

Cell Processing Specialist I, PM Shift

Job ID
REQ-10017065
Sep 06, 2024
USA

Summary

#LI-Onsite

This role is located on-site in Morris Plains, NJ. Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

365 days a year, we aspire to be the best manufacturer of Cell & Gene therapies to ensure our patients have the treatments they need to live longer, healthier lives.

The Cell Processing Specialist is responsible for cell washing operations and verifying cell processing intermediate processing days of patient derived clinical and commercial cellular immunotherapy products. The CPS I will also be responsible for the formulation and verification of all media lots. Due to the nature of the starting material (patient cells) this role requires high level of proficiency and ownership of the process and media formulation.

About the Role

Key Responsibilities:

- Ability to gown aseptically and work in a clean room environment (ISO 8, 7 and ISO 5) areas for extended periods of time. Cell washing with the ability to work with automated equipment.
- Verification of intermediate process days which include expertise with the wave bioreactor, NC-200 and in process environmental monitoring.
- Maintains and prepares equipment/environment for use, proficient in the use of production related IT systems such as SAP, LIMS and MES, documents all steps in the assigned batch record in line with GMP requirements.
- Conduct all necessary processing/verification steps for the assigned lot with highest skill level of aseptic technique.
- Conduct all necessary processing/verification steps for assigned lots of media with the highest skill level of aseptic technique.
- Conducts routine and dynamic environmental monitoring as required.
- Assist on Deviation Investigations and Inspections and participation in assigned qualification/ validation activities.
- Responsible for successful on time completion of required training curriculum comprising of the necessary Global Operating Procedures (GOPs), Standard Operating Procedures (SOPs) and Aseptic Techniques, Gowning Qualifications and other relevant training including HSE for the specific role.

Additional Specifications:

- Ability to work different shift, weekends and overtime will be required. Your shift will be fixed according to business need.
- Ability to work with magnetic field equipment.
- Ability to lift 50 lbs., assisted.
- Ability to stand for an extended period of time.
- Requires handling of chemicals such as corrosives, solvents & bio-hazardous materials.

Essential Requirements:

- HS diploma or GED required. A minimum of 1 year experience in cGMP, academic or lab setting with aseptic experience.
- Associate's degree or Bachelor's degree in relevant Engineering or Scientific discipline may be considered in lieu of industry experience.
- Ability to perform complex calculations and an understanding of scientific notations required.
- Experience in cell therapy manufacturing preferred.
- Experience desired in: Aseptic processing in ISO 5 biosafety cabinets.
- Universal precautions for handling human derived materials in BSL-2 containment areas. Knowledge of cGMP regulations and FDA guidance applicable to biologics and cell therapy manufacturing.

The pay range for this position at commencement of employment is expected to be between \$28.37 to \$43.22/hour; however, while salary ranges are effective from 1/1/24 through 12/31/24, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

Commitment to Diversity & Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? <https://www.novartis.com/about/strategy/people-and-culture>

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Division

Operations

Business Unit

Innovative Medicines

Location

USA
Site
Morris Plains
Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation
Functional Area
Technical Operations
Job Type
Full time
Employment Type
Regular
Shift Work
No
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