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GMP Systems Specialist II, Validation

Job ID 13974 **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 GMP Systems group is a compliance function within the Cellular Processing Facility (CPF). The CPF is a manufacturing organization that executes process operations in the production of modified cellular products for patients participating in cell therapy clinical trials in the Fred Hutch Cancer Research Center. GMP Systems is responsible for developing and administrating a variety of quality systems to ensure compliance with applicable regulations. The groups focus is on all aspects of GMP equipment life cycle, as well as on raw materials inventory management.

The **GMP Systems Specialist II** will primarily address facilitation of process equipment commissioning and qualification, routine calibration, maintenance, and repairs of GMP manufacturing and laboratory equipment to ensure a continued state of regulatory compliance and continuity in support of clinical manufacturing operations.

Responsibilities

- Track, schedule and ensure on-time completion of routine equipment service events.
- Establish and manage service providers and vendor contracts related to equipment maintenance, calibration, and repair.
- Maintain pertinent documentation and equipment files, including drawings, O&M manuals, equipment logbooks and service records in accordance with GMP record keeping practices.
- Facilitate shipment of equipment serviced off-site.
- Identify and communicate deviations from established procedures.
- Respond to notifications of malfunctioning equipment, participating in investigation to diagnose cause, coordinate repairs by Fred Hutch Engineering or other service provider, as necessary.
- Facilitate verification of restored performance following equipment repairs, to ensure equipment is suitable to return to service.
- Support development of equipment specifications (user requirements) for new equipment, participate in equipment selection, procurement, installation, etc.
- Facilitate commissioning and qualification of new equipment.
- Author equipment validation protocols and reports. Assist in execution of validation protocols. Investigate and document validation deviations.
- Support development of operation and maintenance Standard Operating Procedures (SOP) for new equipment.
- Assist manufacturing staff with troubleshooting and/or continuous improvement of equipment operations.
- Provide additional support for GMP equipment life cycle, as needed.

Qualifications

Minimum Requirements:

- BS in a Biological Science or Engineering, or relevant experience in biologics manufacturing and/or cellular therapeutics processing.
- Experience working in a regulated (GxP) environment, including a thorough understanding of GMP record keeping and documentation practices.
- Experience creating and revising SOPs.
- Strong troubleshooting and problem solving skills.
- Must be able to work efficiently, with strong attention to detail in a regulated environment.
- Must be able to communicate effectively in a diverse team environment in support of team goals.
- Must demonstrate solid time management and organizational skills, with good verbal and written communication.
- Must be able to wear appropriate clean room attire and have the ability to wear surgical masks and all required Personal Protective Equipment (PPE).
- 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.
- Experience with basic Microsoft Office Software (Word, Excel, Visio, etc.)

Preferred Skills:

- Experience working as a customer service provider.
- Experience working in cellular therapeutics and/or biologics manufacturing environment.
- Experience creating equipment SOPs for GMP clinical process equipment, and other GMP documents (reports, user requirements, etc.)
- Experience in developing and authoring equipment validation protocols and reports
- Experience in assisting with facilitation of facility start-up and shut down activities
- Strong administrative and logistics skills required to track a large variety and volume of tasks simultaneously.

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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