Job Title: MS&T Scientist III
Location: US-NJ-Lakewood

Overview:
As MS&T Scientist III, the successful candidate will work on significant technical/scientific project activities to execute strategies and technical solutions that meet Renaissance's and their client's needs and expectations through broad expertise. The successful candidate will be expected to maintain a high level of expertise within their field and engages in creation of processes and equipment design for clinical, scale up, and/or registration batches, including technology transfer of projects from client sites. Assume technical ownership of a given product across the various stages of development and commercialization in coordination with other functional areas.

The MS&T Scientist III will be responsible for designing, leading, and executing studies to support product and process optimization and automation, investigation on deviation and root cause analysis; technology transfer activities, and product characterization studies, and any other activities required by the MS&T organization.

Responsibilities:
• Utilize and apply knowledge of basic scientific principles, theories and concepts to develop solutions to problems of moderate to high complexity. Lead multidisciplinary teams in developing and implementing solutions.
• Perform site transfer activities to Renaissance from business partner locations and provide scientifically sound development reports.
• Develop and optimize manufacturing processes for clinical, registration and commercial scale batches for sterile and non-sterile formulations.
• Prepare and review Master Batch Records for experimental/engineering, registration, scale-up and process validation batches.
• Prepare robust pharmaceutical/process development reports and other CMC documentation for regulatory submissions and represent Renaissance as SME during internal/external regulatory audits.
• Use statistical process control and other statistical tools for comparison and hypothesis testing. Apply engineering, pharmaceutical sciences or materials sciences fundamentals to model the product and process to solve complex technical problems.
• Evaluate and implement advance technologies for process evaluations and

optimization (e.g., Process Analytical Technology, electronic batch records etc.)
• Review and provide inputs for validation master plans, validation protocols, validation reports, continued process verification (CPV) plans and statistical sampling plans, among other important strategic documents.
• Acts as internal/external Subject Matter Expert (SME) for drug product and process related technical issues and provide technical support to Formulation, Manufacturing, and Quality.
• Identify potential root causes of variation and deviations using a systematic approach. Expertise in use / application of variety of problem-solving tools e.g. Ishikawa, Kepner-Tregoe (KT), five-whys, etc. and lead technical Deviation write-ups and CAPA assignments.
• Work closely with process engineering team to develop robust user requirement documents for process equipment including manufacturing and packaging.
• Provide technical input to management team regarding site capacity to evaluate new projects.
• Lead and guide other scientists/associates in process development and manufacturing.

Qualifications:
• Experience in cGMP manufacture of commercial or late phase clinical products. Experience with technology transfer and scale up is required.
• Familiarity with statistical process control (SPC), complex data analysis, mathematical modeling, and optimization software (like MiniTab, JMP, etc.) is a must.
• Knowledge and experience in cGMP, risk assessment and investigation tools and techniques.
• Able to work on multiple projects simultaneously. Familiarity with project management concepts is preferred.
• Proficiency with Quality by Design (QbD) concepts and design of experiments required.
• Demonstrated ability to provide scientific input and make decisions to resolve problems with minimal supervision.
• BS/MS/Ph.D. in pharmaceutical sciences/chemistry (or related field like organic, physical, biochemical, chemical engineering) with 6+ years (BS,), 4+ years (MS) or 2 years (Ph.D.) industrial GMP experience.