Operations Associate I, Viral Vector

Phone :
Web :

Job Summary

Vacancy :
Deadline : Aug 29, 2024
Published : Jul 29, 2024
Employment Status : Full Time
Experience : Any
Salary :
Gender : Any
Career Level : Any
Qualification :

Job Description

About CCRM:
CCRM, based in Toronto, Canada, is a unique not-for-profit group that is developing and commercializing cell and gene therapies and regenerative medicine technologies. We are leveraging our network of academics, industry partners and investors to tackle significant problems and advance our most promising technologies to the market to meet the needs of patients. For more information about CCRM, please visit our website at http://www.ccrm.ca.

Position Summary:
As an Operations Associate I at CCRM, you will be part of a diverse bioengineering team focused on designing and implementing good manufacturing practices (GMP) production projects for CCRM's GMP facility. You will provide technical expertise and will work with the team to define and execute project tasks. You will be an operations leader in bringing new and innovative products to market to enable life-saving advances in cell and gene therapy and regenerative medicine.

Responsibilities:
• This position will have responsibilities in CCRM's GMP facilities.
• Extract information from equipment manuals and other source documents, and write easy-to-understand, simple, user-friendly standard operating procedures (SOPs) that describe the equipment, key operating parameters, maintenance and cleaning procedures.
• Responsible for cleaning, maintenance and documentation of equipment in the cleanroom for use.
• Responsible to perform process validation, process optimization and process development as required.
• Responsible to assist in the design/execution of the production batch records or other high-quality documents (i.e. HVAC validation) that meet applicable standards and are appropriate for the intended audience.
• Responsible to ensure that the controlled Grade A and B manufacturing areas are clean and remain in a state of control.
• Support the development and execution of appropriate Safety, Training, Gowning, Material Movement, Cleaning, and Scheduling.
• Complete Batch Records (BRs), Logbooks, Forms, etc. under cGMP, and documents in detail through the use of SOPs and BRs for the processes and manufacturing steps
• Responsible to write and update standard operating procedures and master batch records.
Adhere to GMPs and GDPs (good documentation practices).
• Operate pilot-scale bioprocessing and interact fluidly with peers and supervisors in Manufacturing, and cross-functionally with Quality Control, Quality Assurance and Logistical counterparts.
• Collaborate with the Process Development and Manufacturing Sciences and Technology group to transfer new projects into GMP
• Implement a program to monitor and control operations from an employee safety perspective.
Other process related tasks that may arise.

Qualifications:
Candidates with more experience are encouraged to apply and will be considered for Operations Associate II position in the same field.
• BSc in Biological or Life Sciences, Biotechnology or Microbiology or equivalent industry experience.
• Bioreactor Experience
• 1+ years of experience in biopharmaceutical based GMP manufacturing operations/Cell Therapy/Human Cell Cultivation.
• Hands-on experience working in a cGMP environment preferred
• Strong English written and verbal communication skills.
• Proven track record of writing GMP documents (i.e. SOPs, validation procedures).

Desired Characteristics:
• Proven track record of working in Grade A and B controlled environments performing aseptic
• processing would be preferred.
• Proven track record of cellular and tissue culture experience, Immune cell isolation and expansion technique preferred.
• Technical understanding of cell culture processes
• Understanding of Health Canada/Food and Drug Administration GMP regulations and Quality Assurance principles.
• Ability to deliver high quality product and other deliverables, paying attention to details.
• Ability to quickly grasp complex technical concepts and make them easily understandable in text and pictures.
• Familiarity with Health and Safety regulations.
• Excellent communication and interpersonal skills with assertive, responsible and accountable attitude.
• Strong working knowledge of Microsoft Office.
• Basic familiarity with enterprise quality management software.
CCRM is a developing organization and represents a fluid working environment. Flexibility and adaptability are essential, and duties will be influenced by the needs of the organization.

Applicants must be legally eligible to work in Canada.

An applicant's compensation package is finalized once the interview process is concluded and accounts for the nature of the role as well as the experience, competencies (job knowledge, skills and abilities) of the applicant and internal equity.

CCRM is committed to accessibility, diversity, and equal opportunity. Requests for accommodation can be made at any stage of the recruitment process, providing the applicant has met the bona fide requirements for the open position. Applicants should make their requirements known once contacted to schedule an interview, or when the job offer has been made.

Education & Experience

Must Have

Educational Requirements

Compensation & Other Benefits