Assistant Manager-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 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 Assistant Manager-Pharmacovigilance, contributing to the accomplishment of the Pharmacovigilance (PV) function objectives. The position will report to Head of Pharmacovigilance. The role would be involved in the below mentioned areas:

- Acting as a team lead for the quality management team (QMT)
- Managing, prioritising and planning resources within the QMT
- Assisting Qualified Person Responsible for pharmacovigilance in the EU (QPPV) for the quality activities
- Having an overview of PV QMS to ensure PV quality documents are harmonised and consistent across the PV system and that all relevant documents are included in PV QMS
- Identifying and investigating concerns arising within the organisation regarding suspected non-adherence to the requirements of the quality and PV systems and taking corrective, preventive and escalation action as necessary
- Monitoring deviation and CAPA status
- Writing and reviewing relevant PV SOPs

- Collating and finalise annual quality plan.
- Ensuring compliance with the legal requirements for pharmacovigilance tasks and responsibilities.
- Quality review of PV documents such as signal management reports, risk management plans (RMP), Addendum to Clinical Overview (ACO), Periodic Safety Update Report (PSUR), pharmacovigilance system master file (PSMF)
- Quality review of documents/responses being submitted to the competent authorities
- Ensuring proper archival of PV documents as per SOP

Candidate Specifications

Education and Experience

- Graduation in life science (B.Pharm/ M.Pharm/ other life sciences) with at least 5 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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