Scientist Cell Culture/Bioreactor Process Development

A Scientist in a Bioprocess Sciences and Technology group within the Pivotal Drug Substance Process Development department

Responsible for developing cell culture and bioreactor processes for recombinant proteins. This will involve bench and pilot-scale process development activities, data documentation, as well as technology transfer to manufacturing facilities. The candidate will work in a team environment, collaborating with various colleagues in process and product development/engineering.

This position will be within an expanding Pivotal Process Development subgroup, located in Cambridge,

Massachusetts.

• Participate in drug substance teams and collaborate cross functionally with analytical and drug product representatives to delivery drug substance manufacturing processes in a phase appropriate manner.

• Work cross-functionally to deliver CMC regulatory documents and supporting documentation in support of Amgen's large molecule regulatory filings.

• Work with external partners to deliver key intermediate or drug substances in support of Amgen's large molecule pipeline.

• Deliver processes amenable to cGMP operation and carry out deliveries of drug substance in a cGMP manufacturing environment.

• Participate on drug substance development teams as a team member or primary department representative.

• Represents the department in various departmental and interdepartmental committees that address scientific and administrative initiatives.

• Participates in and can direct team efforts directed at advancing development/technology programs within the department.

• Applies team experiences to facilitate cohesiveness and build team spirit.

• Authors, or provides direction for the authorship of, technical reports or regulatory submissions which may require minimal additional editing.

• Gives presentations within the department and to senior management with minimal supervision.

• Actively creates, generates, and presents paper/presentations at scientific meetings.

• Organize and conduct meetings.

Basic Qualifications

Doctorate degree OR Master's degree & 4 years of scientific experience OR Bachelor's degree & 6 years of scientific experience

Preferred Qualifications

Ph.D. in Chemical Engineering, Biochemistry, Biotechnology, Bioengineering, Biomedical engineering, or Bioprocessing discipline or relevant experience in the pharmaceutical or related industry

Experience in bioreactor process development or cell line development. High throughput screening (HTS) technologies

Scientific understanding of current bioreactor technologies, as well as the ability to explore and develop new approaches to further advance innovative bioreactor technologies

Understanding of protein characteristics and critical attributes so as to direct bioreactor development and product/process control strategies

Independently uncovering and resolving issues associated with cell culture and harvest and implementation of scientific projects

Ability to execute projects as part of a team

Demonstrated collaborative experience and ability to effectively work through others

Strong technical communication skills, both written and verbal, to interact effectively and appropriately with all stakeholders and document learned information, improvements, and value generated

Knowledge of license applications and the drug development process

Exposure to cGMP manufacturing and CMC components of regulatory submissions

Well-recognized in the scientific community through a sustained record of peer-reviewed publications and patents

Leadership experience of progressively increased scope