

Senior Director, Quality, Technical & Regulatory Affairs

Date	Department	Location
July 18, 2024	Regulatory and 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 Senior Director, Quality, Technical & Regulatory Affairs serves as the lead on quality & chemistry, manufacturing & controls (CMC), and over-the-counter (OTC) medicines. As a subject matter expert, the Senior Director leads and serves as the staff liaison on several CHPA committees and subcommittees. The position also interfaces with several stakeholder groups, including but not limited to USP, GSCF, and FDA. The position also creates educational content for CHPA meetings such as RSQ and Consumer Healthcare (CH) 101. The Senior Director serves as the main point of contact for members when they have issues relating to changes at FDA or other regulatory bodies.

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 and direct science-based policy and implement action plans for technical and regulatory issues via the Association's Quality & Manufacturing Committee and subcommittees.
- Monitors Federal Register, scientific literature and other sources of data for information regarding OTC, Dietary Supplements, and medical device (Class I/II) activities.
- Lead or assist in preparation of the Association's response to regulatory actions, including but not limited to, regulatory guidance, regulations, and requests for stakeholder input.
- Prepare and issue industry technical guidelines and best practice summaries.
- Assists members, internal staff, and the public with questions about OTC products and medical devices.
- Provide support to Government Affairs team for state and federal legislative issues.
- Represent CHPA to FDA and other regulatory agencies
- Represent CHPA at meetings and conferences and present relevant materials at such forums.
- Contribute to the annual planning and implementation of the CHPA Regulatory, Scientific and Quality Conference (RSQ) and CH-101.
- Hold cGMP related training for members.
- Direct the development and execution of additional technical meetings, workshops, and training based on member feedback
- Perform pharmaceutical research in the areas of regulatory and manufacturing science.
- Form coalitions and partnerships with USP and IPEC to leverage support on issues of interest to CHPA members.
- Act as CHPA's representative to organizations with similar regulatory and product quality interests (CDC, GRMA, GSCF, NSF, NJPQCA and PCPC).

Other Duties

- Other duties as assigned

Required Education and Work Experience

- Minimum: Bachelor's degree in chemistry or life science; 7-10 years of experience in the consumer products industry, particularly in manufacturing, quality, and regulatory affairs
- 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.
- Meetings management, including drafting/developing the meeting agenda, conducting/steering/managing the meeting and summarizing outcomes (drafting meeting minutes).
- Advocacy – effectively promote and represent CHPA members' views at various forums for positive outcomes.

Preferred Education and Work Experience

Preferred: master's degree in chemistry or life sciences; 10+ years of experience in OTC medicines, with additional experience in Class I/II devices and/or dietary supplements a plus.

- Note: Relevant FDA experience may be substituted for some of the industry experience
- Trade Association experience
- Industry-specific experience related to development of products including medicines, medical devices, and dietary supplements
- Industry-specific experience related to regulation, formulation, and manufacturing
- International experience, including ability to travel outside the U.S.

Supervisory Responsibility:

None

Travel:

25% with some international travel

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, QTARA 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”).