GeneLeap Biotech (Luye Life Science) is working to develop first-in-class messenger RNA (mRNA) based therapeutics and vaccines. We are looking for a highly motivated and innovative candidate as senior scientists joining GeneLeap’s mRNA PD team at Woburn, MA. Our PD team focus on envision, development, scale-up and validation of GMP mRNA manufacturing process, while produces high-quality mRNA to support research candidate evaluation by our early discovery team. The successful candidates will have the experience leading the efforts of mRNA downstream process development from early stage process design to late stage GMP process implementation.

**Responsibilities Including, But Not Limited To**

* Apply deep knowledge in chromatography, solid-liquid separations, clarification, and tangential flow filtration to lead scalable mRNA downstream process development
* Lead screening, optimization, and scale-up efforts on plasmid isoform separation and mRNA purification after IVT **synthesis and enzymatic modifications.**
* **Design and execute DOE studies & high-throughput screen** for purification process improvements and advancements including parameter optimization, scale-up, process window determination and process capability evaluation
* Lead downstream process tech transfer to pilot plant and GMP facility via drafting SOPs, oversee scale-up, verification & validation activities
* Support the development of in-process assay and final product release testing to evaluate mRNA purity profile
* **Assist in the development of automated mRNA purification system to support high-speed downstream process screen**
* **Work closely with cross-functional teams including** CMC scientists to develop mRNA production strategies to meet ambitious project timeline.
* **Communicate effectively with regular verbal and formal updates to project teams and management.**
* **Maintain necessary documents including laboratory notebooks, process development reports, technical transfer records, and process related documents.**
* **Build and promote GeneLeap’s value and culture, result oriented, work with can-do attitude, team player mentality, constantly inject positive energy into the working environment.**

**Qualifications**

* Degree in Biotechnology, Bioengineering, or a related scientific field. BS with 10+ years of directly related experience, MS with 8+ years of directly related experience, or PhD with 4+ years (preferred) of directly related experience.
* Strong understanding of purification of biologics, specifically mRNA, including process scale-up. A proven track record of purifying multiple drug modalities is strongly preferred.
* Strong hands-on experience with a wide range of purification techniques for large nucleic acid molecules including affinity capture, ion exchange, hydrophobic interactions, is a must
* Strong hands-on experience with a wide range of downstream techniques including Depth filtration, UF/DF, TFF, is highly desired
* Proficient with ÄKTA systems and UNICORN control software
* Experience in high-throughput screen and DOE statistical tools for process development techniques is highly desired
* Experience with tech Transfer of manufacturing processes is a strong plus
* Experience in cGMP requirements for process development is a strong plus.
* Experience in standard analytical technologies for biologics including HPLC, agarose gel electrophoresis, capillary electrophoresis, qPCR, ELISA is a plus.
* Experience with automated systems and programming is a plus
* Experience in author & technical review on supporting documentations for CMC and regulatory filings is a plus.
* An ability to work independently, meet deadlines and prioritize work effectively. Must be able to thrive and deliver results on goals in a fast-paced, dynamic and highly multi-tasking environment.
* Demonstrated capabilities to implement advance technologies and persist to successful outcomes.
* Experience in large-scale process of mRNA automation synthesis and purification is highly desired.