Deputy QPPV

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

A fantastic opportunity has arisen for a Deputy QPPV role at Bluefish Pharmaceuticals.
We are looking for an experienced Pharmacovigilance professional to join our company as Deputy QPPV to support the Qualified Person responsible for Pharmacovigilance (QPPV) and ensure complete oversight of the Bluefish Pharmacovigilance System.

You will be involved in reviewing PSURs, RMPs, addendum to the clinical overview and other scientific documents. Together with the QPPV, you shall promote strong working relationships with local Drug Safety Officers in EU Countries and Global Pharmacovigilance Department.
This is a permanent position, located either in Stockholm (Sweden), Dublin (Ireland), Madrid (Spain) or Frankfurt (Germany).

- Deputy QPPV, reporting to the Head of Pharmacovigilance will act as a back-up and support for the QPPV. Core duties include:

- Act as a 24-hour back-up in the case of QPPV absence.
- Support the QPPV function within the company and globally, ensuring constant compliance with European PV Legislation and European Regulations and maintaining the companies Pharmacovigilance system
- Ensuring awareness of compliance with PV requirements. This includes but is not limited to individual case reports and aggregate reports quality and submission timeliness, and implementation of risk minimization activities
- Review of labelling updates
- Working with safety data exchange agreements (SDEAs)
- Acting as an ambassador for PV governance within and outside the company
- Participate in Signal Management activities; contribute to identification and evaluation of safety signals from all available sources

Candidate Specifications

Education and Experience

- A degree in Pharmacy, Biology, Nursing, Toxicology, Medicine or an equivalent degree from the Life Science field
- Min 5 years of experience in Pharmacovigilance
- Demonstrable Expert knowledge in EU PV legislation
- Experience in regulatory agency inspection planning, preparation, conduct, management and agency interactions
- You are used to work in a multidisciplinary team and have great organizational skills
- Strong planning and organization skills and communications skills
- Advanced in English is a requirement, advanced in other European languages is an advantage

Skills & Abilities Requirements

- Must have good communication, presentation and problem-solving skills
- Must have ability to meet deadlines, and work on multiple projects simultaneously
- Must be a team player and be able to interact with staff at all levels of the company and with external parties as well
- Must have ability to work independently

Location

Based either in Stockholm (Sweden), Dublin (Ireland), Madrid (Spain) or Frankfurt (Germany)

Email: hr@bluefishpharma.com

Applications are reviewed continuously.