Position: Process Engineer
Location: Maryland Heights, MO

Summary of Position
The (Contractor) Process Engineer – Active Pharmaceutical Ingredient (API) Hot Products provides technical discipline and leadership required to maintain, plan and implement robust and capable cyclotron derived API manufacturing processes, as well as upstream process activities at the Maryland Heights, MO facility.

This role will be responsible for performing the following: identifying and implementing improvements and new technologies to processes to increase productivity, improve quality and reduce costs; leading API process equipment troubleshooting efforts along with coordinating other support groups to return equipment to service; serving as a Subject Matter Expert (SME) and leading API product/process failure investigations, implementing corrective actions, and preparing sound scientific reports; authoring and providing technical support for developing new processes and equipment documents including URS (user requirements specifications), DOE's (design of experiments), and validation documents; authors and/or reviews change control submissions to ensure the validated status of equipment is maintained; and reviewing, monitoring and trending operating data, consistently applying operational excellence and continuous improvement skills / tools in evaluating the data, and issuing related reports and recommendations for maintaining and improving process reliability.

Technical requirements will also include a thorough and demonstrable knowledge of cGMP's (Current Good Manufacturing Practice) and applicable industry standards. The Process Engineer – API Hot Products will be responsible for working in collaboration with other manufacturing production, maintenance, and engineering team members, this role will also readily coordinate with members from the R&D, project engineering, quality assurance, quality control, validation, procurement, commercial sales and marketing, and distribution teams within Curium.

Work Schedule: Monday - Friday 7:00am - 3:30pm
Essential Functions
- Leading process troubleshooting and remediation efforts.
- Maintain control of API process changes including change control management and documentation.
- Providing adequate and documented monitoring of the department API processes through trending, run reports, and tracking through SPC (Statistical Process Control) or other tools.
- Identify and support departmental change initiatives for continual process improvement, specifically around Operational Excellence, 6-Sigma and Lean Manufacturing applications. Will serve as a departmental driver for cost reduction initiatives.

- Assist in the development and maintenance of process equipment, procedures, batch records, and training materials.
- Ability to influence proper operating procedures during the manufacture of API pharmaceuticals (Compliance with regulations, GMP behaviors / techniques, etc.)
- Identifying capital needs for the department processes.
- Support annual capacity analysis.
- Facilitate technical transfers from R&D.
- Provides technical expertise and support to project management teams during project lifecycles.
- Executes low to medium complexity projects, including:
    - o Purchasing equipment to support API processes or manufacturing areas.
    - o Composing associated capital request and processing financial information.
    - o Capital funding for outside services as it relates to manufacturing (equipment upgrades, facility improvements, risk assessments, validation services, process engineering assistance).

Requirements

- Bachelor Degree in Engineering or related field required.
- Three years or more of experience working as an engineer in an FDA regulated, GMP facility.
- Three years or more of manufacturing experience; preferably in the manufacture of API and/or finished pharmaceuticals.
- Experience in preferred in the following areas:
    - o Ion-exchange chromatography
    - o Electroplating
    - o Small (volume), high value API production batches
- Verifiable knowledge of and experience in application of cGMP's, validation, quality systems, document control and the impact of regulatory considerations on engineering initiatives.
- Experience in applied knowledge of necessary behaviors and techniques associated with pharmaceutical production.
- Knowledge of current industry practices and technologies
- Proven experience in supporting and optimizing processes and equipment, as well as leading small teams, groups or efforts relating to those activities.
- Experience applying formal Root Cause Analysis and problem-solving methodologies
- Experience using SPC and other Operational Excellence methodologies; Lean and/or Six Sigma certification preferred
- Experience with radioactive isotopes and radiation safety programs is preferred

Working Conditions:

- Willingness to work in a plant producing radioactive materials and requiring all employees to participate in safety programs designed to minimize potential and/or actual exposure levels.
- Standard office environment, coupled with approximately 40% time in controlled radiopharmaceutical manufacturing environments.
- Must be willing to wear a variety of personal protective equipment.
- Responsibilities also include the ability to lift up to 70 lbs, walk, bend, stoop, push, pull, reach, and climb stairs with or without accommodation.

Disclaimer

The above statements are intended to describe the general nature and level of work being performed by employees assigned to this classification. They are not intended

to be construed as an exhaustive list of all responsibilities, duties and skills required of employees assigned to this position.

Equal Opportunity Employer
Curium is an equal opportunity employer and believes everyone deserves respect, dignity and equality. All applicants will be considered for employment without attention to race, color, religion, sex, sexual orientation, gender identity, national origin, veteran or disability status.