Director, Regulatory Global Labeling

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 Global Labeling to join our team. This is an exciting opportunity to join a rapidly growing, innovative company!

Position Summary

The Director, Regulatory Global Labeling is a strategic and operational role to manage labeling projects from cradle to grave. The incumbent will be responsible for the development and maintenance of regulatory compliant, competitive, and up-to-date core labeling and local labeling documents for assigned key development projects and future marketed products throughout the product's lifecycle. The Director is responsible for the management of labeling for multiple products in development and commercial distribution. The Director of Regulatory Global Labeling provides strategic and operational regulatory labeling input to labeling content, submission, production, and implementation worldwide. The Director works in close collaboration with subject matter experts on Global Core Teams with Program-specific teams, and Senior Management.

Key Responsibilities

- Provides regulatory strategic guidance and oversight of global labeling activities for development products and commercial products.
- Provides regulatory strategic guidance to development teams on the clinical design requirements to support labeling claims
- Leads the Product Labeling Teams to develop labeling content for global and local labeling worldwide including the development and management of the Company Core Data Sheets (CCDS) that ensure commercial product labeling is compliant with the worldwide regulations and is of the highest quality
- Organize and lead cross functional expert labeling Product Labeling Teams (PLT) (including experts from Regulatory, Clinical, Safety, Technical Operations, Supply Chain, Pharm Tox, REG CMC, etc.) to discuss labeling strategy, reach consensus on global labeling matters, assess impact of regional/local labeling changes on the CCDS, and assist with the preparation of high quality documents to support the creation of the CCDS and/or changes to the local labeling for assigned development projects or marketed products.
- Represent Regulatory Affairs as a member of product core teams present strategic global labeling issues to Regulatory Management on an ad-hoc/issue-driven basis for assigned projects/products.
- Provide strategic input on interpretation and implementation of key regional labeling regulations, guidelines, and best labeling practices
- Prepare and manage international labeling including tracking differences in local labels to the CCDS, ensuring local requirements are met, and translations are properly executed.
- Provide RA input to Periodic Safety Update Report (PSUR) and Annual Reports for assigned products.

Knowledge, Skills and Experience

- 8 to 10 years required of regulatory pharmaceutical industry experience and extensive experience (at least 3 years) in global labeling, or equivalent experience
- Outstanding interpersonal and communication (written and verbal) skills.
- Attention to detail and highly organized.
- Thorough understanding of regulatory labeling requirements and strategic labeling planning.
- Prior experience leading cross functional teams.
- History of solving regulatory labeling related problems exhibiting superior judgment and a balanced, realistic understanding of issues.
- Fluency in English as business language
- US regulatory experience required; EU experience desired.

Education Minimum requirements

- BS or MS with requisite experience and demonstrated capability. Advanced degree (MD, Ph D, PharmD) preferred
- Ability to travel up to 20% of the time domestically and internationally

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