Executive-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 – Pharmacovigilance/Quality management team, contributing to the accomplishment of the Pharmacovigilance function objectives. The position will report to Asst. Manager. The role would be involved in the below mentioned areas:

- Maintenance of pharmacovigilance (PV) quality management system in accordance with EU and worldwide PV legislations
- Bluefish PV record retention process
- Standard Operation Procedures (SOPs) and policies in the Electronic Quality Management System (EQMS)
- Responsible for PV training
- Assisting Qualified Person Responsible for Pharmacovigilance in the EU (QPPV) and Head of PV India for the quality activities
- Review the PV quality system at regular intervals in risk- based manner
- Audit

- Monitoring of deviation and CAPA status
- Review of Signal management reports, Risk Management Plan (RMP) and risk minimisation activities, Addendum to Clinical Overview (ACO), Periodic Safety Update Report (PSUR), PV intelligence report including EURD list, Pharmacovigilance System Master File (PSMF)
- Random quality review of ICSRs in Bluefish safety database and preparation of report
- Random quality review of EVWEB cases and triage
- Ensuring compliance with the legal requirements for PV tasks and responsibilities
- Monitoring metrics and regular reporting tools to ensure oversight by the QPPV and Head of PV India

Candidate Specifications

Education and Experience

- Bachelor's Degree in any life sciences or Pharmaceutical sciences
- Excellent computer skills, including Word and Excel in a Microsoft Windows environment
- Excellent interpersonal skills
- 2 years of relevant Pharmacovigilance experience

Skills & Abilities Requirements

- Must have good communication skills
- Safety of the workforce
- Personal development thru' self-learning

Email: hr@bluefishpharma.com
Website: **www.bluefishpharma.com**