Auditor, 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 Auditor, Pharmacovigilance, to be responsible for leading and performing audits with a focus on Pharmacovigilance (PV) activities. The position will report to Head of Pharmacovigilance.

The PV Auditor (GVP) will:

- Maintain the global PV risk-based strategy for audit and risk assessment activities
- Lead, plan, conduct, and support internal and external GVP audits
- Maintain the annual PV audit programme
- Follow-up on the development, implementation and completion of corrective and preventive actions with auditees
- Maintain a tracking tool for audits, findings and corrective and preventive actions
- Ensure the maintenance of the required Quality Documentation
- Ensure SOPs/ WINs are compliant with applicable requirements and regulations

- Support to the Qualified Person Responsible for Pharmacovigilance in the EU (QPPV).

Candidate Specifications

Education and Experience

- Graduation in life science (B.Pharm/ M.Pharm/other life sciences) with 5+ years of experience in PV operations; 2+ years of experience conducting audits within PV
- Excellent computer skills, including Microsoft Office/Suite
- Excellent interpersonal skills
- Solid analytical and critical thinking skills

Skills & Abilities Requirements

- Must have solid understanding of PV requirements
- Solid understanding of Audits and CAPA management
- Solid understanding of Change Management processes
- Must have excellent communication skills (written and verbal)
- Strong attention to detail
- Highly organized
- Personal development through self-learning

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