Assistant Manager-Quality Assurance

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 Assistant Manager-Quality Assurance, contributing to the accomplishment of the Quality Assurance function objectives. The position will report to Sr. Manager. The role would be involved in the below mentioned areas:

- Overall responsible for all activities related to EU Labs
- Sampling of batches at import warehouse.
- Handling of Invoices
- Represent Quality Assurance during cross functional Operations meetings and update team on EU labs batch testing status and escalation if any.
- Building good relations with EU labs
- Meet the KPI requirements.

EU lab co-ordination:

- Sharing the Quarterly forecast of batches received from supply chain to all EU labs.

- Management of Working / Reference standards / placebo required for EU testing of product.
- Send Testing request for analysis to all EU labs.
- Ensure on time completion of AMT for all new products and for transfer of existing products to new EU labs.
- Tracking the lead time for analysis and to follow up with EU labs for CoA required for batch release.
- Sharing the testing priorities with the labs and address the issues if any through routine communication.
- Drafting and processing of EU labs Technical Agreements.
- Handling of OOS/OOT.

Bluefish Sweden Import Warehouse Co-ordination:

- Arrangements of sampling and sharing the sampling and data logger check list to import warehouse.
- Tracking the lead time for sampling at warehouse
- Handling of additional sampling request wherever applicable.

Handling of Invoices:

- Reviewing of Invoices related to EU lab analysis, consumables (HPLC filters, Columns, and standards) and PQR's.
- Approving the Invoices as per service agreements and agreed cost by Bluefish.

General:

- Training co-ordinator from QA in EQMS
- Archival/retention of documents based on written procedure.
- Provide support to CMO and Bluefish cross functional team for any technical issues etc.
- Product pack data upload to EU Hub via Tracelink serialisation system.

Candidate Specifications

Education and Experience

- Graduate Degree in any life sciences or pharmaceutical sciences
- Professional experience of 8-10 years with similar Job responsibility elaborated above.
- Excellent interpersonal skills and Computer skills in MS office tools.

Skills & Abilities Requirements

- Must have good communication skills.
- Safety of the workforce
- Personal development thru' self-learning
- Demonstrates good knowledge in EU GMP regulations (e.g., EudraLex,)
- Uses and interprets qualitative/quantitative data to drive decision making.
- Good communication skills to have active participation during discussions. (Internal and External meetings)
- Hands on knowledge in Microsoft applications such as Word, Excel, and PowerPoint.

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