Aristo

Berufseinstieg in Regulatory Affairs in München

REGULATORY AFFAIRS ASSOCIATE (m/w) (befristet auf 12 -18 Monate)

Essential Duties and Responsibilities

Regulatory Submissions

Prepares regulatory submission documentation with direct supervision from line manager to ensure all regulatory submissions to local HAs are done in line with local HA requirements, SOPs and business objectives for assigned product(s) or projects.

Main types of submissions are (not-exhaustive):

- Clinical trials applications, amendments and other clinical trials submissions
- Variations and other MA maintenance applications
- Risk minimization materials
- Dear Health Care Professional communication

Interaction with Local Health Authorities (HA)

- Supports the interaction and communication with the local HAs.

Compliance with the Relevant Laws and Regulations that Relate to the Core Activities of Regulatory Affairs

- Support to ensure compliance with local law and regulation and consistency with global procedural documents.
- Contributes as requested to the creation, maintenance, training, evaluation and tracking of all local regulatory owned procedural documents including policies, SOPs, manuals and working instructions that are needed locally to fulfill regulatory obligations.
- Supports the activities needed to ensure compliant labeling for medicinal products in the country (SmPC, PIL, packaging) and manage timely updates for assigned product(s).

Key Differentiating Responsibilities / Contributions

- Preparation of regulatory submissions with direct supervision from line manager which require interactions with departments outside of Regulatory Affairs for investigational and commercial products in line with European and national regulatory requirements, and company policies and procedures.

- Responsible for ensuring product packaging and associated information is updated and maintained in accordance with the product license for assigned products and territories:
  - Management and review/proofreading of product information texts for various German compendia.
  - Review and proofreading of product labels and patient information leaflets.

- Participate in group meetings and present project status updates.
- Responsible with manager for development and acquisition of required regulatory skills and knowledge.
- Contribute to local process improvements, which have a significant impact on the working of the Regulatory Affairs function or other departments.
- Work is performed under supervision of senior regulatory personnel.

Professional Experience / Key Skills

- Degree in a scientific field (pharmacy preferred) and/or master in regulatory affairs; experience in regulatory affairs preferred, but not mandatory.
- Experience in and understanding of role of RA and regulatory requirements in Pharmaceutical / Biotech Industry including ICH requirements and regional requirements and have an understanding of current trends in the local territory is preferred
- Excellent organization skills and ability to work on a number of projects with tight timelines is required.
- Excellent verbal and written communication skills (German and English) and interpersonal skills are required.

Bitte senden Sie Ihre Bewerbungsunterlagen (Lebenslauf, Anschreiben und Zeugnisse) an:

Iryna Pryval
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089 599 18 27 200

Für Rückfragen stehe ich Ihnen gerne zur Verfügung,
Iryna Pryval