

**Job Title:** Validation Specialist

**Department/Division:** Quality Assurance

**Reports to:** Validation Manager

**Grade:**

# Job Summary:

Completes projects that provide general quality technical support for new and commercial product manufacturing operations and validation testing of production quality systems.

## Duties/Responsibilities:

**Essential Functions -** These duties are essential to the effective performance of the key functions that are required for this position.

**Pharmaceutical Production Systems Validation Support.**

* + Write validation test protocols and technical reports. Protocols types include Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ), and Process Performance Qualification (PPQ).
  + Perform monitoring, sampling, and testing to validate equipment, systems, and manufacturing/packaging processes per validation test protocols.
  + Analyze validation test data to provide statistical conclusions and recommendations to customers and Tapemark.
  + Coordinate validation activities with other Tapemark functional groups and customers to complete them according to the established project timeline.
  + Provide research and background support data for equipment, systems, and processes to be validated.
  + Write manufacturing process project plans and summary reports.
  + Provide impact assessments for any changes made to validated equipment, systems, and processes; and execute any identified revalidation actions to maintain the validated status.
  + Participate in the collection and analysis of process performance trend data of validated manufacturing/packaging processes.

**Validation Technical Support**

* + Support corporate scientific studies and analysis to investigate exception occurrences, atypical observations, customer complaints, and CAPA events.
  + Provide validation technical support review for the design and development activities for new or transferred manufacturing/packaging processes. Support actions can include technical support in creating process master batch records, contributing in process and contamination control risk assessments, and participating in equipment and process design reviews.
  + Providing validation technical support to the qualification of new facilities, utilities, and processing equipment. Support actions can include contributions to define equipment user requirements, review and assistance in generating and executing factory acceptance testing (FAT) and site acceptance testing (SAT) actions and generating IQ/OQ/PQ test protocols.
  + Review cleaning validation test protocols, reports, risk assessments, and support documentation for acceptable validation strategy and compliance with FDA cleaning validation guidelines.
  + Provide validation subject matter expert support in answering questions for project management projects, customer queries, and audits.

**Secondary Functions -** These duties are important for optimally supplementing and supporting the essential functions outlined above.

* + Maintain familiarity of and comply with current FDA requirements, cGMP regulations, and current validation practices in the pharmaceutical and medical device industries.
  + Maintain familiarity of and comply with Tapemark safety requirements.
  + Complete departmental training as required.

**Knowledge and Abilities:**

* + Knowledge of manufacturing equipment and processes.
  + Working knowledge of cGMP, ISO, ISPE, ANSI/ASQ standards and guidelines.
  + 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.
  + Basic working knowledge of ISPE GAMP 5 guideline concepts for GxP computerized system.
  + Working knowledge of risk management and risk management tools and their applications.
  + Ability to work with minimal supervision and to prioritize project work activities.

**Language/Writing Skills:**

* + 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.
  + Effective oral and interpersonal communication skills to interact with Tapemark colleagues and customers to convey information and solving problems.
  + Ability to interact collaboratively with project team members to effectively complete team objectives.

**Mathematical Skills:**

* + Working knowledge of general mathematic concepts for applications of fractions, percentages, ratios, and proportions, as well as a basic understanding of algebraic functions and geometry concepts.
  + A basic understanding of general probability and statistical inference principles.

**Computer Skills:**

* 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) and database software.
* Experience with statistical software is a plus.

**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.

**Work Environment:**

* + The work environment in which the employee is exposed can include moving mechanical parts, moderate noise, moderate temperature and humidity conditions, adequate lighting.
  + The employee will be equipped with the appropriate PPE safety equipment and training.

**Contacts -** The following is a list of Tapemark and outside personnel that contacts this position:

* + Quality Assurance department personnel and management.
  + Representatives of departments outside the Quality Assurance department including R&D, Operations, Quality Control, Project Management, Production Scheduling, Maintenance, Engineering, Purchasing.
  + Contracted technical and test services technicians and consultants.
  + Tapemark customer representatives.

## Education and Experience:

* + Bachelor’s degree in engineering or life science fields OR 2 years of college or vocational education (preferably in engineering or life science fields) with 2-5 years of experience in the pharmaceutical and/or medical device industries.2 to 5 years experience in the pharmaceutical and/or medical device industries.

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