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Rest of World Regulatory Labeling Lead

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Company: Astellas Pharma Inc.

Location: Netherlands

Category: computer-and-mathematical

Description: Rest of World Regulatory Labeling LeadAbout Astellas: At Astellas we can offer an inspiring place to work and a chance to make your mark in doing good for others. Our expertise, science and technology make us a pharma company. Our open and progressive culture is what makes us Astellas. It's a culture of doing good for others and contributing to a sustainable society. Delivering meaningful differences for patients is our driving force. We all have a significant opportunity to make that difference, working locally in the areas we know best, whilst drawing inspiration from the different insights and expertise we have access to globally and from our innovative, external partners. Our global vision for Patient Centricity is to support the development of innovative health solutions through a deep understanding of the patient experience. At Astellas, Patient Centricity isn't a buzzword - it's a guiding principle for action. We believe all staff have a role to play in creating a patient-centric culture and integrating an awareness of the patient into our everyday working practices, regardless of our role, team or division. Our ethos is underpinned by the Astellas Way, comprising five core values: patient focus; ownership; results; openness and integrity. We are proud to offer an inclusive and respectful working environment that fosters collaboration and ownership. Our aspiration is to bring the best brains together, to provide them with world-leading tools and resources and a unique structure that fosters real agility and entrepreneurial spirit. About this role:The Rest of World Regulatory Labeling Lead is a pivotal role at Astellas Pharma Global Development, reporting directly to the Head of Regulatory CCDS and Labeling. As a key member of the labeling leadership team, you will play a crucial role in providing regulatory leadership and support for CCDS and product

labeling across the Rest of World Established and International market products. Your responsibilities will encompass new product labeling development, life cycle management, and ensuring strict compliance with regulatory guidelines. Hybrid working: At Astellas we recognise the importance of balancing your work and home life. This role offers a remote working solution so you can optimise the most productive work environment for you to succeed and deliver. In this role, you will:
Lead ROW labeling development and implementation for Astellas products. throughout the product lifecycle.

Manage the labeling content review and approval process, ensuring regulatory, therapeutic area, and clinical knowledge is applied.

Provide oversight to other Regulatory personnel, including regional implementation labeling leads.

Implement process improvement changes to enhance the efficiency of the label review process.

Participate in the identification of risk areas and develop alternative courses of action including anticipation of regulators' responses through scenario and development of contingency plans.

Assess the impact of new labeling regulations and implement appropriate changes.

Essential Knowledge & Experience:
Advanced experience in the pharm industry, preferably including area of
labeling development and review for prescription pharmaceutical or similarly regulated industry.

Excellent planning, organizational, analytical, problem-solving, and decision-making skills.

Ability to lead and motivate others, with a proven track record of success as a leader driving projects to completion.

Proficiency in regulations, guidelines, and precedents related to pharmaceutical product development, with a focus on product labeling and packaging.

Proven experience in navigating regulatory landscapes, especially in diverse international markets.

Preferred Experience:

Scientific knowledge in chemistry, general biological/physical science, and the ability to apply that knowledge to regulatory issues and product development.

Proficiency in a second language is a plus.

Ability to lead and motivate others, drive projects to completion, and exercise sound judgment.

Strong computer skills, including electronic document management systems.

Required qualification:

Bachelor’s degree in a life science field or equivalent.

Additional information:

This is a permanent full-time position.

Position is based in the United Kingdom or the Netherlands.

This position is 100% home/remote based.

We are an equal opportunity employer and all qualified applicants will receive consideration for employment without regard to race, colour, religion, sex, national origin, disability status, protected veteran status, or any other characteristic protected by law.

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