NEW VISION PHARMACEUTICALS	**JOB DESCRIPTION**	**Page 1 of 3**
POSITION TITLE: Technical Services Specialist	**DEPARTMENT:** Technical Services	
REPORTS TO: Sr. Manager, Technical Services	**FLSA DESIGNATION:** Non-Exempt	
DATE WRITTEN/REVISED: 02/23/2021	**HR APPROVAL/DATE:** **QA APPROVAL/DATE:**	

JOB SUMMARY

The Technical Services Specialist is responsible for supporting and sometimes leading cGMP commercialization activities including Scale-Up, Technical Transfer, batch record generation and Process Validation. This position is responsible for development of the Technical Transfer Data Packages used to transfer product and process knowledge from R&D to Production for commercial scale manufacturing. He/she will participate in the evaluation of equipment, materials, processes, and manufacturing strategies, to support commercial scale manufacturing and optimize efficiency and control costs. Provides support for development of batch records, cleaning validation, media fill, data analysis, and statistical evaluations. Responsible for manufacturing feasibility of new products from R&D or from external sources, to support scale up and the validation of new processes / products.

The Technical Services Specialist will have interactions at the highest levels with regulatory agencies, certifying bodies, management, and critical customers to support compliant technical transfer and process validation programs.

CORE DUTIES AND RESPONSIBILITIES

- Works with the internal and external clients to gather all information about the product / process to be transferred in order to develop the technical transfer data package.
- In conjunction with Production will develop production and technical transfer quotes for clients by gathering information needed from Unipharma departments.
- Supports the process validation program by gathering or developing the documentation necessary (technical transfer data package, CQAs / CPPs, process flowcharts, data analysis, risk assessments, etc.) to successfully execute process validation.
- Works with the Management Team to establish and define the culture of the company incorporating elements of best practices, process validation and quality philosophies.
- Partners with cross-functional groups in programs and processes for Continuous Improvement, Cost Reduction, Scrap Reduction, and Safety.
- Will provide support for the troubleshooting and resolution of manufacturing performance and manufacturing related efficiency and quality issues relevant to all products produced at Unipharma.
- Will provide support for media fill validation including updating and executing media fill protocols and writing the report.

SUPPORTIVE FUNCTIONS

In addition to performance of the essential functions, this position may be required to perform a combination of the following supportive functions, with the percentage of time performing each function to be solely determined by the manager based upon the particular requirements of the plant:

- Performs training and ensures transfer of knowledge to ensure successful implementation of new equipment and processes, training of employees on batch records, and introduction of new products and procedures.
- Ensures that operations are executed in accordance with company policy and in compliance with GMP, FDA, OSHA and other regulatory requirements.
- Develops collaborative relationships with Production, R&D, and Quality Assurance to assist in resolving manufacturing issues, support continuous improvement, cost reduction, support QA investigations, and transfer manufacturing processes to new equipment.
- May be required to develop collaborative relationships with vendors and contract manufacturers to facilitate sourcing of components, and outsourcing of manufacturing or specific unit operations.
- Provides support to Quality Assurance for audits and inspections.

SPECIFIC JOB KNOWLEDGE, SKILLS AND ABILITIES

- Must possess excellent technical writing, communication and interpersonal skills.
- Must have demonstrated ability to analyze complex data, identify problems, draw conclusions, and then develop and execute solutions.
- Must have process validation and product / process technical transfer experience.
- Strong working knowledge of the FDA's Guidance for Industry Process Validation: General Principles and Practices, including process controls, and process validation is required.
- Proficiency in the use of Microsoft Office suite of programs: Outlook, Excel, Word, Visio, Project, PowerPoint, etc. is required.
- Strong organizational skills for managing multiple projects is required.
- Proficiency working in a team environment with cross functional groups is required.
- Knowledge of quality system and regulatory requirements pertaining to the development and validation of processes associated with FDA regulated products is required.
- Media fill validation experience is a plus.
- Must be able to meet the training requirements for the Technical Services Specialist position.

PHYSICAL DEMANDS

- Must be flexible in terms of working hours to meet requirements of the position.
- Must be able to fit and wear respiratory, hearing, gowning and other personal protection as required for entry and work in Unipharma facilities.
- Must be able to sit, walk, and/or stand for a minimum of 12 hours per day.

- Must be able to exert well-paced ability in limited space and to reach other locations of the plant on a timely basis.
- Vision occurs continuously with the most common visual functions being those of near and color vision and depth perception.
- Must be able to speak clearly on the telephone.
- Ability to sit at a desk and work for extended periods using a computer.
- Must be able to lift up to 35 pounds.

CRITICAL TASKS

- Responsible for reviewing formulations developed by the R&D department or by external clients to assure that the product can be manufactured on existing Unipharma equipment.
- Responsible for oversight of field work and interaction with various departments in connection with product transfer and scale up studies which may include project support, auditing, sampling, evaluation of R&D batch data, and issuance of conclusions and summary reports as required.
- Responsible for product, process and formulation review including proof of concept, process development, technology transfer, and process validation.
- Responsible for writing and reviewing bulk solution manufacturing (BC) and primary packaging (FP) batch records.

QUALIFICATION STANDARDS

BS Degree in Chemical Engineering or a related scientific discipline. Will accept a combination of a 2-year associates degree in a related scientific disciple with direct experience in pharmaceutical or biotech process validation and technical transfer.

Experience:

A minimum of five years' experience in technical transfer and process validation of pharmaceutical processes / products, is required. Candidate should have a working knowledge of manufacturing principles, process controls, with experience in manufacturing of sterile products a plus.

Grooming:

All employees must maintain a neat, clean and well-groomed appearance per Unipharma standards.

This job description is not an exclusive or exhaustive list of all job functions that an employee in this position may be asked to perform from time to time.