Job Specification and Requirements:

Job Role:	GMP Cell Therapy Production manager
Hours:	37.5 per week
Department:	GMP
Line manager:	Immetacyte Director of Cell Production
Responsible to:	Immetacyte Director of Cell Production Immetacyte Licence Holder

Production manager duties and responsibilities

GMP Production

- To review and approve the implementation of appropriately validated or/and translation of introduced AT(I)MP activities developed within the Cellular Therapeutics Ltd or their collaborative partners and customers
- To approve the required documentations or instructions relating to CTU policy and production operations and to ensure their strict implementation as part of the CTU quality system
- Overseeing the scheduling and manufacturing of AT(I)MPs
- To ensure the qualification and maintenance of the production department, premises and equipment
- Ensuring, prior to initiation for each scheduled process, suitable levels of reagents and consumables required to carry out the procedure are available.
- To ensure that the products are produced and stored according to the appropriate documentation in order to obtain the required quality
- Ensuring where changes to production activities are required, necessary review & approval has been made in conjunction with the Director of Cell Production and Quality Manager prior to implementation
- To ensure that production records are evaluated and signed by authorised personnel
- Deputising where delegated for authorised person(s) in their absence in which case the Deputy Production Manager may act up to fill Production Manager role for those delegated activities.
- Critically checking the records of production staff and/or external contractors/supplier, recording/transcribing and communicating translational & GMP procedures where they relate to production activities.
- Ensuring that critical samples are collected & tested for the manufacture of AT(I)MPs
- Ensuring suitable equipment & consumables are available and routine stock checking has been performed to maintain levels of critical stock
- Reviewing and approval of the appropriate regular facility cleaning, monitoring and disposal of waste

Quality management

- Represent 'Production' in the weekly and monthly Quality meetings reporting of all production associated activities, agree actions and overseeing the production associated implementation of such actions
- Ensuring documented policies and procedures are followed and where changes are required this is communicated to the Quality manager and managed within controlled procedures
- Ensuring that manufacturing processes are validated and all staff are trained to the validated procedures
- Informing the Director of Cell Production, Quality Manager and/or QP of all quality incidents, non-conformances and deviations
- To maintain the awareness of updated regulatory requirements (GMP) relevant to CTU and the manufacture of medicinal products to ensure compliance with the regulations

General activity

- Line manage a team of GMP Production Scientists, Technicians and support staff.
- Represent 'Production' on the Immetacyte senior management committee
- Oversee the management of CTU assets, premises and equipment and the required servicing with external contractors for equipment calibration, maintenance and repair
- Review and approve the introduction and sourcing of new consumables/equipment as required
- To be able to document and communicate results clearly

Training activities

- Oversee the training of new starters in critical equipment, products and procedures to ensure staff are trained in the specific production processes and that only trained staff carry out procedures
- To ensure that the continuing training of production staff personnel is carried out and adapted according to need
- To ensure all staff are trained in GMP (Good Manufacturing Process), the tasks performed and the equipment used for the manufacture and release of any AT(I)MP

Safety activities

- Be aware of and follow the Health & Safety Regulations and Agenda and comply with the associated COSHH and Risk Assessments
- Review and agree CTU facility housekeeping including management of COSHH and Risk assessments associated with Production activities

Skills & Experience

Essential Requirements:

- At least 5 years GMP production experience in the Bio-industry
- At least 1 year of experience as a Production Manager, Deputy Production Manager or Senior Production Scientist
- Knowledge of a range of research techniques and methodologies
- Excellent communication skills – written and oral
- Ability to work well with others in a team environment
- Willingness to learn and apply new techniques

- Ability to plan and prioritise own work and the work of others in order to meet deadlines, including using initiative to plan GMP production activities and change implementation programmes
- Experience in contributing to general lab duties

Desirable Skills:

- BSc in Immunology, Molecular Biology or related discipline
- Excellent tissue culture technique
- Knowledge and expertise in flow cytometry, molecular biology and gene transfer techniques
- Knowledge of cell therapy, molecular biology and bioassay development related to cell function
- Knowledge and experience of molecular biology techniques relevant to adoptive cell therapy research
- Closed system manufacturing
- Advanced Cell Therapy manufacturing for medical use
- Clinical translational expertise in the biological/cell therapy field
- Knowledge of the immunotherapy field