CHPA® | CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Taking healthcare personally.

# Senior Director, Medical Science and Regulatory Affairs

| Date | Department | Location |
|---|---|---|
| 7/19/2024 | Regulatory & Scientific Affairs | Washington, D.C. |
| **Classification/Status** | **Employment Terms** | **Reporting Relationship** |
| Full-Time, Exempt | At Will | VP, Regulatory & Scientific Affairs |

## Organization Overview

Founded in 1881, the Consumer Healthcare Products Association (CHPA) is the national trade association representing the leading manufacturers and marketers in the consumer healthcare industry with its core capabilities, including scientific and regulatory affairs, government affairs, and communications. CHPA is the leading voice fighting to ensure that Americans have access to beneficial over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices they can count on to be reliable, save money and time, and deliver new and better ways to get and stay healthy. CHPA partners with its member companies to promote a more inclusive industry and to support a broader diversity, equity, and inclusion effort to ensure equity for CHPA's staff and consumers in the United States.

CHPA fosters employee engagement and rewards staff through challenging work, competitive compensation and benefits, flexible scheduling and time-off options, and opportunities to grow and develop professionally.

## Position Summary

The Sr. Director, Medical Science & Regulatory Affairs addresses medical, clinical, safety, and toxicology issues impacting OTC medicines. The position also serves as CHPA's liaison to various committees, subcommittees, task and working groups. This role also interfaces with various regulatory and stakeholder groups such as FDA, and USP. In this role the incumbent will also work with members to design and conduct scientific studies.

## Essential Functions

This position description is not designed to cover or contain a comprehensive listing of activities, duties, or responsibilities that are required for this job. Activities, duties, and responsibilities may change at any time with or without notice. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions:

- Develop, direct, and implement action plans for science-based policy initiatives related to OTC drug products

- Provide advice and leadership on scientific issues and regulations impacting OTC medicines

- Represent CHPA at meetings and conferences and present relevant materials focused on OTC topics of interest.

- Monitor, assess, and interpret scientific literature and other sources of data related to dietary supplements, product safety, quality/manufacturing issues

- Direct the development and execution of technical meetings, workshops, and training based on feedback from members, and external stakeholders including FDA, USP and other organizations, as relevant and appropriate.

- Build relationships and cultivate interactive communication with industry member groups and FDA staff, including agency senior leadership as appropriate.

- Form and lead coalitions and partnerships to leverage support on issues of interest to CHPA members.

- Prepare and issue industry guidelines and best practice summaries.

- Work with non-profit scientific institutions, universities, and non-governmental organizations to advance knowledge through support of research in the areas of regulatory and manufacturing science.

- Assist in preparation of comprehensive submissions to FDA on OTC monograph drugs

- Act as the industry representative for contracted research studies and expert consultancies assisting with study design, planning, conduct, analysis and reporting as needed

- Works with and communicates with FDA staff regarding OTC monograph ingredients, providing updates to members.

- Provide programming content for CHPA annual meetings and various webinars

- Other duties as assigned

## Required Education, Work Experience and Skills

- Advanced degree in life sciences (MD, Ph.D., Pharm. D.)
- 10+ years of experience in the OTC medicines industry
    - Note: FDA experience may be substituted for some of the industry

experience

- Strong oral and written communications skills; capable of communicating scientific information clearly to a wide range of internal and external audiences, including non-scientific stakeholders.

- Project management including demonstration of collaborative skills when working with diverse stakeholder groups

- Strategy development and goal setting

- Consensus building to understand individual members or organizational issues and priorities.

- Advocacy – ability to effectively promote and represent CHPA members' views at various forums.

## *Preferred* Education, Work Experience and Skills

- Trade association experience
- Regulatory affairs experience
- Broad and detailed understanding of FDA regulations related to OTC medicines, consumer medical devices and dietary supplements.

- Industry-specific experience related to product development.

## Supervisory Responsibility:
None

## Travel:
5%

## Work Environment:
This job operates in a professional office environment. This role routinely uses standard office equipment such as computers, phones, photocopiers, filing cabinets, and fax machines.

## Physical Demands

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job.

While performing the duties of this job, the employee is regularly required to talk or hear. The employee frequently is required to stand; walk; use hands handle, type or feel; and reach with hands and arms.

This is largely a sedentary role however some filing is required. This would require the ability to lift files, open filing cabinets, and bend or stand on a stool as necessary.

This position requires the ability to occasionally lift office products and supplies up to 10 pounds.

## Position Type/Expected Hours of Work

This is a full-time position. Some flexibility in hours is allowed, but the employee must be available during the "core" work hours of 10:00 am to 3:00 pm and must work at least 37.5 hours each week to maintain full-time status. Occasional evening and weekend work may be required.

## How to Apply

Please enter Sr. Director, MSRA in the subject line of your message and email the following items to jobs@chpa.org.

- Letter of interest
- Resume or CV

## EEO Statement

Consumer Healthcare Products Association is committed to equal employment opportunity and makes all employment-related decisions without regard to race, religion, color, national origin or ancestry, age, sex, disability, pregnancy, childbirth or related medical conditions, sexual orientation, gender identity or expression, genetic information, marital status, family responsibilities, personal appearance, political affiliation, matriculation, veteran or military status, union affiliation or any other categories protected by federal, state, or local law (the "Protected Categories").