Commissioning & Qualification (CQ) Specialist / Senior Specialist

The Commissioning & Qualification (CQ) Specialist/ Senior Specialist report directly to the Team Leader, Manager, or Director of the Consulting Team, depending on the organizational structure. These positions are exempt. Up to 100% percent travel may be required.

Expectations:

CQ Specialists perform commissioning, qualification, and validation testing on manufacturing process equipment and instruments; author protocols, initiate controlled documentation, and provide client support for CQ projects either independently or as part of a larger team. Responsibilities may include generation of documents such as master plans, design qualification, equipment, facility and utility commissioning and qualification protocols, cleaning validation, computer validation, sterilization validation, data reviews, SOP development, and development of final reports. Position requires extensive interaction with clients to identify CQ needs and work towards solutions that meet schedule, cost, and Quality expectations and requirements. They take a proactive role in supporting CQ projects and in providing client support. They build a high level of trust with internal and client personnel. This trust is developed through consistently upholding PCI Values and demonstrating Honesty, Integrity, Pride, Accountability, Teamwork, and Commitment.

In addition to the above, Senior CQ Specialists initiate, develop, and lead CQ projects and/or teams (internal and at client sites) with both PCI and non PCI team members. They are accountable for CQ project initiation, inception, design, development, implementation, management, follow up, and maintenance.

Responsibilities / Assignments

CQ Specialist
- Performs commissioning, qualification, calibration, and validation testing on manufacturing process equipment and instruments.
- Authors protocols, initiates controlled documentation in support of CQ projects.
- Provides project planning, management, execution, and follow up.
- Reviews equipment specifications, manuals, and develops an understanding of how an instrument works; tests equipment to accurately verify it is working as intended.
- Investigates failures and deviations, creates reports.
- Spare parts review, fit for purpose, and analysis.
- Reviews design specs to establish fit-for-purpose for systems.
- Reviews engineering drawings for accuracy.
- Performs system walk-downs, and change control of processes.
- Initiates and resolves client Corrective and Preventive Actions (CAPAs).
- Investigates deviations and failures.
- Provides summary and analyses reports
- Create and maintain job plans, maintenance and PMs’

Senior CQ Specialist (in addition to those listed above)
- Independently and with minimal oversight initiates, establishes, provides direction, execution, and follow up of commissioning, qualification, calibration, and validation projects.
- Subject matter expert who provides high level direction, tactical thoroughness, reliability, strategic initiative and consistent follow-through.
Commissioning & Qualification (CQ) Specialist / Senior Specialist

- Interfaces and networks with industry professionals through professional organizations i.e. ISPE, PDA, NCSL, or ASQ. Shares SME knowledge through presentations, training sessions, or meetings.
- May implement controlled documentation systems in support of CQ projects.
- Proactively assesses and evaluates situations to initiate and develop/revise design specs and engineering drawings to establish fit-for-purpose for systems.

Skills Required

CQ Specialist

- Expert understanding and work habits compliant with cGMPs and pharmaceutical and biopharmaceutical unit operations.
- Basic understanding and application of commissioning and qualification and willingness to learn.
- Exceptional writing skills required to author and execute DQ/FAT/SAT/CTPIQ/OQ/PQ/PV documents, developing SOPs, final reports and author/adhere to the validation and quality policies/procedures/guidelines.
- Thorough understanding, knowledge, and application of current industry guidelines, standards, P&IDs, and familiar with working in a construction environment.
- A thorough and working knowledge/application of GMPs, GCPs, GLPs, GAMP and Part 11 compliance as they relate to qualification of systems and validation of processes.
- Proficient with Microsoft Word, Excel, Project, with hands-on experience working in a corporate setting, and as a productive and supportive member of a project team.
- Validation experience in the following areas: manufacturing and utility systems, CIP & SIP, autoclave validation, qualification of controlled temperature environments, process validation, cleaning validation, equipment qualification, and use of the Validator 2000 and/or Kaye Digistor.
- Ability to provide self-direction, detail oriented, with superior skills in planning, organizing, and communicating CQ project tasks across a multidisciplinary team. Must be capable of working independently as well as in a team.

Senior CQ Specialist (in addition to those listed above)

- Subject-Matter-Expert (SME) with commissioning and qualification and proven history of successful implementation of various manufacturing and utility systems, CIP & SIP, autoclave validation, qualification of controlled temperature environments, process validation, cleaning validation, equipment qualification, and use of the Validator 2000 and/or Kaye Digistor.
- Proven project and people leader with exceptional skills in planning, organizing, and history of driving and delivering successful results.
- Exceptional communication skills between Team members, clients, and project leads.
- Industry expert on Regulatory issues and requirements, ability to convey and conform systems and processes.

Experience & Education Required for CQ Specialist:

BS in Engineering, Life Sciences, or equivalent training and four years of applicable (Commissioning, Qualification, or Validation) experience or the equivalent combination of education and experience. Quality System/Life Science manufacturing industry experience is required.
Experience & Education Required for Senior CQ Specialist:

BS in Engineering, Life Sciences, or equivalent training and five years of applicable (Commissioning, Qualification, or Validation) experience or the equivalent combination of education and experience. Extensive subject-matter-expert (SME) Quality System/Life Science manufacturing industry experience is required.

Approval: [Signature]  Date: 6-20-16

Wm. Andy Ferrell, President, PCI LLC