



## **LIFE SCIENCE COMMISSIONING ENGINEER**

Are you looking for a career with a sense of purpose? Our purpose is to help all our clients achieve theirs! Join a company that provides decisive and measurable solutions for complex challenges in the Life Science Industry. We can turn what can be challenging situations into actionable and realistic solutions. Among our many exciting projects, we have helped clients “Feed the World,” “Detect Cancer Early, When it Can be Cured,” “Create the First Bioengineered Human Acellular Vessel (HAV),” and “Lower the Cost of Life-Saving Pharmaceutical and Biotechnology Products to Improve the Life of All Patients”.

PEG is a full-service program, project, cost, and construction management firm that delivers customized innovative solutions focused on the Life Science industry. We work on a variety of project sizes and types and our expert, in-house team provides program and project management, construction management, cost estimating and management, scheduling, and commissioning services.

We are a Service-Disabled Veteran-Owned Small Business (SDVOSB), North Carolina state HubZone certified, and a State of Virginia Small, Women-owned, and Minority-owned Business (SWaM) firm that offers a host of project support services to clients nationwide.

This is a full-time, permanent position in a fast-paced environment. The role could alternate between our HQ office located in the Research Triangle Park, NC, and Client's locations.

### **Job Overview:**

Commissioning engineers perform commissioning testing on facilities and manufacturing equipment; author commissioning plans, risk assessments, commissioning protocol, and standard operating procedures; and, provide client support for projects either independently or as part of a larger team. In addition, commissioning engineers initiate, develop, and lead projects and teams at client sites. They are accountable for project initiation, inception, design, development, implementation, management, follow-up, and maintenance. Commissioning engineers take an active approach to championing projects and providing client support.

### **Primary Responsibilities:**

- Generate documents such as commissioning master plans, design qualification, equipment, facility and utility commissioning protocols, and final reports
- Perform commissioning and qualification testing on utilities and manufacturing process equipment and instruments
- Provide document control strategies in support of projects
- Provide project planning, management, and execution as needed
- Execute project management activities to ensure projects are on time, within scope, and within budget
- Manage multiple projects and resources simultaneously
- Provide design qualification services by reviewing engineering drawings for accuracy and act to correct any errors

- Review and assess systems
- Develop and review design specifications and engineering drawings to determine if systems meet project intent
- Review equipment specifications, user manuals, and engineering documentation to understand systems operation; test equipment and systems to assure they meet project requirements
- Investigate any deviations; manage client Corrective and Preventative Actions (CAPAs) and, provide data analysis and summary reports
- Develop and review spare parts lists; ensures spare parts are adequate and cost effective; and, setup spare part rooms operations for clients
- Create preventive maintenance strategies and maintenance job plans
- Perform system walk-downs and testing, identify gaps and non-conformances; analyze options and solutions; and, make technical changes to systems
- Participate in professional organizations such as ISPE, PDA, ASQ, NCEES, NCBELS, AERGC or other professional organizations relevant to their area of expertise
- Become a “Subject Matter Expert” (SME) in his/her area of expertise, and share knowledge through presentations, training sessions, or meetings
- Develop and manage quality control, document control, and communication plans
- Provide constructability and document reviews during project execution
- Manage project change control to ensure project remains compliant
- Provide project commissioning updates on a consistent basis to various stakeholders
- Work collaboratively and build effective relationships with Client's project team, owners and final users, design team, contractors, and local jurisdictional personnel
- Maintain a positive attitude in a fast-paced environment

### **Required Qualifications:**

- Engineering, Technical or Life Science degrees preferred
  - <5 years of experience as project manager for junior levels
  - 5<15 years of experience as project manager for proficient levels
  - >15+ years of experience as project manager for senior levels
- Extensive interaction with clients to identify project needs and work towards solutions that meet schedule, cost, and quality expectations and requirements
- Organizational skills, oral & written communication, and team attitude
- Strong interpersonal skills and extremely resourceful in managing stakeholders
- Experience with working in a corporate setting as a member of a project team or with working independently with minimal supervision, if needed
- Proficient at technical writing of documents such as: commissioning master plans (CMP): user requirements specifications (URS): risk assessments (RA): design qualification (DQ): factory acceptance tests (FAT): site acceptance tests (SAT): pre-functional tests (PFT): functional tests (FT): commissioning test plans (CTP): integrated system tests (IST): maintenance, calibration and spare parts assessments and plans: standard operating procedures (SOP): procedures: and, guidelines
- Strong understanding of mechanical, electrical, and automation systems: ability to read, interpret, and correct P&IDs: and, experience with working in construction environments

- Detail-oriented with the ability to compile, analyze, summarize, and present data in a concise manner
- Excellent analytical skills and proven ability to solve problems creatively
- Strong familiarity with project management software tools, methodologies, and best practices
- Experience with seeing projects from conceptual design through operations
- Proven ability to complete projects according to outlined scope, budget, and timeline
- Experience with working on regulated industries and knowledge of regulatory and compliance requirements: FDA regulations, USDA Regulations, Good Engineering Practices (GEP), current Good Manufacturing Practices (cGMP), and Good Documentation Practices (GDP)
- Familiarity with the Code of Federal Regulations (CFR) as related to cGMP in Manufacturing, Processing, Packaging, and Holding of Drugs and Finished Pharmaceuticals; Dietary Supplement & Human Food; Biological Products & General Biological Products Standards; Good Clinical Practices for Medical Devices; and, Quality Systems regulations
- Previous project experience in one or more of the following technologies and platforms: manufacturing and utilities systems; clean and aseptic rooms; clean in place (CIP): steam in place (SIP): autoclaves: vapor hydrogen peroxide (VHP) sterilization: solid dose preparation areas; powder feeding and continuous manufacturing; blending, milling, granulation, and formulation; fermentation, purification, and conjugation processes: controlled temperature environments, injectables sterile fill and packaging facilities; conveyors and clean packaging automation; GMP warehousing; and, automated storage and retrieval warehouse systems
- Proficient with computerized systems, information technology, and information systems related to project and construction software packages

Compensation will be determined based on education, years of project management experience, and alignment within the Life Science industry.

If you are interested in applying to work with PEG Contracting, please send your resume and contact information to [info@pegcontracting.com](mailto:info@pegcontracting.com). PEG will not work with unsolicited staff placing agencies, please refrain from submitting information.

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