Executive- Regulatory Affairs/Pharmacovigilance

About Bluefish Pharmaceuticals

Founded in Sweden, with its long tradition of industrial entrepreneurship, Bluefish Pharmaceuticals has become one of the most progressive generics pharmaceuticals companies. At Bluefish, we strive to make quality medicine accessible to more people.

Bluefish creates value in the full pharmaceutical value chain from developing to manufacturing and successfully marketing generic pharmaceuticals and we take pride in doing this in an innovative, responsible and cost-efficient way. Bluefish currently conducts operations in 19 countries in Europe and, over the next few years, will also expand outside Europe with the aim of becoming a global player.

Our corporate culture and close collaboration with development and manufacturing partners are integral parts of our effort to deliver quality products at affordable prices.

We offer a product portfolio consisting of a broad range of high-quality generics for all major therapeutic areas. It is part of our long-term strategy to expand the product portfolio of off-patent blockbusters while at the same time offering a broader range of niche products within more narrow disease areas.

Bluefish products all originate from a generic substance, where the efficacy and safety are well documented. Through our many collaborating partners, we have access to a vast range of technology platforms, enabling us to develop and enhance the intellectual property of our product portfolio.

Our strategy of developing products based on well-known substances with an improved value to patients results in a product portfolio with a significant market potential. We achieve this with a relatively short development time, low risk, and limited investment.

By focusing on innovation and simplicity in both thought and action, and by taking responsibility on all markets and cost efficiency in all stages, we are creating a strong and vibrant brand that offers quality pharmaceuticals at prices affordable to all.

Bluefish provides quality generic pharmaceuticals at affordable prices. Its product portfolio contains a wide range of products within all major therapeutic areas.

Since its inception, Bluefish has developed the platform and know-how to participate in and to be an integral part of all major steps of the value chain in the offering of generic pharmaceuticals. With the vision of offering quality pharmaceuticals at prices affordable to all, we have to be innovative and at the same time cost-efficient in all stages. This includes operational excellence in departments such as product development, quality assurance, pharmacovigilance, IP and supply chain as well as marketing and sales.

Profile Description

Bluefish is looking for profiles to fill the position of Executive Regulatory Affairs/Pharmacovigilance, contributing to the accomplishment of the Regulatory Affairs and Pharmacovigilance function objectives. The position will report to Head-Regulatory Affairs & team lead Case Management Team. The role would be involved in the below mentioned areas:

- Local PV / Local RA
- Acting as a supporter to Bluefish Pharmaceuticals with regards to Pharmacovigilance and regulatory activities towards patients, healthcare professionals and Competent Authorities in the territory
- Keeping the Art.57 database (XEVMPD) up to date
- Monitor and give feedback to Bluefish Pharmaceuticals on national legislation and its implementation regarding the areas of interest (i.e. RA/PV)

Tasks Regulatory Affairs:

- Lead submissions of applications for new licenses and variations, following up the process with MPA and if needed negotiating with the national authority
- Translation of texts for labelling, PILs and SmPCs and review changes required to these by national authority
- Submission of national notifications to MPA and timely follow up for approvals
- Review and approval of artworks in line with approved texts, national authority regulations (Blue box)
- FASS update, Liiv Update
- Other task allocated by the manager from time to time

Tasks Pharmacovigilance:

- Managing submissions of XEVMPD
- Back-up for local drug safety officer in the North Region
- Case management

Administrative activities:

- Keeping databases up to date at all times.

Candidate Specifications

Education and Experience

Minimum of a state examination, master's degree or equivalent in Pharmacy (preferred), Biology, Chemistry or related life sciences and at least 2 years of experience in Regulatory Affairs in Pharmaceutical industry. Previous experience of XEVMPD (Art.57 database) would be advantageous.

Skills & Abilities Requirements

- Good Team-worker
- Positive and “can do” attitude
- Personal development through self-learning
- Good command of the Swedish and English language, familiarity with common MS-Office programs (in particular word and excel). Ability to work independently, accurately, and reliably. High degree of organizational talent and good team worker

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