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Head of Regulatory Affairs EMEA

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Company: Argenx

Location: Ghent

Category: other-general

For the expansion of our EMEA team, argenx is looking for a Head of Regulatory Affairs, EMEA.

argenx

argenx is a fast-growing global immunology company committed to improving the lives of people suffering from severe autoimmune diseases. Thanks to colleagues based in Europe, the United States and Japan, we translate immunology breakthroughs into a world-class portfolio of novel antibody-based medicines.

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PURPOSE OF THE ROLE

The Head of Regulatory Affairs, EMEA, is a key member of the global regulatory team as well as the EMEA Leadership Team (ELT). This role serves as a close business partner and facilitator of regulatory activities, and is expected to contribute to build and grow the organization across the region. The individual will play a critical role across the product life cycle and will be a key advisor and enabler of successful product launches and commercialization at a regional and country level across the region. In close collaboration with other functional heads and the broader regulatory team, this role is responsible for high quality and timely guidance in all areas of the business, from pre-approval activities, to filing, distribution, and post-approval regulatory activities, among others.

ROLES AND RESPONSIBILITIES

An important aspect of the role is to work with the Global Head of Regulatory to develop and

implement infrastructure and process improvements to enhance the efficiency of the Global RA organization with a view to enabling more simultaneous submissions.

Establish the EMEA regulatory strategy for marketed and pipeline products and ensure it is in line with the global regulatory strategy, taking into account the diverse needs of the EMEA region

Perform or oversee the preparation of the registration dossiers and adequate response to all agency questions

Ensure the labelling components relevant to the region are based on the company core datasheet and prepared in conjunction with the EMEA team

Secure regulatory approvals within the EMEA region, on time as per plan, ensuring cross-functional partners are fully aware of procedures and timelines to guarantee organizational readiness

Proactively seek out robust cross-functional input to help inform decision-making and appropriate trade-offs regarding labelling, procedural steps, and overall probability of regulatory success

Collaborate with supply chain, CMC, distribution, and market access colleagues to ensure regulatory strategies are aligned with broader organizational strategies

Monitor regulatory approvals, trends, and dynamics in clinical areas of interest to the company, and proactively share regulatory intelligence internally, as appropriate

Provide strategic, operational and tactical regulatory insight on pre-approval activities, including EAP development and roll-out

Serve as the regulatory affairs business partner to local commercialization teams on all matters related to product promotion and materials review

Partner with medical, legal, quality, PV, market access and distribution teams to ensure regulatory input is provided in a timely matter to support business decisions

Ensure alignment between business strategy within the EMEA team and the broader global regulatory strategy and development teams

Support the EMEA business in all other regulatory-related activities, this includes local regulatory activities in individual member states, where needed.

Oversee regulatory affairs vendors involved in filings and help ensure high quality interactions with the EMA and other EMEA agencies

Lead and develop the EMEA regulatory team.

SKILLS AND COMPETENCIES:

Prior experience in the build-out of organizations and the creation of regulatory infrastructure to support commercialization from scratch

A thorough understanding of the drug development process with expertise in orphan drugs, along with knowledge of and monitoring of the evolving landscape of regulations and guidelines, specifically in Europe, Middle East and Africa

Demonstrated ability to coordinate the development of critical regulatory documents involved in the approval of medicines in Europe, including direct experience leading end-to-end regulatory submissions

Affinity with science and ability to interact with scientists and clinicians, internally and externally

Direct experience interacting with regulatory authorities across EMEA, and a successful track record of interactions among regulatory agencies

A clear communicator who can influence stakeholders effectively, both internally and externally, with outstanding presentation, written and verbal communication skills in English and at least one other major EU language, to succeed within a multi-cultural and multi-lingual global environment

Create a culture of collaboration, excellence and innovation which inspires team members to be trailblazers and perform at their highest abilities, optimizing their effectiveness to enable the timely and quality creation of local submissions

You show strong leadership with proven ability to build, motivate and develop a team of full time and contingent workers

You resonate with the values of argenx and you are ready to drive the Company Culture

You combine strategic thinking with the ability to execute, both individually and by leading teams, to achieve operational excellence in the face of challenging goals

Is agile and demonstrates adaptability, comfort with ambiguity, trust-building, and resilience

Demonstrable experience with project management, proactive planning, priority setting, and securing alignment

Ambitious, inquisitive naturally, a quick study, with demonstrated eagerness to continuously learn, self-improve and develop. This includes being comfortable giving and receiving feedback in a diverse environment.

Passionate and prepared to lead and contribute to our culture, which is driven by our corporate values of co-creation, innovation, empowerment, excellence, and humility

EDUCATION, EXPERIENCE

Minimum 10 years of regulatory affairs leadership experience within biopharmaceutical organizations, of which at least 5 years must have been in senior leadership roles overseeing European regulatory activities

PhD or PharmD preferred

Join argenx

At argenx, we build our culture from the collective power of the team and the knowledge that together, we are better. If you are entrepreneurial, curious and committed to making a difference for patients and thrive on creating solutions for rare autoimmune diseases, then argenx is for you.

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