Location: Leiden
Fulltime contract

Pharming Group N.V. develops innovative protein therapeutics for the treatment of genetic disorders. At this moment, the company is focused on furthering science, technology and new product development as well as the commercial roll-out. Within our organization in Leiden, the Netherlands, we are looking for a:

Regulatory Affairs Biomedical Senior Specialist

The Regulatory Affairs (RA) Biomedical Senior Specialist, in close collaboration with the Director RA, will be responsible for the creation (writing and/or compilation) of documents and adherence to appropriate legislation and regulations pertaining to the biomedical regulatory part of the medicinal product dossier. The RA Biomedical Senior Specialist is well aware of the Competent Authority expectations and can pro-actively and independently convey these expectations within the organization.

TASKS AND RESPONSIBILITIES:

Documentation & management

- Investigate and analyse requirements for regulatory procedures based on legislation and regulations and ensure appropriate documents are in place. Coordinate with the relevant Pharming departments (e.g. Pharmacovigilance, Medical, Clinical, Marketing & Sales, and Supply Chain) according to the purpose of the procedure, based on the requirements of the (regional) Competent Authorities.
- Dependent on content expertise, write and/or review, guide, compile, and submit documents (CTAs, PSURs, DSURs, PIP, labelling, Policy 0043/0070 documents, protocols, educational materials, artwork mock-ups, promotional materials) for different regulatory procedures.
- Guide, coach, teach and/or instruct other Pharming departments on how regulatory requirements can be met.
- Evaluate compliance of advertising and / or medical information material with (inter)national legislation.
- Compile, finalize and distribute internally and/or externally regulatory documents such as product information (Module 1.3.1 - 1.3.2), CPPs, etc.
- Maintain overviews, archive documents, follow procedures, perform life cycle management activities (e.g. in eDMS).
- Ensure that eCTD files are brought and maintained up-to-date.

Planning & organization:

- Collect/compose required documents, set-up meetings with relevant stakeholders, create reports/minutes of meetings.
- Develop regulatory strategies for procedures (in collaboration with the Director RA), take initiatives and gain support for this in the relevant Pharming departments.

Communication & support:

- Participate in project teams. Provide support in biomedical fields of RA to project teams.
- In consultation with Director RA, act as contact person for regulatory authorities and provide internal and external communication regarding registration requests.
- Be the contact person for (inter)national partners/sites (such as eCTD publisher, pharmacovigilance provider(s), regulatory consultants, translation agencies, artwork agency/manufacturers)

- In consultation with the Director RA act as the internal RA representative in project teams
- In consultation with the Director RA act as the RA lead in assigned project teams

JOB REQUIREMENTS:

Education:

A university degree (MSc.) in a relevant discipline such as Pharmacy, Pharmacology, (Medical) Biology, (Biomedical) Pharmaceutical Science.

Additional training:

- Good command of the Dutch and English language in word and writing
- Experience with MS-Word, MS-Outlook, MS-Excel
- Knowledge of regulatory procedures and EU guidelines for the content of regulatory dossiers, product information, pharmacovigilance, and drug advertising
- Knowledge of and experience with electronic document management systems (eDMS)
- Knowledge of and experience with eCTD life-cycle management

Experience:

At least 4 years of experience in RA
Relevant experience is experience with regulatory procedures and compilation and/or writing of dossier module texts

COMPLEXITY:

Internal contacts:

RA, PV, QA, Marketing & Sales, Medical (writer) & (pre)Clinical, Supply Chain, Legal

External contacts:

(national) Competent Authorities, eCTD vendor, CROs, medical writing agency, manufacturing and/or design agencies for artwork, packaging company, translation agencies, lawyers, PV-service provider, etc.

COMPETENCES:

- Accuracy, attention to detail
- Structured, ability to plan and organize
- Ability to familiarize oneself quickly with new and complicated matters
- Ability to take responsibility
- Independence
- Collaborative orientation
- Good communication skills
- Proactive attitude
- Results-oriented
- Ability to set priorities
- Both resilience and flexibility
- Ability to convey regulatory expectations diplomatically in appropriate (multidisciplinary) project teams and gain support for this.

More information:

For more information concerning this position please send an e-mail to HR-EU@pharming.com.
Please apply per email: vacatures@pharming.com