Job Title	:	**Cell Specialist (Manager / Senior Manager), Translational Services and Regulatory Management**
Business Entity	:	Advanced Cell Therapy and Research Institute, Singapore (ACTRIS)

Overview

The Consortium for Clinical Research and Innovation, Singapore (CRIS) brings together six national R&D, clinical translation and service programmes to advance clinical research and innovation for Singapore, and establish important capabilities for a future-ready healthcare system.

The Business Entities under CRIS include:

- Singapore Clinical Research Institute (SCRI)
- National Health Innovation Centre (NHIC)
- Advanced Cell Therapy and Research Institute, Singapore (ACTRIS)
- Precision Health Research, Singapore (PRECISE)
- Singapore Translational Cancer Consortium (STCC)
- Cardiovascular Disease National Collaborative Enterprise (CADENCE)

Together, CRIS makes a positive difference to Singapore patients and researchers by ensuring that these clinical research platforms and programmes are at the cutting edge of capability development and innovation. If you are as passionate as we are in clinical trials and research, we want you!

ACTRIS

The Advanced Cell Therapy and Research Institute, Singapore (ACTRIS) was established to meet the increasing clinical demand of using cellular therapeutics to treat various life-threatening diseases. ACTRIS' vision is to be the national and regional Centre of Excellence for discovery, process development and manufacturing of cellular-based therapeutics across the broad spectrum of immunotherapy and regenerative medicine, encompassing both investigational and approval products for the local market. We also provide value-added services such as workforce training, regulatory facilitation and ancillary material standardization, pertaining to delivery of cellular therapy to patients.

What you will be working on

(A) GENERAL

The Manager / Senior Manager, Translational Services and Regulatory Management, also referred to as Cell Specialist, will be responsible for the successful technology transfer of cell and gene therapy processes into Good Manufacturing Practices (GMP)-compliant production. The Cell Specialist must be able to lead and work cross functionally and collaboratively with internal and external stakeholders to meet project milestones.

- Support technology transfer of new cell and gene therapy processes to GMP manufacturing.
- Provide technical and scientific expertise to evaluate, optimize and develop processes and SOPs for new projects and perform process development and process validation related hands-on activities along with data analysis and related documentation activities.

- Evaluate technology and equipment suitability for GMP manufacture.
- Understand manufacturing processes to support gap and risk analysis.
- Establish, optimize, and develop new processes and equipment for manufacturing and product characterization.
- Design and execute analytical product and process characterisation assays.
- Draft validation plans and Standard Operating Procedures (SOPs), with support from other technical team members.
- Oversee validation runs, that will generate manufacturing data required for CMC documentation.
- Analyse manufacturing data obtained from validation runs, incorporating various operational parameters to ensure for process and facility fit.
- Be the primary point of contact for technical support for assigned projects as Subject Matter Expert.
- Coordinate root cause analysis for major process deviations during process development and manufacturing.
- Assess documentation and processes for continuous process improvement.
- Perform consultancy activities with early-stage product / process / assay developers in order to guide GMP-compliant development of the assets.
- Lead and train other technical team members to enable effective knowledge sharing and expansion, and to provide support in delivery of projects that are assigned to junior team members.

What we are looking for

(A) EDUCATION, TRAINING

PhD in the field of cell therapy or M.S/B.S. in Biological Sciences applicable to cell therapy.

(B) EXPERIENCE

Significant years' of experience in process development, process support, research or a related manufacturing environment is advantageous.

(C) ATTRIBUTES

- Strong knowledge of and experience with mammalian cell culture experimental techniques and equipment.
- Experience in operating cell therapy manufacturing and product characterization equipment as well as data analysis.
- Knowledge of Excel as well as Statistical Data Analysis tools.
- Experience in troubleshooting processing related issues and/or equipment.
- Excellent communication skills, outstanding action orientation, and ability to work well in a fast pace, cross-functional technical environment.

What you need to know

Successful candidate will be offered a 3-year contract, renewable. Please send your application to career@cris.sg with the subject **Cell Specialist (Manager / Senior Manager), Translational Services and Regulatory Management, ACTRIS**. We regret that only shortlisted candidates will be contacted. For more information about CRIS and the Business Entities, visit our websites below:

- CRIS – https://www.cris.sg
- SCRI – https://www.scri.edu.sg
- NHIC – https://www.nhic.sg
- ACTRIS – https://www.actris.sg
- PRECISE – https://www.npm.sg
- STCC – https://www.stcc.sg

- CADENCE – https://www.cris.sg/our-programmes/cadence/