Manager-Quality Assurance (Audits)

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 Manager-Quality Assurance (Audits), contributing to the accomplishment of the Quality Assurance function objectives. The position will report to General Manager-QA. The role would be involved in the below mentioned areas:

- Management of audits at manufacturer/supplier facility (API/FP manufacturer, Key Starting Material & Analytical labs). Documentation of the audit activities as per the current SOP.
- Ensure compliance with the current EU requirement and the technical agreement during the audit.
- Perform and document supplier evaluation for Bluefish vendors as per the SOP.
- Preparation/revision and periodic review of the audit calendar/schedule.
- Preparation, review and implementation of Standard Operating Procedures (SOP) as required within the scope of primary responsibility.
- Coordination for employee training on audit and supplier evaluation.
- Review of EU GMP guidance documents as relevant for the task.

- Assist QP in providing the necessary audit reports to issue the QP declaration.
- Continuous monitoring on improvement areas in quality system.
- Archival/retention of documents based on written procedure.
- Provide support to CMO and Bluefish cross functional team for any technical issues

Candidate Specifications

Education and Experience

- At least 4 years of university level education in the pharmaceutical or natural sciences or technology with minimum of 3 years of experience in audit management
- Excellent computer skills, including Word and Excel in a Microsoft Windows environment
- Excellent interpersonal skills
- Skills in database management and record keeping

Skills & Abilities Requirements

- Must have thorough knowledge of systems, processes and procedures related to QA
- Must have good communication and problem-solving skills
- Safety of the workforce
- Personal development thru' self-learning

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