

**Job Title:** Quality Engineer

**Department/Division:** Quality Services

**Reports to:** Validation Manager

# Job Summary:

This job will support the Quality Services department mission to compete and maintain actions for the validation of GMP manufacturing processes to reliably produce quality Tapemark products throughout their development and commercial production life cycle. Quality Services will also provide technical quality support to other internal department customers as defined and requested to assist the successful completion of their projects.

This position will provide the following services to support the three stages of the process validation lifecycle.

## Duties/Responsibilities:

New Development Support (Validation Stage 1):

* + Participate as a Quality Services representative and validation subject matter expert (SME) for all new project teams.
  + Generate process validation strategies and plans for commercial manufacturing and packaging processes.
  + Provide investigation and technical quality support as requested for process development, process capabilities, and registration batch actions.

Commercial Product Maintenance Support (Validation Stages 2 & 3):

* + Generate the *commercial production* manufacturing and packaging batch records for new commercial products and corresponding training.
  + Generate and execute initial process validation test protocols for new commercial production processes.
  + Generate and execute any addended validation protocols as needed to preserve the initial validation status from any changes or potential change control impact.
  + Provide validation services to support the design of and to approve processing equipment qualification protocols.
  + Provide validation services for generating and executing qualification test protocols for facilities equipment and systems.
  + Provide technical quality services as requested to support nonconformance investigations and CAPA improvements.
  + Perform annual product quality reviews and process performance validation reviews with corresponding data analysis reports. Facilitate annual facilities equipment and systems performance review with data analysis report.
  + Provide technical quality services as required to support change control initiatives for changes to qualified equipment and validated processes. Services include commercial production batch record revisions, validation impact assessments, revalidation action plans, equipment requalification support, and risk assessment support.

Other GMP Systems Support:

* Provide technical quality services to support the software validation program and Part 11 compliance.
  + Provide validation SME information as requested by project teams and other Tapemark departments.
  + Participate as requested to support internal, customer, and regulatory audits.

## Education and Experience:

## Bachelor’s degree in science, engineering, or life science fields with a minimum of 5 years experience in a regulated pharmaceutical, biopharmaceutical, or medical device position(s).

## 3-5 years of process validation and/or equipment qualification experience.

## Knowledge of manufacturing equipment and processes.

## Working knowledge of CGMP, ISO, ISPE, ANSI/ASQ standards and guidelines.

## Basic working knowledge of ISPE GAMP 5 guideline concepts for GxP computerized system.

# Preferred Skills/Abilities:

* Ability to observe and understand cause/effect phenomena and apply scientific methods to gain technical information and solve problems.
* Ability to systematically collate, organize, and interpret data, as well as to derive problematic solutions from observed data.
* Working knowledge of risk management and risk management tools and their applications.
* Ability to work with minimal supervision and to prioritize project work activities.
* Ability to read, analyze, interpret, apply, and communicate (verbally and in writing) technical information including drawings/schematics, process flow diagrams, statistical data, and specifications.
* Ability to write reports, protocols, and business correspondence.
* Ability to interact collaboratively with project team members to effectively complete team objectives.
* Working knowledge of general mathematic concepts for applications of fractions, percentages, proportions, as well as a basic understanding of algebraic functions and geometry concepts.
* A basic understanding of general probability and statistical inference principles.
* To perform the essential functions of this position, basic computer skills are required.
* Foundational skills that are essential to this position include experience with word processing and spreadsheet software (e.g. Microsoft Word & Excel).
* Supplemental skills which are beneficial to this position include graphics (e.g. Microsoft Powerpoint, Visio), database software, and statistical software.

## Physical Requirements:

* The physical demands for this position are representative of those that enable the employee to successfully perform the essential functions. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.
* In performing functional duties, frequent sitting, standing, use of hands and fingers, hearing, speaking, and near and color vision can be required.

The above job description does not constitute a contract of employment, and Tapemark may exercise its employment-at-will rights at any time.

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Employee Signature Date