

**TITLE:** **Heath Authority Outreach**

**IMMEDIATE SUPERVISOR: Sr. Director Regulatory Operations**

**DEPARTMENT: Regulatory Affairs**

**LOCATION: Remote**

**CATEGORY: Exempt**

**General Summary**

You have a passion for influencing better healthcare outcomes. You are looking to build upon your pharmaceutical /regulatory experience in a position where you can impact industry efforts to develop, manufacture and reliably deliver quality medicines to patients.

The International Society for Pharmaceutical Engineering (ISPE) is a not-for-profit association serving its members by leading scientific, technical, and regulatory advancement throughout the entire pharmaceutical lifecycle. ISPE provides a neutral environment where regulators and industry can exchange knowledge to achieve common goals. In this role you will be integral to building and maintaining a strong network of contacts with key regulators (primarily North America but also global) and obtaining their engagement in ISPE mainly as speakers and reviewers of ISPE draft publications. You also will drive intelligence gathering on regulators’ areas of interest, looking for synergies with ISPE’s strategic goals. You must be a persuasive communicator and have the composure and credibility to interact with government officials at all levels, exhibiting diplomacy, tact and professionalism. This is an outward facing role and, as such, will have a significant level of interactions with regulators as well as pharmaceutical industry professionals.

**Principal Duties and Responsibilities**

**Essential Functions:**

* Support Sr. Director of Regulatory Operations in implementing ISPE’s Regulatory Engagement Strategy.
* Build and maintain a strong network of contacts with key regulators and their support staff in ISPE strategic areas of focus, working with ISPE volunteers and Advisor Consultants as needed.
* Work closely with ISPE conference and publications staff, serving as an informed resource for obtaining regulatory speakers and document reviewers.
* Identify obstacles to regulators engaging as speakers, document reviewers, or becoming members of ISPE, which may differ from organization to organization, from agency to agency and from country to country. Work with the relevant ISPE staff teams on approaches to mitigate obstacles.
* Working with ISPE’s regulatory volunteers, gather intelligence on regulators’ current interests/concerns/priorities using various means, disseminate relevant intelligence to ISPE staff and volunteer teams.
* Contribute to the development of ISPE’s Regulator Database by identifying key regulators within global HAs, researching their respective expertise, and entering data as needed.
* Track and report appropriate engagement metrics.
* Monitor key health authorities to identify drafts released for consultation meeting criteria for ISPE comment. Work with ISPE volunteers and consultant advisors to produce comments that are organizationally sourced and of high quality.
* Write, source, and/or review content for ISPE publications (generally in the 900 – 1200-word range) such as reports of ISPE regulatory activities, summaries of ISPE comments on regulatory documents.
* With Senior Director of Regulatory Operations, ensure ISPE regulator engagement communications such as speaker invitations, document commenting, document review, etc. and align with authority requirements or industry best practices.
* Act as backup staff project manager to ISPE regulatory committees and working groups.
* Other projects, duties and responsibilities as assigned.

**Job Requirements**

**Education and work experience:**

1. Bachelor’s degree in a STEM, public policy, or other relevant field required.
2. One or more of the following:
   1. Five or more years’ pharmaceutical manufacturing experience, preferably in regulatory, manufacturing, quality or a related area with GMP/CMC experience. Experience with both small molecule (chemical entities) and biotechnology preferred.
   2. At least three years’ regulatory agency experience, preferably in compliance or review.
   3. Demonstrable comparable experience.
3. Experience interfacing with government regulatory agencies preferred.
4. Experience reading and analyzing legislation and regulations preferred.
5. Professional association experience a plus.

**Skills and knowledge:**

1. Results oriented self-starter.
2. Must possess a solid understanding of the regulatory touchpoints in the drug development process from IND/NDA/ANDA through post-marketing and how they map to the functions of the US FDA. Knowledge of other global regulatory agencies a plus.
3. Ability to establish and maintain relationships.
4. Must have strong writing, project management and communication skills.
5. Ability to work both independently and collaboratively, remain flexible, positive, proactive, resourceful and efficient.
6. Ability to speak English fluently and write to high standards is required. Fluency in other languages is a plus.
7. Must possess multi-cultural sensitivity.
8. Prior work with volunteer organizations is helpful, but willingness to understand a volunteer-driven operation is essential.
9. Knowledge of Microsoft Office Suite products.
10. Ability to travel (less than 10%)

**The above declarations are not intended to be an "all-inclusive" list of the duties and responsibilities of the job described, nor are they intended to be such a listing of the skills and abilities required to do the job. Rather, they are intended only to describe the general nature of the job and are a reasonable representation of its activities.**