

## **JOB DESCRIPTION**

**Position:** Manager, Standards Development  
**Department:** Scientific and Regulatory Affairs  
**Reports To:** SVP, Scientific and Regulatory Affairs  
**FLSA Status:** Exempt, Full Time

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### **Summary Description:**

**Primary Goal:** This position manages the development, setup, and maintenance of the American National Standards Institute (ANSI) Standard Development System for PDA. The candidate will manage the activities and schedule of the Consensus Body teams developing the standards. Strong interpersonal skills are required, with the ability to communicate effectively with all levels of staff and PDA volunteer members, including non-technical and technical personnel.

### **Duties & Responsibilities:**

- Manages Consensus Body teams developing standards to the prescribed activities and timeline of the PDA standards development process.
- Tracks materials produced and submitted for ANSI standards development procedure compliance.
- Conducts standards development training for PDA employees and Consensus Bodies as needed.
- Processes standards submissions and submits materials following ANSI guidelines.
- Responsible for document review and approval of standards development documents, including balloting and comment resolution.
- Maintains tracking system and records in the online document control system.
- Responsible for the retention of standards development documents.
- Supports requests for documentation and updates.
- Other duties as assigned by the supervisor.

### **Education/Experience:**

- Bachelor's Degree, preferably in a related field, and minimum of 5 years' experience or equivalent combination of education and experience
- Standards development experience; formation of teams, production, materials submission, and commenting process
- Project management of multi-disciplinary teams. PMP certification a plus.

**Competency:** To perform the essential functions of this position and the job successfully, an individual should demonstrate the following competencies.

- Experience with electronic documentation required.
- Must be quality oriented and willing to promote quality standards.
- Must be detail-oriented and possess strong organizational and time management skills with the ability to prioritize and manage completion of multiple tasks/projects with company personnel.
- Strong computer skills (Microsoft Office products including Word, Excel and PowerPoint) required.
- Possess strong verbal and written communications
- Familiarity of documentation control practices (e.g., ANSI, ASTM, FDA, or ISO guidelines) desired.
- Familiarity with pharmaceutical or medical device manufacturing a plus.
- Familiarity of ISO and GMP regulations a plus.
- Ability to deal effectively and professionally with a variety of persons

**Qualifications:** To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required.

- Ability to take direction, and accomplish tasks efficiently, on time and accurately
- Ability to prioritize work and to organize an office environment

- Ability to work independently with minimal guidance as well as within a team
- Ability to apply sound judgment and use discretion when dealing with sensitive information
- Excellent interpersonal, analytical and communication (both written and oral) skills
- Ability to work in a team-oriented environment
- Excellent organizational skills
- Knowledge of Microsoft Word/Excel/ PowerPoint/Outlook and Adobe Acrobat
- Can conform to shifting priorities, demands and timelines through analytical and problem-solving capabilities
- Reacts to project adjustments and alterations promptly and efficiently
- Ability to read communication styles of team members and contractors who come from a broad spectrum of disciplines

**Special Requirements:**

**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. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Ability to independently ascend and descend stairs
- Ability to independently reach, twist and bend
- Ability to independently remain stationery for extended periods of time
- Ability to independently lift up to 30 pounds when required by work assignment

**Employee Acknowledgement:** I have read the above position description and I understand and agree with the terms and requirements for this position. I also understand and agree that such requirements may be amended and/or adjusted at any time.

Persons with mental and physical disabilities as defined by the American's With Disabilities Act are eligible for this position as long as they can perform the essential functions of the job after reasonable accommodations are made to their known limitations. If the accommodation cannot be made because it would cause the employer undue hardship, such persons may not be eligible for this position.

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Employee's printed name

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Employee's signature Date

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Supervisor's printed name

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Supervisor's signature Date