# MEDICAL 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 Medical Executive (Pharmacovigilance), contributing to the accomplishment of the Pharmacovigilance function objectives. The position will report to Deputy General Manager (Pharmacovigilance). The role would be involved in the below mentioned areas:

- Support to the Qualified Person Responsible for Pharmacovigilance in the EU (QPPV), Deputy QPPV and General Manager for the safety activities of the company products.
- Medical review of all cases in safety database
- Medical support and advise for Med Info queries
- Review of the product information and providing medical impact assessment on patient safety for updated product information through safety variation procedure.
- Responsible for establishment and maintaining of Bluefish Pharmacovigilance Risk Management System (RMS)
- Overall management, authorship and medical review of PSUR and timely submission.
- Overall management, medical review and authorship of RMP and safety communication.

- Authorship and medical review of Clinical overview.
- Medical support for in-licensing activities and due diligence support
- Medical monitoring of safety signals, that arises from multiple sources, which suggests a new potentially causal association, or a new aspect of a known association and preparing action plan to address safety signals as required.
- Planning, implementation, monitoring, and tracking of RMP commitments and post approval commitments.
- Medical review of Literature for new safety information review for signal management and PSUR
- Help to prepare response to competent authority's requirements regarding pharmacovigilance.
- Assist in pharmacovigilance audits and inspections

## Candidate Specifications

### Education and Experience

- MBBS graduates with 1-2+ years of Pharmacovigilance experience
- MD Pharmacology would be given preference
- Excellent computer skills, including Word and Excel in a Microsoft Windows environment
- Excellent interpersonal skills
- Skills in medical review of cases via safety database
- Good safety analysis and presentation skills.
- Experience in PV audit and inspection participation is an added advantage

### Skills & Abilities Requirements

- Must have thorough knowledge of systems, processes and procedures related to Pharmacovigilance, especially EU GVP
- Must have good communication skills
- Aggregate report authorship and review experience is preferred
- Personal development through self-learning

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