# Global Head of Regulatory Affairs (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 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), breakthrough designation for treatment of chronic Hepatitis D at the FDA and has been granted Conditional Marketing Authorisation from EMA since July 2020.

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 Global Head of Regulatory Affairs (m/f/d).

## Your profile

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

- Degree in life science, medicine or pharmacy
- Min. 2 years of 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

## Advantages

- PhD degree advantageous
- Min. 5 years of experience in regulatory affairs

## Your tasks

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

- Being accountable to lead the global regulatory strategy for the Company's product
- Have oversight and accountability of the Company's interactions with global regulatory authorities
- Interaction with regulatory authorities (e.g. EMA, FDA, CFDA)
- Represent organizations before domestic or international regulatory agencies on major policy matters or decisions regarding company products
- Provide responses to regulatory agencies regarding product information or issues
- Develop relationships with state or federal environmental regulatory agencies to learn about and analyse the potential impacts of proposed environmental policy regulations
- Provide regulatory guidance to departments or development project teams regarding design, development, evaluation, or marketing of products
- Management of documentation for submissions: reports, dossier, brief books and so on
- Review all regulatory agency submission materials to ensure timeliness, accuracy, comprehensiveness, or compliance with regulatory standards
- Internal interface and across departments for regulatory questions.
- Communicate regulatory information to multiple departments and ensure that information is interpreted correctly
- Management of external regulatory agencies and consultants
- Operative and strategic planning of regulatory activities and budget planning
- Oversee documentation efforts to ensure compliance with domestic and international regulations and standards
- Managing the pharmacovigilance provider of the company: ensuring all PV functions are performed by the provider as required by GVP and national requirements, communication with QPPV, implementing the PV processes inside the company

**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
- Strong team-work between and within departments
- Friendly, dynamic atmosphere
- Continuous opportunities to learn by being involved in various tasks

**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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