POSITION DESCRIPTION

POSITION TITLE: Production Manager
CLASSIFICATION: STO5
DEPARTMENT: Scientific Services
DIVISION: Support
LOCATION: Herston

POSITION OBJECTIVES
The primary objectives of this position are to:
- Manage and co-ordinate production process, including housekeeping functions of cleaning, waste management, media preparation and sterilisation;
- Ensure compliance with the relevant Therapeutic Goods Administration (TGA) Good Manufacturing Practices (GMP) and other relevant regulatory requirements, including completing validation requirements for all production processes; and
- Oversee maintenance of the facility and equipment.

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 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.

This role is the Production Nominee for QIMR Berghofer’s Licence to Manufacture Therapeutic Goods, as the person having control of production under of the Therapeutic Goods Act, 1989.

REPORTING STRUCTURE
This position reports directly to the Facility Manager and has three direct reports (Scientific Technical Officers and the Equipment and Training Coordinator).
PRIMARY RESPONSIBILITIES

- Nominee on the TGA GMP license as the responsible person for production.
- Manage and co-ordinate production processes, including:
  - Ensure the processes are completed in accordance with quality principles.
  - Co-ordinate scheduling of processes and availability of clean rooms for clients.
  - Ensure stock is available and managed in accordance with quality requirements.
  - Ensure project documentation, risk assessment, planning, and project review is in accordance with Q-Gen Project Management procedures
  - Approve Standard Operating Procedures (SOPs) that govern production processes and ensure their strict implementation.
  - Ensure cleanrooms used for aseptic manufacture of therapeutic products are cleaned as per SOPs, which includes completion of relevant records.
  - Ensure general laboratory housekeeping and technical support is provided, such as sterilising of laboratory consumables, media preparation and aliquoting of reagents.
  - Oversee the maintenance and service of the facility and equipment in keeping with their use for GMP processes.
  - Perform validation of production equipment.
  - Perform tracking and archiving of manufacturing and compliance documents.
- Lead a team through:
  - Managing team members’ performance by communicating expectations, providing regular performance feedback, coaching for improved performance, and developing/encouraging professional and personal growth.
  - Fostering positive and productive working relationship between team members and effectively managing conflict.
  - Monitoring work practices within the work area to ensure compliance with the requirements of the Work Health and Safety Act, related legislative requirements and the Institute’s OH&S policies and procedures.
  - Oversee training for all new operators in relation to production duties.
- Using expert knowledge, create and maintain production documentation consistent with Q-Gen quality policies.

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

**Essential**

- Degree level qualifications in a life science;
- Significant demonstrated practical experience in cGMP manufacturing practices with thorough understanding of GMP principles and regulatory requirements;
- Demonstrated supervisory skills and ability to manage a small team;
- Understanding of microbiological concepts, including cell culture and quality control techniques;
- Excellent communication skills particularly dealing with clients;
- Project management knowledge;
- High level organisational skills with the ability to manage multiple competing priorities and meet deadlines;
- Demonstrated ability to interpret and translate written procedures into practice;
- Good attention to detail;
- Competent use of Microsoft Office programs;
- Ability to work independently and as part of a team;
- Initiative and flexibility to changing work requirements.
Desirable

- Training qualifications
- Project management qualifications
- Stock management experience
- Knowledge of contamination control procedures and aseptic manipulation techniques