

#### Job Title

Laboratory Officer (3-year Contract)

### About ACTRIS

The Advanced Cell Therapy and Research Institute, Singapore (ACTRIS) was established on 20 April 2020 to meet the increasing clinical demand of using cellular therapeutics to treat various life-threatening diseases. ACTRIS's 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. ACTRIS aims to achieve accreditation from national and international regulators to ensure quality compliance of resource-efficient cellular therapy manufacturing. Our common goal is to promote and foster the entire value of chain of cellular therapy ecosystem through enabling translational research and development, manufacturing, clinical service provision, and commercialisation by serving the healthcare, academic and industrial sectors. ACTRIS will also provide value-added services such as workforce training, regulatory facilitation and ancillary material standardization, pertaining to delivery of cellular therapy to patients.

## **Job Description**

- Production support of cGMP batches in the manufacturing facility; including waste disposal, product storage, shipments, sampling etc
  - Demonstrated understanding and compliance in Standard Operating Systems,
    Current Good Manufacturing Processes (CGMP) & Good Documentation (GDP).
  - Executes processes in production while strictly adhering to cGMP, environmental health and safety guidelines and any other related regulations which could apply
  - For aseptic operations strictly follow aseptic techniques and practices practice as per relevant SOPs.
  - Perform routine QC sampling and in-process testing of the product at various stages throughout manufacturing (e.g. bioburden sampling, water sampling).
  - Timely completion of relevant batch record and logbooks for the tasks performed and with adherence to GDP (Good Documentation Practice).
- Perform routine and repetitious work within defined parameters.
- Ensure safety, security, and the environment in all aspect of the daily activities and any potential safety hazardous are addressed and corrected immediately.
  - Follow safety and quality compliance at all times and communicate in a timely manner to the superior if any anomalies are observed.
- Perform simple calibration and maintenance of all equipment in manufacturing facilities to ensure proper working conditions
- Perform regular environmental monitoring and sanitization of facilities to maintain facilities standard
- Participate in the development of new manufacturing and quality control processes.
  - o Identify processing gaps and assist with implementation of new technologies.

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- o Revise complex procedures or initiate new procedures as applicable.
- o Participate in departmental projects and quality working teams.
- Support process validation activities under the supervision of Manufacturing Lead (IQ, OQ, PQ, PV)
- Support out-of-specifications manufacturing investigations, change control and root cause investigations for non-conformance.
  - o Troubleshooting of acute production problems.
  - Draft complex Document Change Requests and complete major Non-Conformance Investigations.
  - Leading root cause analysis when complex abnormities are detected and implementation of the correct preventive actions.
- In charge and responsible for assigned workstation or area of manufacturing.
  - Carry out the cleaning and upkeep of the production equipment and classified areas in manufacturing area as per relevant SOPs and the Batch Record.
  - Perform stock check of consumables and inform Manager/Lead technician for required materials.
  - If required, perform Microbial sampling and swabbing of room and equipment.
- Responsible for production documentation of the equipment and batch records.
  - o Handling compliance records such as deviation reports and change controls.
- Ensuring the equipment is validated and well maintained and ensuring there is enough capacity to meet the production demand.
- May act as delegate to the Lead and/or Supervisor and may conduct departmental activities in their absence.
- Any other duties as and when assigned by the Manager.

## Requirements:

- Minimum Diploma in Engineering (Chemical/Biomedical), Biotechnology, Life Sciences or equivalent.
- 3 to 5 years of relevant experiences in biopharmaceutical and/or medical device manufacturing industry and prior technical knowledge in batch biopharmaceutical processing will be an advantage
- Clean room with sterile or aseptic processing knowledge and experience.
- Good understanding of safe working practices and cGMP.
- Highly motivated to work in pharmaceutical Industry.
- Able to work as a team.
- Able to work rotating shift if required.
- Demonstrated ability to elevate issues effectively and apply appropriate corrections.
- Highly motivated, proactive, and enthusiastic team player with demonstrated history of flexibility
- Ability to work independently, collaborate cross-functionally, and utilize resources efficiently
- Able to provide feedback for operations & elevate concerns as needed.
- Excellent organizational, interpersonal, verbal, and written communication skills.

Please send your application to career@cris.sg

Please indicate in your email the following header: Application for Laboratory Officer

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# **Company Overview**

The Consortium for Clinical Research and Innovation Singapore (CRIS), a wholly owned subsidiary of MOH Holdings, was established in 2020 with the goal of strengthening synergies and promulgating strategies for national-level clinical research and translation programmes under the stewardship of the Singapore Ministry of Health. The former Singapore Clinical Research Institute Pte Ltd was repurposed to form CRIS which brings together five entities as business units under a common management and governance structure. These are the Singapore Clinical Research Institute (SCRI), the National Health Innovation Centre (NHIC), the Advanced Cell Therapy and Research Institute Singapore (ACTRIS), the Precision Health Research Singapore (PRECISE), and the Singapore Translational Cancer Consortium (STCC).

## **Additional Company Information**

Average Processing Time Industry

25 days Healthcare / Medical

### **Benefits & Others**

Dental, Miscellaneous allowances, Medical, Regular hours, Mondays-Fridays