Senior Manufacturing Engineer, System Owner (Bioreactors)

Job ID: 202104-109924

Job Function
Production Engineering

Schedule
Full time

Location
Vacaville, California

Company/Division
Pharmaceuticals

Job type
Regular

Job Level
Individual contributor

The Position

At Roche, 94,000 people across 100 countries are pushing back the frontiers of healthcare. Working together, we've become one of the world’s leading research-focused healthcare groups. Our success is built on innovation, curiosity, and diversity. We believe every employee makes a difference. We are passionate about transforming patients’ lives. We are courageous in both decision and action, we believe that good business means a better world.

The focus of the Vacaville Operations Facility is Drug Substance bulk manufacturing. We have a passion for science, technology, innovation, professional development, and diversity and inclusion. We are also deeply respected for our unique and special culture; one that centers around the people we attract and hire. Our Pharma vision is to have a greater overall patient benefit and impact. This focus includes personalized healthcare, designing the processes with the patient in mind, and improving their quality of life. We hope you consider joining our team and being a part of one of the largest biotechnology facilities in the world!

Job Summary:

The Bioreactor System Owner (BRX SO) will be reporting to the GMP Services Upstream Manager. The System Owner will be accountable for the availability of the Bioreactor systems to manufacturing that will operate in safe and quality compliant manner. The BRX SO will be accountable for all 80L/160L, 400L/5000L, 2000L biomass scale-up reactors and 12kL/25kL Production Bioreactors located in CCP1 and CCP2 plants. The BRX SO will coordinate all activities related to the Bioreactor systems design, operation, troubleshooting with Quality Validation, Safety / Health / Environmental, Facility & Engineering, Maintenance, and Manufacturing groups.

The BRX SO will ensure an integrity, maintainability, reliability, and fit for use performance of the Bioreactor systems with all associated support equipment, instrumentation/analyzers, piping and valves. The BRX SO will lead a team of specialists for equipment, automation, and documentation. The BRX SO shall be accountable for the training of the Manufacturing personnel involved with operating Bioreactors. and will provide leadership decision making in process and problem solving. The BRX SO will be accountable for ensuring that capital
projects deliverables related to the Bioreactors are technically viable and consistent with user/operational requirements.

The BRX SO shall serve as a Subject Matter Expert on the Bioreactor Equipment Systems and associated processes with an in depth knowledge of the equipment functionality.

Requirements:

Education/Experience:

- Bachelor Degree in Chemical, Mechanical, or Bio-Chemical Engineering is preferred. Degrees in other Engineering fields as well as in Scientific disciplines (e.g. Chemistry, Biology, Physics) are considered
- 10-12 years of design and/or operational experience related to Large Scale Biopharmaceutical Upstream processing with at least 3 years of team leadership experience

Knowledge/Skills/Competencies

- Demonstrates a complete quantitative and qualitative understanding of process engineering principles and concepts with an ability to provide solutions to complex technical problems in the bio-pharmaceutical processing
- Complete technical, design, and operational competence of Bioreactor System Class (es) within area of responsibility, and good understanding of complete Mammalian Cell Culture Process Upstream, Downstream, Process Supports and Utilities functions
- Experience with manufacturing processing equipment that includes automated systems as fermentation and bioreactors, harvest centrifuges, depth filtration, process tanks, clean-in-place & steam-in-place systems, hydraulics and heat transfer, instrumentation and controls, hygienic design / BPE principals
- Capable of providing creative, out of the box approaches to design and operating challenges
- Proven ability to understand Project Management requirements, scope, and execution phases / technical deliverables required for each phase
- Working knowledge of applicable Quality Systems (e.g. Clean Utilities, sampling /QC)
- Working knowledge of cGMP practices, experience of working in a cGMP environment
- Excellent written, verbal, and presentation skills with proven ability to use market available software

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Who We Are

Genentech, a member of the Roche group and founder of the biotechnology industry, is dedicated to pursuing groundbreaking science to discover and develop medicines for people with serious and life-threatening diseases. To solve the world's most complex health challenges, we ask bigger questions that challenge our industry and the boundaries of science to transform society. Our transformational discoveries include the first targeted antibody for cancer and the first medicine for primary progressive multiple sclerosis.

Diversity and Inclusion (D&I) are critical to the success of our company and our impact on society. We believe that by championing diversity of background, thought and experience, we can foster a sense of belonging and provide an environment where every employee feels valued, included, and able to contribute their best for the patients we serve. We're focused on attracting, retaining, developing and advancing our people to their full potential by
rewarding bold ways of thinking and integrating inclusive behaviors into every aspect of our work.

Genentech is an equal opportunity employer & prohibits unlawful discrimination based on race, color, religion, gender, sexual orientation, gender identity/expression, national origin/ancestry, age, disability, marital & veteran status. For more information about equal employment opportunity, visit our Genentech Careers page