

Associate Director, Process Development

Location: Cambridge, MA
Full-time, Exempt

About Codagenix:

Codagenix Inc. is a clinical-stage synthetic biology company that uses AI-aided software to recode the genomes of viruses to design prophylactic viral vaccines and novel virotherapeutics for cancer. Codagenix's recoded vaccine candidates are a perfect antigenic match to the target virus and induce a robust immune response to all viral antigens. Our nimble platform allows us to turn a virus into a potential prophylactic vaccine.

Summary Description:

We are seeking a subject-matter expert and highly-skilled professional to lead our Process Development team. This includes guidance and oversight over design and development of GMP-translatable manufacturing processes for live virus production. This is a scientific leadership position for a virus product pipeline including characterization, formulation design, analytical methods, process characterization and final formulation studies. Reporting to the VP, Biologics CMC, this position will require excellent leadership, people management, technical, analytical and problem-solving skills, along with ability to operate independently on complex activities and projects and lead technology transfers to CDMOs.

This role is based in our new, state-of-the-art research facility at Kendall Square in Cambridge, MA with some remote work available.

Responsibilities include:

- Oversee and/or provide guidance on bench-scale and pilot-scale experiments for process and formulation development including cell culture optimization, downstream development and formulation screening.
- Participate as a member of a cross-functional team for the development and optimization of production processes and formulation/fill finish of drug product.
- Lead technology transfer of developed manufacturing processes to CDMO for scale-up and clinical manufacturing.
- Identify product or process improvements and offer solutions to technical challenges and troubleshooting.
- Review of laboratory assays results and analytical reports to assess process development and formulation experiments (ELISA, gels, residual impurity analyses, PCR, etc.).
- Write, review and approve protocols and reports including analysis of data and plans for further action, and present results to team members and management in a clear and timely manner.
- Maintain knowledge of scientific trends and industry processes through readings, conferences, and seminars; keeping up with literature to enhance or improve manufacturing procedures and methods.

- Communicate findings through technical reports as well as GMP documents to support regulatory filings.
- May require up to 25% travel to CDMOs and our Headquarters in Farmingdale, NY.

Required Qualifications:

- Requires B.S. or M.S. in a scientific discipline (Microbiology, Biochemistry, Cell Biology, Biochemical Engineering or related discipline) with a minimum of 7 years of relevant industry experience, or a Ph.D. degree with a minimum of 3+ years of relevant industry experience.
- Prior leadership experience is required.
- Experience working with Viruses (Live Attenuated Viral vaccines). Hands-on experience with various cell culture, purification, filtration and formulation equipment and techniques preferred.
- Full competency in aseptic and sterile techniques; GXP recommended.
- Demonstrated leadership, problem solving and critical thinking skills.
- Ability to prioritize, manage time efficiently, and implement creative solutions to meet program needs in a faced environment.
- Strong communication skills, both verbal and written, with the ability to collaborate with colleagues in a cross-functional, fast paced team environment.
- Excellent problem-solving skills including critical and analytical thinking.
- Comfort with statistical analyses and related software (Excel, GraphPad, JMP, Prism).
- Prior experience and a track record of working on project teams toward successful drug milestones (INDs, BLAs, etc.).

Preferred Qualifications:

- High degree of independence, proactivity, and a strong sense of accountability.
- Experience using Design of Experiments (DOE) and Quality by Design (QbD) methodologies.
- Experience and/or working knowledge of analytical and assay development.
- Technology transfer and process fit experience.

Interesting?

If you are excited about joining the Process Development function at Codagenix and rolling up your sleeves to have a big impact on our virus product pipeline, we'd love to hear from you! All applications can be submitted [here](#).

Note: Candidates for this position must be currently authorized to work in the United States on a full-time basis, and Codagenix will not sponsor applicants for work visas. In compliance with federal law, all persons hired will be required to verify identity and eligibility to work in the United States and to complete the required employment eligibility verification form upon hire.

Codagenix is an equal opportunity employer and values diversity. All employment decisions are made on the basis of qualifications, merit and business need.