hameln

To support our teams, we are looking for a position in Hameln or Solingen as soon as possible

Regulatory Affairs Manager (f/m/d)

Full or part time

What you can expect:

In your function as Regulatory Affairs Manager, you are responsible for the preparation and application of international marketing authorizations (MAs), including the development of the regulatory strategy for our various finished products. Handling of deficiency letters from authorities and maintenance of the existing MAs over the entire product life cycle is within your sphere of responsibility. In addition, you monitor the normative modifications and coordinate the maintenance activities for the countries you're responsible for. You will work collaboratively with international partners, the relevant public authorities and colleagues at our locations. As part of your job, you have to take care about electronic document archiving and maintenance of the regulatory databases.

What we expect:

- Successfully completed studies in natural sciences (chemistry or pharmacy) or a comparable qualification with at least 3 years of professional experience in a regulatory affairs department
- Very good knowledge of the eCTD, especially in the area of module 1
- Good knowledge of the national and international regulatory requirements for new marketing authorizations and maintenance of medicinal products in the EU and/or international
- Initial experience in project management and working with the Registration Information Management Systems are an advantage
- Self-motivation and self-organization as well as a careful and efficient working style
- Very good written and spoken German and English skills
- An additional foreign language is an advantage
- Confident use of MS Office and modern communication methods
- A high degree of flexibility, communication and team skills and enthusiasm for continuous learning

What we offer:

- Versatile, varied tasks and cooperation with international teams
- Extensive, industry-specific onboarding
- A dynamically growing company in a "future-proof" industry
- Flat hierarchies, an open corporate culture and strong team spirit
- Flexible working hours and the possibility to work remotely
- Fair, attractive remuneration
- Subsidies for company pension schemes and savings plan benefits
- Versatile training and development
- Attractive, modern work environment with ergonomically designed workstations

hameln pharma gmbh is the headquarters of an international owner-managed pharmaceutical group, now in its fourth generation, specializing in the development, approval and marketing of generic pharmaceuticals. Doctors, pharmacists and nursing staff in more than 55 countries value and trust our know-how and experience in the field of injectable dosage forms.

If you are interested in this role and believe you can contribute to our success, we would love to meet you.
We look forward to receiving your complete application, stating your earliest possible starting date and your salary expectations.

hameln pharma gmbh
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