Associate Director, Regulatory Affairs

Do you want to be part of building a fully integrated biopharmaceutical company together with a team of highly skilled colleagues who are passionate about developing best-in-class therapeutics that address significant unmet medical needs? Then Ascendis Pharma is committed to support your personal development on our journey towards becoming a leading rare disease company.

Ascendis Pharma is looking to hire an experienced Associate Director, Regulatory Affairs to join our team. This is an exciting opportunity to join a rapidly growing, innovative company!

Position Summary

The Associate Director, Regulatory Affairs will be responsible for developing and implementing global regulatory strategies encompassing clinical, non-clinical and CMC disciplines. Ensures timely preparation of organized and scientifically valid submissions. Provides expertise in translating regulatory requirements into practical, workable plans for project teams with international participants. May mentor and potentially supervise other regulatory professionals working on the project team and regulatory process-related topics. Requires ability to work both independently and in a team environment. The position will be based in Palo Alto, CA.

Key Responsibilities

- Responsible for strategic and operational regulatory input for cross functional (CMC, non-clinical and clinical) areas in collaboration with other project team members, including CMC regulatory team members.
- Contributes to the development of global clinical and regulatory plans and strategies, identifies and proposes risk mitigation strategies, and influences project teams and sub teams across international site locations.
- Contributes to development of global labeling documents (prescribing information and patient information).
- Prepares and/or manages submissions that are technically complex and require extensive interaction with departments outside of regulatory affairs.
- Maintains knowledge of highly complex regulatory requirements up to current date and communicates changes in regulatory information to project teams.
- Schedules and arranges own activities and those of direct reports.
- Work is performed under direction of a Senior Regulatory Affairs professional.

Knowledge, Skills and Experience

- Minimum of 8 years overall regulatory experience, and preferably including experience managing investigational and marketed products
- Prior experience representing Regulatory Affairs on cross-functional teams is desirable; Must be capable of effectively leading teams in preparation of submissions.

- Experience working on international teams desirable
- Must have an extensive knowledge of regulatory requirements, including ICH and regional requirements, and have an understanding of current global and regional trends in regulatory affairs and ability to assess the impact of these requirements to the business.
- Must be capable of critically reviewing complex technical documents and influencing colleagues across functions.
- Experience with drug-device combination products preferred, but not required.
- Ability to travel up to 10-20% of the time domestically and internationally
- Must have experience in filing regulatory dossiers including CTAs, IMPDs, INDs required; experience with BLAs/NDAs/MAAs a plus

Want to apply? Please send your resume to HumanResources@ascendispharma.com. Please write "Associate Director, Regulatory Affairs" in the subject field.