



LEAD DOWNSTREAM MANUFACTURING PROCESS TECHNICIAN

The **Lead Downstream Technician** is responsible for manufacturing revolutionary clinical and commercial nucleic acid based pharmaceuticals by interfacing with manual and automated production systems and controls in cGMP manufacturing environment while maintaining areas in a state of compliance with internal quality systems. Follows standard operating procedures to operate production equipment for upstream operations. Maintains records, process and clean room environment to comply with regulatory requirements utilizing current Good Manufacturing Practices (cGMP) and Standard Operating Procedures (SOP). Responsible for proficiency in assigned functional area: Upstream Manufacturing. Understands and applies biological, chemical and mechanical principles and techniques.

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

- Manufacture plasmid DNA conforming to GMP guidelines and VGXI SOPs
- Executes production plan by assigning personnel, accomplishing work results, establishing priorities, monitoring progress, and reporting results of the processing flow to shift supervisor
- Follow production records or SOPs and accurately document work to conduct cell banking, fermentation, and lysis processes for plasmid DNA manufacture.
- Perform work following aseptic processing guidelines as appropriate.
- Prepare solutions required for the production process (media and buffer make-up).
- Clean, assemble, and sterilize equipment for production by operating glass washers and autoclaves.
- Write or Revise Standard operating procedures
- Install, commission and troubleshoot equipment as needed.
- Responsible for documentation and maintenance of equipment, such as: documenting new equipment and equipment changes, conducting and documenting PM as required, ensuring proper documentation of equipment repair, etc.
- Perform daily cleaning and sanitization of Production Areas.

EDUCATION and/or EXPERIENCE

- Bachelor's or Associate's degree or equivalent from college or technical school; or three to five years **in a regulated manufacturing environment** and/or training; or equivalent combination of education and experience.

Equal Opportunity Employer