Engineer IV, Pilot Plant Upstream

Upstream Development Engineer, Pilot Plant at Takeda Pharmaceutical (takedajobs.com)

Are you looking for a patient-focused, innovation-driven company that will inspire you and empower you to shine? Join us as an Engineer IV, Pilot Plant Upstream in our Lexington, MA office.

At Takeda, we are transforming the pharmaceutical industry through our R&D-driven market leadership and being a values-led company. To do this, we empower our people to realize their potential through life-changing work. Certified as a Global Top Employer, we offer stimulating careers, encourage innovation, and strive for excellence in everything we do. We foster an inclusive, collaborative workplace, in which our global teams are united by an unwavering commitment to deliver ***Better Health and a Brighter Future*** to people around the world.

POSITION OBJECTIVES:

Engineer IV, Pilot Plant Upstream will be a key member within a group responsible for executing large scale upstream operations and development experiments, including the cell expansion, cell culture, and clarification of non-GMP batches to support development timelines and manufacturing support. The individual will independently execute both routine and complex operations. Additionally, this position participates in planning unit operations/experiments and drafting support documentation (SOPs, batch records, and/or reports). They will collaborate within our multi-disciplinary environment including the upstream/downstream pilot team, process development, manufacturing, and manufacturing technical support teams. They will possess excellent problem-solving abilities and hold strong coaching and supervisory skills. They will apply knowledge from various technical areas, industry practices, and standards, and provide quality and productive output that is consistently timely, reliable, and reproducible. The candidate must be customer focused, results oriented, science driven, and have high attention to detail.

POSITION ACCOUNTABILITIES:

- 60% of the time: Lead/Perform non-GMP cell culture campaigns (pilot scale) to support new product development, material supply needs and demonstration runs for multiple programs spanning all phases of biopharmaceutical development. Lead project team to support the transfer of all information including long lead items, batch record development, sample plan building, ordering and vendor management, and on-floor support schedules. Record, trend, and interpret data independently, and organize and present issues and results at departmental and project meetings. Identify complex technical issues and implement solutions under supervision.
- 25% of the time: Actively participate and interact with process development groups to identify and troubleshoot problems, support large scale studies, and support project goals. Design and develop pilot scale operating procedures and records suitable for use in the production of non-GMP material. Author documents such as reports, protocols, and internal presentations that may require substantial edits. Assist senior personnel with publications, external abstracts, and presentations, as needed.
- 10% of the time: Evaluate and implement novel large scale technologies that meet a generic platform across multiple processes.
- 5% of the time: Mentor junior members of team in developing required skillsets.

EDUCATION, EXPERIENCE AND SKILLS:

Education and Experience:

Required:

- Associate's degree in chemical engineering, biotechnology, chemistry, biology, pharmacy, engineering or related pharmaceutical science; 7+ years relevant industry experience
- Bachelor's degree in chemical engineering, biotechnology, chemistry, biology, pharmacy, engineering or related pharmaceutical science; 5+ years relevant industry experience
- Master's degree in chemical engineering, biotechnology, chemistry, biology, pharmacy, engineering or related pharmaceutical science; 3+ years relevant industry experience
- Previous Process Development, Manufacturing Sciences, or Manufacturing hands-on experience working with bioreactors/fermenters from bench top to production scale, including process monitoring and process control.

LINE FUNCTION SPECIFIC QUALIFICATIONS

Biologics – Pilot Plant – non-GMP:

- The candidate should possess experience and knowledge of activities routinely performed in upstream manufacturing (vial thaw, cell culture expansion, large scale bioreactor setup and control, centrifugation, depth filtration, ultrafiltration, and media/buffer preparation). Knowledge of single-use systems, DeltaV, and OSIsoft Pi is preferred. Knowledge of downstream purification processing is a plus.
- The candidate must demonstrate excellent written and verbal communication skills and have an ability to independently operate pilot scale equipment, interpret data and maintain an organized lab area. In addition, the individual should be a self-starter and be able to communicate effectively with external and internal stakeholders. Candidate must have excellent problem-solving skills and be able to work in a fast-paced team environment.
- The candidate should display excellent leadership skills, documentation skills and troubleshooting abilities. The candidate will document development activities accurately in research notebooks and paper/electronic batch records as per corporate guidelines and provide concise reports and updates to management as required.
- The candidate will be expected to effectively complete day to day operations while managing data and communicating with external stakeholders. The candidate will be expected to work closely with PD operations management, deliver detailed updates, and display sense of urgency while completing critical tasks. The candidate will be expected to provide solutions to help troubleshoot pilot scale operations and central service-related issues.
- This role will occasionally require adjusted work schedules to meet operational demands.

Knowledge and Skills:

- Analytical and Problem-Solving Skills -Able to troubleshoot critical issues or problems and resolve routine issues using appropriate information. Stands accountable and consistently follows through on work assignments and personal objectives to deliver high quality results despite obstacles.
- Teamwork -- Ability to work within department groups/team.
- Communication Skills - Expresses one's self clearly and concisely within function; documents issues and/or concerns concisely with colleagues; timely and effectively communicates issues to supervisor.
- Organization – Exercises good time management skills. Effectively manages multiple priorities and outcomes of critical tasks.
- Technical - Proficient in use of applicable lab equipment and operations.

PHYSICAL DEMANDS:

- Ability to wear personal protective equipment such as safety glasses/goggles, gloves, and safety shoes.
- Ability to lift, pull, or push equipment requiring up to 25-75 lbs of force.
- Ability to stand for 6 hours in a suite.

- Ability to climb ladders and work platforms.
- Ability to stoop or bend to check or troubleshoot equipment operations.

TRAVEL REQUIREMENTS:

- The candidate may be asked to travel occasionally (domestically and internationally) for conferences, seminars, and project specific needs (approximately 5% travel).

WHAT TAKEDA CAN OFFER YOU

- 401(k) with company match and Annual Retirement Contribution Plan
- Tuition reimbursement
- Company match of charitable contributions
- Health & Wellness programs including onsite flu shots and health screenings
- Generous time off for vacation and the option to purchase additional vacation days
- Community Outreach Programs

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No Phone Calls or Recruiters Please.
#LI-AA1
This job posting excludes CO applicants