Job Title	:	**Head, Quality**
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 Head of Quality must possess extensive biologics, cell culture and/or pharmaceutical quality operations leadership experience. The incumbent provides leadership for all Quality Assurance staff and Quality Assurance at the facility including: Quality Operations, Validation, Quality Systems (including IT capabilities), Inspection and Audit Management, Project Support and other functional areas.

- Deploy the quality and compliance strategy to deliver strategic objectives.
- Ensure that the quality assurance system is deployed and is compliant and effective, in line with corporate requirements, industry best practices / standards and current regulatory requirements.

- Support the development and harmonization of quality standards and processes across various projects conducted at the facility.

- Build and maintain expertise in QA Validation teams; ensure execution and expertise is effective in supporting site operations through ongoing development of staff.

- Ensure that QA team maintains appropriate independence to ensure that there is no conflict of interest between regulatory requirements and day-to-day operational priorities.

- Ensure effective internal GMP audit programs are deployed and effective; ensure that the site is “audit ready” and compliant at all times. Act as primary point of contact with regulatory authorities regarding issues at the site.

- Partner with customers on Quality Assurance strategy and Quality system execution.

- Ensure QA review and approval/rejection of all GMP related procedures, documents and records. Enforcement of investigations for non-conformance issues.

- Ensure that all personnel training, investigation, deviation actions, critical documentation and audit actions are completed on time. Ensure necessary training and education is available to support the maintenance of cGMP at the site.

- Ensure risk management principles, the essence of ICHQ10 and a continuous improvement culture are built into QA ways of working.

- Interface and communicate with Process Development, Production, Business Development and Quality Control to ensure that production batches are reviewed and released in a timely manner.

- Ensure the necessary training within the department is carried out and modified according to need.

- Ensure appropriate hygiene practices are followed.

- Report the performance of the Quality System to the Management Committee for necessary review and improvements.

- Ensure the inspection, investigation and taking of samples is appropriate in order to monitor factors which may affect product quality.

- Ensure all necessary testing is carried out in a timely and compliant manner.

- Designate and monitor the storage conditions for materials and products.

- Manage the Quality Assurance budgets.

- Full authority for the Quality Systems and GMP implementation and improvements.

- Authority to approve changes made to the Quality System.

What we are looking for

(A) EDUCATION, TRAINING

BS Degree in Science, M.S. or Ph.D.

(B) EXPERIENCE

Preferably 7 – 10 years' relevant experience in the appropriate field that includes but not limited to R&D in biomedical research institutes/companies.

(C) ATTRIBUTES

- Group leadership, must be capable of managing motivating and developing the QA teams, both by personal example and by credibility and influence.
- Applicant must be familiar with working in a GMP environment with thorough understanding and keeping up to date with current GMP whilst able to be flexible and work with regulatory to change as needed due to new regulatory standards and new technologies as relevant to the stage of clinical trial from phase 1,2 and 3 to commercial production.
- Good number of years of Quality Assurance or Manufacturing operations experience.
- Good experience in Quality or manufacturing positions in a Biotechnology company manufacturing therapeutic products.
- Experience in managing QA Department and undergoing audits by regulatory authorities.
- Good communication skills and openly communicate any relevant issues to appropriate stakeholders.

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 **Head, Quality, 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/