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Head of Regulatory Affairs Benelux

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Company: Aspen Pharma Group

Location: Belgium

Category: other-general

Head of Regulatory Affairs Benelux

Aspen Pharma Group

2023-07-07 Belgium

Job Ref #: AP-4195

Industry: Pharmaceutical And Medical/Healthcare

Job Type: Permanent

Positions Available: 1

Applications are invited for the above indicated vacancy that exists in the Regulatory Affairs department in Benelux region. This full-time permanent position iwill be based in either Belgium or Netherlands. The successful incumbent will report to the Head of Regulatory Affairs Europe CIS.

Job Description

Manage and oversee regulatory activities for the Benelux region, ensuring compliance with local regulations.

Provide regulatory support for distribution and sales processes.

Manage regulatory submissions and ensure timely completion according to company strategy and registration deadlines.

Compile registration dossiers in accordance with EU and local requirements, addressing any

deficiencies.

Proactively identify and communicate risks related to marketing authorization applications.

Respond promptly to health authorities' queries and deficiencies.

Support and prepare data for registration fees.

Maintain marketing authorizations through variations and renewals.

Track submission progress and communicate with stakeholders and service providers.

Communicate health authority approvals and decisions to relevant parties.

Collaborate with other departments for timely product introductions.

Lead and develop the Benelux Regulatory team.

Stay updated on local regulatory requirements and maintain regulatory knowledge within the department.

Assess the impact of new regulatory requirements on existing documentation.

Cooperate with other Aspen entities to obtain timely product approvals.

Provide support in registration strategy and monitor the changing regulatory environment.

Monitor approval timelines and intervene when necessary to minimize delays.

Organize national translations efficiently to meet registration timelines.

Assist in due diligence processes for new business development.

Implement and adhere to regulatory procedures, provide training, and ensure accurate record-keeping.

Job Requirements

High level education such as BSc, MSc, PhD or Pharmacist in Life sciences or related area

At least 5 years in a similar role in Regulatory in the pharmaceutical industry

Results and performance driven – deliver results that meet or exceed expectations

Accountability and ownership – deciding and initiating actions

Sense of urgency – responding to issues and opportunities in a timely manner

Intellectual curiosity – willing to suggest and try new ideas

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