PROCESS DEVELOPMENT SCIENTIST

Responsible for design, execution and data analysis for Process Development (PD) projects related to plasmid DNA (pDNA) and messenger RNA (mRNA) production including fermentation, purification, and analytics. Responsible for the design of experiments to evaluate and test new technologies and analytical methods for process improvements. Assist in the development of scalable processes and novel quality control analytics for transfer to cGMP. Author and review research testing protocols and development reports to summarize data. Perform research scale production of pDNA and mRNA in the process development lab. Assist with root cause analysis, investigational report writing and corrective and preventative action implementation for cGMP production activities.

ESSENTIAL DUTIES AND RESPONSIBILITIES include the following. Other duties may be assigned.

- Optimize processes through all facets of production and analytics for the manufacture of pDNA and mRNA.
- Design and execute new PD projects, evaluate new technologies and transfer technology for client specific protocols and production platforms.
- Install, commission and generate protocols for the use of new equipment as needed.
- Author and execute research testing protocols.
- Author development reports assessing the feasibility of implementation of process improvements, technology transfer and new technology to cGMP production.
- Report back to Managment/Sr. Scientists on the general status of operations and specific improvements/efficiencies identified as needed.
- Monitor publications, presentations, etc., to stay current on all processing technology and recommend process improvements over time.
- Work closely with the QC department for assay development to establish, qualify, and transfer novel analytical methods.

EDUCATION and/or EXPERIENCE

- Bachelor's Degree (B.S.) and/or five or more years related experience and/or training; Master's Degree and three years of related experience or training; PhD in related field; or equivalent combination of education and experience.

- Experience with nucleotide production, Mass Spectrometry, qPCR, HPLC, Akta Chromatography systems and sequencing are a plus. Strong technical writing skills and proficiency with Word, Excel are required.

Equal Opportunity Employer