Manager/Senior Manager, Regulatory & Scientific Affairs

Date	Department	Location
May 17, 2021	Regulatory & Scientific Affairs	Washington, DC

Classification/Status	Employment Terms	Reporting Relationship
Full-Time, Exempt	At Will	VP, Regulatory & Scientific Affairs

Organization Overview

Consumer Healthcare Products Association (CHPA) is the 140-year-old national trade Association representing the leading manufacturers and marketers of over-the-counter (OTC) medicines, consumer medical devices, and dietary supplements. CHPA is committed to empowering consumer self-care by preserving and expanding choice and availability of consumer healthcare products. We foster employee engagement and reward staff through challenging work, competitive compensation and benefits, flexible scheduling and time-off options, and opportunities to grow and develop professionally.

In 2020, CHPA expanded its scope to include consumer medical devices, reflecting the role these products play in the selfcare continuum. This new position builds upon the association's well-established and comprehensive role representing manufacturers of OTC drugs and dietary supplements, with core capabilities including scientific and regulatory affairs, government affairs, and communications.

Position Description

Consumer Healthcare Products Association (CHPA or the Association) is seeking a full-time manager/senior manager, regulatory & scientific affairs (manager/senior manager). This is a new position that will support the Association's representation of consumer medical devices (i.e., FDA-regulated medical devices available over-the-counter (OTC) or without a prescription) and digital health. To that end, only applicants with medical device and/or digital health experience will be considered.

This manager/senior manager will be a key member of the regulatory & scientific affairs department within CHPA and a thought-leader in a variety of ways, including interfacing with CHPA staff on consumer medical device and digital health issues; working to evaluate science and technology; shaping regulatory policy; communicating with regulators and policymakers, and assisting with the Association's expanded representation of consumer medical devices. The manager/senior manager will assist an interdisciplinary internal team to develop and deliver a program of work primarily related to consumer medical devices. This position is stationed at the CHPA office located in Washington, DC.

Essential Functions

These essential functions are 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: To that end, the manager/senior manager is responsible for the following:

- Assisting the Vice President, Regulatory & Scientific Affairs in developing and delivering a sector strategy and program of work for consumer medical devices, including digital health, with CHPA members.
- Providing advice and strategic leadership to member companies, CHPA departments, committees, and working groups on scientific advances and regulations impacting consumer medical devices.
- Monitoring and interpreting the scientific literature and/or regulatory notices pertinent to consumer medical devices, including a critical review and summary of the information.
- Maintains awareness of general issues around medical devices in industry, government, academia, consumer behaviors, etc.
- Writing correspondence on a variety of topics to different audiences (e.g., members, regulatory agencies, consultants, and technical experts).
- Supporting and/or representing CHPA to FDA and other regulatory agencies and non-governmental organizations.
- Supporting and/or representing CHPA at relevant meetings and conferences and delivering presentations on relevant topics.
- Serving as a spokesperson for CHPA in comments to the media and other public forums primarily for medical devices.
- Interacting with other trade Associations, stakeholder groups and standard-setting bodies with interests in medical devices; proposing research projects.
- Conduct daily Federal Register notice scan and distribute to members and relevant stakeholders.
- Develops specific metrics to evaluate program success.
- Collaborate with all departments within the organization.
- Performing other duties that may be assigned.

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 10lbs.

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.

Travel (estimated percentage)

≈5% in the first year.

Work Environment

The CHPA office is in Washington, DC. This job usually operates in a professional office environment but currently requires remote work due to current COVID-19 restrictions (which are subject to change when return-to-office plans are feasible). This role routinely uses standard office equipment such as computers, phones, photocopiers, filing cabinets, and fax machines.

Desired Skills and Experience

A successful applicant should possess the following skills and experience:

- A broad understanding across a wide range of topics related to medical devices, including regulations, innovation/research & development (R&D), product claims support and manufacturing. Experience with digital health and digital technology is desirable.
- Effective oral and written communications skills; capable of communicating scientific, regulatory, and/or technical information clearly to a variety of audiences internally and externally.
- Organizational and project management capabilities; goal setting, consensus building; ability to understand individual member or organizational issues.
- Ability to manage assignments and projects, and to work independently.
- Excellent writer with ability to create diverse content for a variety of audiences, including both highly technical and basic literacy levels.
- Ability to multitask, work well under pressure, balance competing priorities, and meet tight deadlines.
- Ability to work collaboratively with others and contribute to supportive working environment.

Required Education and Work Experience

- Minimum: Bachelor's Degree in a life science or engineering discipline, 1-3 years of experience in the medical device industry and/or with the FDA (manager level); 3-5 years of experience (senior manager level).
- FDA experience within CDRH may be substituted for industry experience.

Supervisory Responsibility

The Manager/Senior Manager does not have direct reports.

EEO Statement

CHPA is stronger by working with people with a diverse set of backgrounds and perspectives. 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").