



MANUFACTURING MANAGER

Supervises manufacturing activities and personnel.

Responsible for manufacturing operations and activities for plasmid DNA, including day-to-day resource allocation. Responsible for maintaining production schedule through adequate campaign preparation, personnel allocation and direct supervisory support. Responsible for analysis of process development data and implementing new technologies for process improvements. Responsible for the implementation of cGMP in the pilot plant. Author/review revisions of SOPs and manufacturing production records.

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

- Establish Manufacturing Team Goals for Quality and Safety.
- Manufacture plasmid DNA conforming to GMP guidelines.
- Ensure on-schedule project completion through campaign preparation, direct supervision of manufacturing operations and resolution of deviations and investigations.
- Mentor staff and support team growth through the supervision of assigned projects.
- Report to VP on the general status of operations, overview of products under development and specific issues of concern as needed.
- Ensure personnel are trained and qualified to perform assigned tasks.
- Work with Process Development to improve processes for the manufacture of plasmid DNA.
- Ensure adequate working inventory of manufacturing supplies and raw materials through communication with Purchasing Agent.
- Help in forming the master validation plan for the validation of equipment, facilities etc.
- Schedule validation activities to meet established timelines and maintain validated status of equipment.
- Specify and procure appropriate equipment as needed.
- Scale-up processes to meet growing demands.
- Author/review revisions to Standard operating procedures, manufacturing production records, and validation protocols.
- Review publications, presentations, etc., to stay current on all processing technology.

- Plans and formulates aspects of development proposals such as objective or purpose of project, applications that can be utilized from findings, costs of project, and equipment and human resource requirements.
- Submits proposals considered feasible to management for consideration and allocation of funds, or allocates funds from department budget.

EDUCATION and/or EXPERIENCE

Bachelor's degree in life sciences or an Associate's degree with 5-10 years of relevant experience and/or training; or equivalent combination of education and experience.

Equal Opportunity Employer