Regulatory Affairs Manager (m/f/d)

Position: full-time, permanent
Location: Bad Homburg v. d. Höhe
Starting date: as soon as possible

Who are we?

MYR Pharmaceuticals is a young German biotech company based in Bad Homburg. Our team office is international and dynamic, and we value flexibility and teamwork, as we believe they are the key to success. We are continuously working on creating a comfortable workplace in which ideas are shared and discussed freely. Our lead product, bulevirtide, has a unique and innovative mechanism of action of HBV/HDV entry inhibition. Bulevirtide has received PRIME status (Priority Medicines) at the EMA (European Medicines Agency) and breakthrough designation for treatment of chronic Hepatitis D at the FDA.

We pride ourselves with the internationality of our company, our team consisting of people from all over the world. We find ourselves incredibly lucky to have a chance to learn from each other, to cooperate tightly, and to share ideas which differ thanks to various backgrounds we have.

What are we looking for?

MYR Pharmaceuticals is growing and developing rapidly. Therefore, we are looking for more colleagues to strengthen our team! At the moment, we are looking for a Regulatory Affairs Manager (m/f/d).

Your tasks

As a Regulatory Affairs Manager, your area of responsibility would include:

- Provide responses to regulatory agencies regarding product information or issues.
- Train staff in regulatory policies or procedures.
- Coordinate internal discoveries and depositions with legal department staff.
- Develop and maintain standard operating procedures or local working practices.
- Establish regulatory priorities or budgets and allocate resources and workloads.
- Maintain current knowledge of relevant regulations, including proposed and final rules.
- Manage activities such as audits, regulatory agency inspections, or product recalls.
- Participate in the development or implementation of clinical trial protocols.
- Communicate regulatory information to multiple departments and ensure that information is interpreted correctly.
- Management of external regulatory agencies and consultants.
- Oversee documentation efforts to ensure compliance with domestic and international regulations and standards.

- Investigate product complaints and prepare documentation and submissions to appropriate regulatory agencies as necessary.
- Contribute to the development or implementation of business unit strategic and operating plans.

Your profile

The following qualifications are required for you to be eligible for this position:

- Degree in life science, medicine or pharmacy
- Experience in pharmaceutical environment
- Very good command of English (both oral and written), as well as German
- Thorough knowledge of guidelines
- Problem-solving skills
- Self-driven and structured/organized
- Strong presentation skills

- 1 year of experience in Regulatory Affairs – advantage

What we offer

At MYR Pharmaceuticals we are looking for unique employees for our unique product. In our team, instead of building walls between different departments, we tear them down together.
In order to make you feel great working with us, we offer:

- A permanent position with the opportunity to develop quickly within the company
- An attractive fixed salary

If this sounds interesting to you, and you see yourself as a part of our team, please get in touch with us without hesitation! Please send us your CV, letting us know which position you are applying for. We are looking forward to meeting you!

For any further information, please do not hesitate to contact us via the E-Mail address which you can find below.

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