Job Title : **Manager, Laboratory & Production**
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 to facilitate 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

1. Develop, plan and implement manufacturing operations and business processes for a new facility start-up. SOPs, workflow and processes will be critically thought out to cater for cell therapy products and must be appropriate for clinical and commercial manufacturing.

2. Assist in the preparation for all licensing and audit inspections for regulatory authorities as necessary.

3. Oversee production of cell-based therapy products in clean rooms, which includes processing, product storage, shipments, sampling etc
   - Ensure for compliance with Standard Operating Systems, Good Manufacturing Practice (GMP) & Good Documentation Practice (GDP)
   - Must be knowledgeable for aseptic operations and standard cell processing procedures such as tissue culture, cryopreservation etc.

- Timely review of relevant batch record and logbooks for the tasks performed and with adherence to GDP (Good Documentation Practice).
- Ensure for compliance to GMP, environmental health and safety guidelines and any other required industry best practices.

4. Ensure that the facility is always in proper working and clean conditions, and that there is enough capacity to meet the production demand.
   - Manage equipment and clean rooms, which include timely maintenance, calibration, monitoring and repair.
   - Plan for sufficient production raw materials and consumables, ahead of production processes.
   - Scheduling for the usage of clean suites.
   - Responsible for production documentation and batch records.

5. Participate in the development of new manufacturing processes, process improvement and risk assessment activities.
   - Jointly lead and drive commissioning, qualification and validation activities for new facility.
   - Perform or supervise process validation activity for incoming new projects.
   - Draft, review or revise SOPS for production related documents.
   - Identify process gaps and opportunities for process and efficiency improvement within the lab.
   - Implement initiatives to streamline workflow workflows and enhance overall lab operations.
   - Identify potential risks, hazards or non-compliances issues and take appropriate measures to mitigate them.

6. Support out-of-specifications manufacturing investigations, change control and root cause investigations for non-conformance.
   - Identify and report production problems and deviations.
   - Able to troubleshoot and conduct investigations.
   - Lead root cause analysis for complex issues and implementation of corrective or preventive actions.
   - Handling compliance records such as deviation reports and change controls.

7. Supervise and mentor laboratory officers, which include providing training, guidance and performance feedback.

8. Actively and jointly participate in the preparation and management of department's goals, project, budget, costing and other activities.

9. Collaborate with cross functional teams, including quality, process development and general operations, to support efficient workflow and time release of cell therapy products.

10. Provide and communicate clear, organized and meaningful updates and analysis on manufacturing-related operations and projects to facilitate decision-making.

11. Complete other relevant work arranged by Head, Laboratory and Production.

What we are looking for

(A) EDUCATION, TRAINING

Bachelors or Masters in Life Science / Biomedical Sciences / Chemical Engineering / Bioengineering / Bio-processing and other relevant scientific or engineering disciplines.

(B) EXPERIENCE

- Preferably 7 to 10 years of relevant experience in cell and gene therapy or related field such as biologics or biopharmaceutical processing. Prior technical knowledge in clinical or commercial manufacturing scale of specific cell types will be an advantage.
- At least 2 years of mid-management leadership experience, with track record of building and leading exceptional teams.

(C) ATTRIBUTES

1. Extensive experience in GMP cleanroom operations and aseptic processing.
2. Strong knowledge and experience in cell therapy manufacturing (or upstream cell culture processes) and cryopreservation.
3. Strong working knowledge of GMP guidelines and relevant regulatory knowledge (HSA, FDA, EMA, PICS)
4. Highly skilled in applying Root Cause Analysis tools and in designing meaningful CAPAs
5. Technical writing skills for the authorship of internal/external documents and approve technical documents
6. Highly proficient with Microsoft Office Suite and able to efficiently utilize MS Excel, MS Word or MS PowerPoint for presentation and management reporting
7. A team player with good time management, interpersonal and communication skills.
8. Highly motivated and self-driven with proven track record of delivering complex projects and working with multi-disciplinary teams
9. Able to work rotating shifts, as required.
10. Excellent organizational, interpersonal, verbal and written communication skills.

What you need to know

Successful candidate will be offered a 3-year contract. Please send your application to career@cris.sg with the subject **Manager, Laboratory & Production (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/