

POSITION TITLE: Chemistry and Analytical Development	DEPARTMENT: Quality Control
REPORTS TO: Director of Quality	FLSA DESIGNATION: Exempt
DATE WRITTEN/REVISED: 12/01/2020	HR APPROVAL/DATE: QA APPROVAL/DATE:

JOB SUMMARY:

The chemistry and analytical development manager represent the quality of two areas Quality Control and Analytical Development, which play an important role *in* the manufacturing and production as a key member of Unipharma’ s Product Strategy Team. Responsible for work closely with all members from the Production, Research and Development (R&D), Engineering and Quality areas of Unipharma LLC.

This position ensures that all aspects of the Quality Control Chemistry and Analytical Development areas are carefully considered cross functionally as part of the Quality Control unit, including assurance, compliance, strategic product sourcing, and the manufacturing, for develop and implementation of quality philosophies, strategies, and policies, as well as providing senior management with strategic guidance appropriate to the full range of products developed and commercialized by Unipharma LLC including cosmetics, dietary supplements, OTC' s and sterile products (RX's).

The chemistry and analytical development manager of Quality Control Unit, is responsible for interaction at the highest levels with qualified and certified scientist which provide new instrumentation Technologies and responsible for participation in the method development method transfer and method validation/verification of new products, and for the evaluation of new equipment from scientific, technical, and regulatory perspectives.

DUTIES AND RESPONSIBILITIES:

- Lead and manage the global Quality Control program, developing replicable protocols across each current product and product development.
- Inspect samples and regular material to identify issues and quality consistency.
- Collaborate with others are teams to identify issues and handle them expeditiously.
- Playing a key role in developing and implementing method development, method transfer and method validation to support the product performance and methodology to complies regulations.
- Executing time, cost and labor studies for our value-added services offering to different areas of the company: production, research and development (R&D) and sales.
- Communicate and interact daily with production as well as global teams within the product lifecycle to resolve ongoing quality concerns.
- Regularly review all quality data points, such as systems, reports to provide direction for continuous improvement.
- Ensure the correct train program for the quality control teams on new instruments and procedures dealing with quality, software, testing.
- Establish goals and strategies for the quality control team and monitor performance.

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- Direct the development, planning, implementation and maintenance of quality control testing methods, processes and operations.
- IL Audit products and samples as they flow through the supply chain process to make recommendations on ways to improve overall quality and productivity.

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.

- Participate in continuous improvement projects, troubleshooting, and technology transfer.
- Participate in the scientific, technical, and regulatory evaluation of new business opportunities and new product development. Assignments may include regulatory due diligence in acquisitions, label claims based on intellectual property, planning for new facilities.

SPECIFIC JOB KNOWLEDGE, SKILLS AND ABILITIES

The individual must possess the following knowledge, skills and abilities and be able to explain and demonstrate that he or she can perform the essential functions of the job, with or without reasonable accommodation, using some other combination of knowledge, skills, and abilities.

- Strategic thinking: Demonstrated ability to understand and consider competitive positioning when solving problems and making decisions.
- Knowledge of the quality control, method development, method validation and method transfer concept, applicability and requirements.
- Technical, regulatory and safety expertise: Demonstrated knowledge of technical research processes, safety and regulatory requirements for cosmetics, dietary supplements, OTC's and Aseptic/Sterile products (OTC's RX).

PHYSICAL DEMANDS

- Must be flexible in terms of working hours to meet requirements of position.
- Must be willing and able to travel moderately for business purposes.
- 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 on a computer as needed.
- Must be able to lift up to 35 pounds.

TRAINING

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The chemistry and analytical development manager must be trained on the following specific SOPs before performing GMP related documentation or plant related tasks:

SOP	Title
0.100	SOP on SOP's
0.101	Document Control
0.102	Change Control
0.103	Training Program, Qualification, and Development (Includes cGMPs)
0.104	Good Documentation Guidelines

The chemistry and analytical development manager must be trained on all available SOPs in the following sections within approximately one year from the start date in the position.

Section	Title
Section 0	General
Section 1	Human Resources
Section 21	QC Laboratory Chemistry
Section 11	Safety

QUALIFICATION STANDARDS

Education: MS Degree, Bachelor's in Pharmaceutical Sciences, related scientific discipline, or equivalent theoretical depth.

Experience: A minimum of ten years of experience in Pharmaceutical, Nutraceutical, Medical Device or related industry is required.

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.

Relevant position titles:

Senior Manager Chemistry and Analytical Development, Pharmaceutical Sciences.