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 related activities across the business including operation of Quality Control (QC) laboratory and Quality Assurance (QA) oversight on manufacturing processes, quality events (Deviation/Investigation, CAPA, Change Control Management, Complain and Recall), Validation, Quality Systems (including IT capabilities), Inspection and Audit Management, Project Support and other functional areas if deem related.

- Deploy the best practice quality vision and GMP regulatory compliance strategy to meet business

strategic objectives and operational needs.

- Develop, lead and manage the Quality Management Systems (QMS), implement new or identify potential improvement in system, where appropriate.

- Build and maintain expertise within department; ensure ongoing development and training opportunity is provided for the staff to allow the team to support site operations effectively.

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

- Manage the Quality budgets.

- Partner with customers on Quality strategy and QMS execution.

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

- Ensure that quality team maintains appropriate independence and there is no conflict of interest between
    - Regulatory requirements and day-to-day operational priorities
    - Quality activities from the production activities for the product batch release.

- Share the responsibility with various stack holder (i.e. production, logistic team) to ensure production and storage is done in accordance with the relevant specification or instruction.

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

- Ensure control (approval/rejection) of raw materials, starting materials, equipment that are used in combined CTGTP, packaging materials, intermediate, bulk and finished product.

- 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 and associate records are evaluated in a timely and compliant manner.

- Ensure that QC operations are carried out using appropriate equipment and premises are maintained under suitable conditions.

- Ensure of conditions for outsourced activities.

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

- Advise or assist in continuous improvement activities throughout the manufacturing cycles to ensure all quality requirements are met.

- Ensure risk management principles, the essence of ICHQ9 and a continuous improvement culture are built into organization.

- Ensure that all investigation, deviation actions, critical documentation and audit actions are completed on time. Ensure GMP activities is performed by competent staff.

- Ensure effective internal and external audit programs are deployed. Ensure corrective actions and non-conformance are resolved within required time-frame.

What we are looking for

(A) EDUCATION, TRAINING

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

(B) EXPERIENCE

Preferably at least 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 and management skills with the abilityof motivating, optimize team performance and development of the Quality 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, Quality Control or Manufacturing operations experience in Biotechnology company manufacturing therapeutic products.
- Ability to plan and deliver against quality process deadlines.
- Experience in managing Quality Department and undergoing audits by regulatory authorities.
- Good communication, relationship management skills and confident negotiator with ability to 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/