MS Remedies Inc.
Serving Healthcare Industry

Job ID: 16-001 **Commissioning and Qualification Engineer**

Job Description

Working as part of the Commissioning & Qualification (C&Q) team, you will work with our client which are Pharmaceutical or Bio-Pharmaceutical companies in the areas of manufacturing equipment, upstream or downstream biopharmaceutical manufacturing equipment and processes, performing the C&Q activities listed below.

Essential Duties And Responsibilities

- Layout development and review for material and personnel flow compliance
- Commissioning and qualification protocols
- Risk assessments and FMEA assessments for process and equipment, HAZOP
- Develop system impact assessments, validation plans, protocols and reports that support the qualification and validation of systems.
- Commissioning and validation of manufacturing equipment, downstream equipment and processes including: High Speed Granulation, Fluid Bed Dryer, Bin Blender, V Blender, Tablet Press, Coating Machine, Semi-solid Manufacturing Vessels, Dispensing Equipment, Buffer Preparation / Holding Tanks, Reactors and Bioreactors, Pool Tanks, Column Packing Skids, Chromatography columns and skids, TFF Skids, UF/DF, Sterile Filtration, Freeze-Thaw Systems, Filter dryer and tray dryer systems, Lyophilizers, Vial filling and capping lines, Vacuum distillation systems, Mixing tanks and process vessels, Centrifuges, Solvent storage and dispensing systems and Single use equipment.
- Commissioning and validation of utilities such as High purity water systems, Clean steam generators, Clean gases and Clean in place systems
- Develop moderate to highly complex protocols for validation projects using a risk based approach that meets regulatory requirements and industry practices.
- Review analyze and interpret system performance data for completed validation and prepare final report packages by summarizing the data.
- Investigate deviations, write investigation reports and create summary reports.
- Promote cGMP and regulatory compliance into assigned projects.
- Exercise good judgment within generally defined practices and policies in selecting methods and techniques for obtaining solutions.

Qualifications

- BS/MS in Engineering or related discipline.
- 3-7 years in validation, quality systems, operations, engineering or any combination thereof.

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- Experience in multiple GMP validation disciplines (process equipment, utility, automation, computer systems, sterilization) with advanced technical knowledge.
- Validation experience using risk based approach (FMEA, PHA, etc).
- Knowledge of Validation Lifecycle approach (URS, FRS, FAT/SAT, Commissioning Protocols, etc) guidelines, international regulatory requirements and standards and other in.
- Experience working with Documentum or Maximo a plus.
- Experience interacting with or creating material for representatives of regulatory agencies and executive level staff.
- Experience with investigations into manufacturing deviations and determination of product impact potential, root cause and corrective actions.

Since 2013, MS Remedies has worked as an integral part of project teams for clients and equipment vendors in the pharmaceutical and biopharmaceutical industries, resulting in the successful construction, commissioning and validation of facilities and equipment. As a member of the MS Remedies team, you will be responsible for providing state-of-the-art custom solutions to leaders in our industry. As we continue to grow our operations globally, we strive to hire the best talent—men and women dedicated to quality and innovation. We offer a collaborative culture, challenging projects, and excellent compensation and benefits.

You Will Find The Following Values Reflected In Our Company

- Family
- Integrity
- Respect
- Wisdom
- Adventure

Approved by:

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