Group, within the Support Division, responsible for providing clean room facilities, storage and quality management for internal and external clients manufacturing investigational therapeutics and facilitating the transition from research to validated manufacturing processes.

## REPORTING STRUCTURE

This position reports directly to the Quality Manager and will be required to work independently and as part of a team towards shared project goals and milestones.

The Quality Control Leader may also receive direction from the Quality Assurance Manager.

## PRIMARY RESPONSIBILITIES

- Lead the day-to-day activities for QCO employees.
- Liaise with external clients, as it relates to Quality Control testing services
- Ensure rooms used for quality control functions are cleaned in accordance with Standard Operating Procedures, and complete relevant records.

- Perform quality control testing and inspection, including cell counting, immunological testing, Endotoxin, sterility and Mycoplasma, in accordance with quality management systems, and complete reporting requirements.
- Liaise with external suppliers in relation to quality testing services, including ID of isolates
- Perform environmental monitoring, including high volume air sampling, particle counting and swabbing of cleanrooms and complete appropriate documentation, reports and trending.
- Inspect and approve stock for use at Q-Gen and maintain stock quality records.
- Maintain documentation consistent with Q-Gen quality policies.
- Perform on-call duties, including response to equipment and facility alarm conditions.
- Perform tracking and archiving of manufacturing and compliance documents.
- Review of Standard Operating Procedures and Quality Forms to ensure compliance with the TGA code of GMP.
- Perform validation activities and reporting, as required.
- Review, inspect and assist during sample collection and administration activities during clinical trials.
- Assist Project Manager's including project documentation, risk assessment, planning, and project review in accordance with Q-Gen Project Management procedures.
- Ensure work practices comply with the requirements of the *Work Health and Safety Act*, related legislative requirements and the Institute's WH&S policies and procedures.

## KEY SELECTION CRITERIA (Qualifications, Experience, Skills and Abilities)

### *Essential*

- Bachelor degree in a related discipline of Science or equivalent experience
- Previous testing experience in a laboratory, hospital or food/pharmaceutical manufacturing setting
- Demonstrated Leadership skills
- Experience in quality control instrumentation, ideally Flow Cytometry and Luminescence
- Demonstrated ability to interpret and translate written procedures into practice
- Thorough understanding and experience in microbiological concepts and testing techniques.
- Excellent communication skills
- High level organisational skills with the ability to manage multiple competing priorities and meet deadlines
- Good attention to detail
- Competent use of Microsoft Office programs
- Ability to work with limited supervision and as part of a team
- Initiative and flexibility to changing work requirements

### *Desirable*

- Previous experience in cleanrooms
- Knowledge and experience with DQ,IQ,OQ and PQ
- Ability to follow, revise and create Standard Operating Procedures
- Understanding of the TGA code of GMP and quality systems
- Knowledge of contamination control procedures and aseptic manipulation techniques

## POSITION LOCATION

The position is located at the Q-Gen Cell Therapeutics Facility at Herston.