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Cellular Production Associate, Therapeutic Products Program

Job ID 13911 **Type** Regular Full-Time **Company** Fred Hutchinson Cancer Research Center US-WA-Seattle **Category** Manufacturing

Overview

Cures Start Here. At Fred Hutchinson Cancer Research Center, home to three Nobel laureates, interdisciplinary teams of world-renowned scientists seek new and innovative ways to prevent, diagnose and treat cancer, HIV/AIDS and other life-threatening diseases. Fred Hutch's pioneering work in bone marrow transplantation led to the development of immunotherapy, which harnesses the power of the immune system to treat cancer. An independent, nonprofit research institute based in Seattle, Fred Hutch houses the nation's first cancer prevention research program, as well as the clinical coordinating center of the Women's Health Initiative and the international headquarters of the HIV Vaccine Trials Network. **Careers Start Here.**

The primary responsibility of a Cellular Production Associate is to execute manufacturing operations in the production of modified cellular products for patients participating in Fred Hutchinson Cancer Research Center cell therapy clinical protocols. Clinical manufacturing in the Cell Processing Facility (CPF) requires following applicable current Good Manufacturing Practices (cGMP) in a cleanroom processing environment.

Responsibilities

1. Utilizing aseptic techniques, perform a variety of open cell product manipulations in an ISO 5 biosafety cabinet.
2. Follow Standard Operating Procedures (SOPs) and complete required processing documentation such as production batch records.
3. Perform cell processing operations such as cell selection/depletion, expansion, stimulation, transduction, cryopreservation, and preparing patient infusions.
4. Develop capability in review of executed GMP process documentation.
5. Submit deviation documentation and assist with investigations of nonconformance.
6. Maintain and operate primary process equipment, such as incubators, centrifuges, cell sorting/selection equipment and controlled rate freezers.
7. Participate in problem solving and troubleshooting of cell processing operations and equipment. Assist in the evaluation of current practices and operations and help to implement changes to improve performance.
8. Participate in Corrective and Preventative Actions (CAPA) development
9. Participate in quality/compliance improvement and technical development projects supporting manufacturing.

We are open to considering candidates of multiple experience levels and encourage you to apply if interested. A more experienced individual may have the opportunity to take on the following responsibilities:

1. Perform routine review of executed GMP process documentation.
2. Submit deviation documentation and complete deviation investigations and reports.
3. Take an active role in problem solving and troubleshooting of cell processing operations and equipment. Evaluate current practices and operations and implement changes to improve performance.
4. Participate in Corrective and Preventative Actions (CAPA) development and completion, and GMP Systems change control.
5. Provide guidance and training to junior staff.
6. Work with Process Engineering and GMP Systems to lead equipment on-boarding and validation projects.
7. Act as Protocol Champion, assigned to specific clinical protocols as a point of contact for manufacturing readiness and execution, reporting out production status and production run summary data as needed.
8. Lead by example and take responsibility in the support of safety and cGMP compliance.

Qualifications

Minimum:

1. Bachelor's degree in a biological science, or equivalent cGMP manufacturing bioprocessing experience.
2. Experience with open aseptic processing, working in biosafety cabinets.
3. Experience with fundamentals of cell culture preferred.
4. Must be able to work efficiently, with strong attention to detail in a highly regulated environment.
5. Computer skills highly desirable (MS Office).
6. Must be able to support and communicate effectively in a diverse team environment.
7. Must demonstrate solid time management and organizational skills, and good verbal and written communication.
8. Must be able to wear appropriate clean room attire and have the ability to wear surgical masks and all required Personal Protective Equipment (PPE).
9. Must have the ability to stand for long periods.
10. Meets physical requirements of the job, as follows: must have the ability to lift a minimum of 50 pounds, the ability to bend, reach, stretch, climb ladders and work in tight spaces in order to complete job tasks.
11. Ability to work non-standard shifts and occasional weekend days or evenings. 4/10 Shifts: Sun-Wed 7AM-5:30PM, Mon-Thurs 11AM-9:30PM, Tues-Fri 7AM-5:30PM (current opening). The current opening is available on the Tues-Fri shift, however we will consider interest in alternate shifts and encourage you to apply if interested.

Preferred:

1. A minimum of three years' experience as a production associate for Cell Therapy product production.
2. Mastery of open aseptic processing, working in biosafety cabinets.
3. Experience with cell culture. Establishing and maintaining long-term T-cell lines/clones preferred.
4. Experience writing or revising standard operating procedures, manufacturing batch records, and other GMP Systems documentation

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Our Commitment to Diversity

We are committed to cultivating a workplace in which diverse perspectives and experiences are welcomed and respected. We are proud to be an Equal Opportunity and VEVRAA Employer. We do not discriminate on the basis of race, color, religion, creed, ancestry, national origin, sex, age, disability, marital or veteran status, sexual orientation, gender identity, political ideology, or membership in any other legally protected class. We are an Affirmative Action employer. We encourage individuals with diverse backgrounds to apply and desire priority referrals of protected veterans. If due to a disability you need assistance/and or a reasonable accommodation during the application or recruiting process, please send a request to our Employee Services Center at escmail@fredhutch.org or by calling 206-667-4700.

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