Job Title: Sr. Project Engineering Manager
Location: US-NJ-Lakewood

Overview:
The Sr. Project Engineering Manager will be responsible for providing Engineering leadership in a CDMO organization. Develop and implement technical solutions to support both development and commercial client needs, while ensuring design for manufacturability and successful design transfer.

This position will introduce technology and equipment/processes that will enhance the efficiency and effectiveness of the Renaissance operations. Manage small- and large-scale projects from concept through implementation, coordinating activities of the various support functions (MS&T, Validations, Quality, Operations, Clients) to ensure successful implementation (commissioning and validation) on time, and on budget. Participate as a member of the Senior Management Team in developing site strategies and policies and represent Renaissance with customers and regulatory agencies.

Responsibilities:
- Define and develop processes to ensure robust equipment start up for successful commercialization. Partner with clients and development teams to ensure design for manufacturability for all parts of the manufacturing process (compounding, filling, assembly, final packaging, serialization, etc)
- Manage small-to-large size projects related to process equipment, automation, and manufacturing.
- Assist in the design review, site acceptance, and installation of equipment.
- Collaboration and coordinate activities across operations, MS&T, validations, development, maintenance, facilities, quality as well as external contractors to ensure successful project implementation.
- Prepare necessary documentation to support engineering projects including project scopes, presentation of conceptual designs, capital requests, specifications, piping and instrumentation diagrams, process flow diagrams, schedules, requests for quotations, project expenditures, project procedure, correspondence, start-up procedures and cost estimates.
- Support QA and Validation departments by preparation of design documents, user requirements specifications, and assisting in protocol generation and execution.
- Implements connective/preventive actions for existing equipment and manufacturing processes.
- Prepare change control documentation.
- Review and modify procedures for the proper operation of new and/or existing equipment.
- Ensure safety requirements and risks are proactively addressed.
- Research and purchase new manufacturing technology and environmentally friendly practices into existing processes.
- Ensure projects are completed on time and financial budgets achieved.
- Develop a high performing team through mentoring, coaching, training and development of employees that fosters employee growth.
- Perform other duties and responsibilities as assigned.

Qualifications:
B.S. degree in Mechanical, Chemical or Electrical Engineering is required. A minimum of five (5) years of relevant experience in the pharmaceutical industry is required.

Must possess:

- A thorough knowledge of cGMPs and sanitary equipment design requirements.
- Advanced knowledge of engineering documentation required for cGMP process equipment; and

Preferred Experience:

- CDMO experience.
- Aseptic processing experience.