Executive-Pharmacovigilance – Quality Management Team

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 QMT lead. The role would be involved in the below mentioned areas:

- Ensuring compliance of all PV activities
- Responsible for maintenance of PV Quality management system in accordance with EU and worldwide PV legislations.
- Assisting QMT Lead, Qualified Person Responsible for pharmacovigilance in the EU (QPPV) and Deputy QPPV for the quality activities of the company products
- Reviewing the PV quality system at regular intervals in risk-based manner to verify its effectiveness and introducing corrective and preventive measures where necessary

- Identifying and investigating concerns arising within an organisation regarding suspected non-adherence to the requirements of the quality and PV systems and taking corrective, preventive and escalation action as necessary
- Monitoring and review of Audit and Inspection findings and CAPA response
- Writing, reviewing, revising, approving, implementation and training of relevant PV SOPs
- Quality review of signal management reports, Risk Management Plan (RMP) and Risk Minimisation Activities, Addendum to Clinical Overview (ACO). Periodic Safety Update Report (PSUR)
- Quarterly quality control of ICSRs in Bluefish safety database and preparation of report
- Maintenance and Quality review of the pharmacovigilance system master file (PSMF)
- Create annual training plan, coordinate PV training schedule and provide annual PV training to Bluefish personnel
- Collate and finalise annual quality plan
- Responsible for management of audit of external parties for ensuring pharmacovigilance compliance
- Monitoring of Deviation and CAPA status
- Quality review of documents/responses being submitted to the competent authorities
- Preparation of annual communication compliance report based on review of Bluefish homepage.
- Preparation of annual record retention management report.
- Agreement coordination.

Candidate Specifications

Education and Experience

- Bachelor Degree in any life science graduates with 1-3 years of Pharmacovigilance experience
- Excellent computer skills, including Word and Excel in a Microsoft Windows environment
- Excellent interpersonal skills
- Skills in database management and record keeping
- Experience of participation in a regulatory inspection or internal company PV audits and CAPA management preferred.

Skills & Abilities Requirements

- Must have thorough knowledge of systems, processes and procedures related to Pharmacovigilance, especially EU GVP
- Must have good communication skills
- Safety of the workforce
- Personal development through self-learning

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