Executive-Pharmacovigilance-Risk Management Team

About Bluefish Pharmaceuticals

Founded in Sweden, with its long tradition of industrial entrepreneurship, Bluefish Pharmaceuticals has become one of the most progressive generic 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, contributing to the accomplishment of the Pharmacovigilance function objectives. The position will report to Senior Manager-Pharmacovigilance. The role would be involved in the below mentioned areas:

- Support to the Qualified Person Responsible for Pharmacovigilance in the EU (QPPV) and Head of PV India, for the risk management activities of the company products
- Responsible for the establishment and maintaining of Bluefish Pharmacovigilance Risk Management System (RMS)
- Preparation of Risk Management Plan (RMP) and assisting the safety communication activities.
- PSUR and Periodic Benefit-Risk Evaluation Report (PBRER) preparation and submission to the worldwide competent authorities
- Preparation of Addendum to Clinical Overview (ACO) and submission within required timeline
- Published literature surveillance for ICSR and aggregated data reporting activities
- Case processing of all Individual Case Safety Reports (ICSRs) in the Bluefish safety database

- Tracking compliance of submission of safety variation and providing necessary documents as required
- Assisting in evaluation/assessment of new products on safety concerns as required by Research and Business Development Department
- Assisting signal management activities as required
- Writing, revision and review of relevant PV SOPs to be in line with legislation
- Documentation, tracking system for various pharmacovigilance processes and archiving as per approved SOP and GVP
- Ensure timely submission of all PV related documents to different stake holders

Candidate Specifications

Education and Experience

- Graduation in life science (B. Pharm/ M. Pharm/ other life sciences) with 1 to 2 years of experience
- Excellent computer skills, including Word and Excel in a Microsoft Windows environment
- Must have thorough knowledge of systems, processes and procedures related to Pharmacovigilance

Skills & Abilities Requirements

- Must have good communication and problem-solving skills
- Excellent interpersonal skills
- Personal development through self-learning

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