Director, Regulatory Writing

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 Director, Regulatory Writing to join our team. This is an exciting opportunity to join a rapidly growing, innovative company!

Position Summary

Serving as a link among key functions, the Director, Regulatory Writing ensures that critical scientific information is communicated with clarity, precision, and accessibility. This position will work cross-functionally with therapeutic teams, including Clinical, Biometrics and Regulatory, to prepare various documents for regulatory submission. In particular, this role will lead the production of documents forming the basis of a BLA/NDA filing with a focus on clinical documents (Modules 2 and 5).

This position will be based in Palo Alto and will report to the VP, Clinical Development.

Key Responsibilities

- Demonstrate a command of therapeutic areas and expertise with assigned products in growth hormone deficiency, hypoparathyroidism, achondroplasia, and new therapeutic areas in development
- Initiate and shepherd Common Technical Documents (CTD) through the content creation, review, approval and submission.
- Research, develop, and write content that is scientifically accurate, evidence-based, grammatically accurate, referenced using appropriate sources, and consistent with quality and regulatory standards
- Interpret and apply clinical data in medical and scientific communications deliverables
- Lead internal author reviews of documents and effectively manage the editing and revision process
- Clearly communicate medical scientific concepts in a condensed, audience-appropriate way
- Demonstrate the flexibility/adaptability necessary to collaborate with and interpret input from different therapeutic teams, including Clinical, Biometrics and Regulatory
- Demonstrate aptitude for technical writing, specifically writing related to medical devices

Knowledge, Skills and Experience

- Educational background (BS, MS, PhD, PharmD, or MD), advanced degree in life sciences preferred
- 5+ years previous experience in medical/scientific communications and medical writing (agency or in house)
- Understanding CTD guidelines and submission process for US FDA and EMA

- Exceptional ability to manage multiple projects in a fast-paced environment, with changing priorities and significant time pressures
- Understands and effectively responds to multicultural communication styles and business practices with vendors, partners, and internal colleagues
- Ability to navigate and be successful in a fast-paced, highly-matrixed work environment
- A high level of initiative and self-motivation
- Substantial drive and goal orientation
- Excellent presentation skills, written and verbal communication skills

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