Qualified Person

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 Qualified Person (QP), contributing to the accomplishment of the Quality Assurance function objectives. The position will report to Head of QA and will be based out of our Stockholm office. As a QP you are responsible for assuring that the quality of released medicinal products are corresponding to the requirements from national laws and current GMP. The role would be involved in the below mentioned areas:

- Review of batch documentation and release of batches for sale
- Handling of complaints, change control and review of quality reports
- Review and approval of deviations and CAPAs
- Approval of QP declarations
- Performing internal audits
- Managing Quality Agreements
- Continuous improvements of the quality system and internal procedures, SOPs

- Contribute with cGMP and cGPD expertise in cross functional teams
- Perform further training in the area of responsibility of other staff
- Depending on experience and competence, additional duties may be added

Candidate Specifications

Education and Experience

- You must fulfill the requirements for Qualified Person according to LVFS 2004:7. This includes a University degree in Pharmacy or Natural Sciences of at least four years of theoretical and practical studies. The degree should include the following courses/topics:
    - General and inorganic chemistry
    - Organic chemistry
    - Analytical chemistry
    - Pharmaceutical chemistry, including analysis of medicinal products
    - Physical chemistry and/or applied physics
    - General and applied biochemistry (medical)
    - Pharmaceutical technology
    - Pharmacology and Toxicology
    - Microbiology
- For this role, you shall have at least ten years of working experience within pharmaceutical industry and specific experience from analysis and finished product manufacturing of oral solids.
- Solid knowledge about cGMP and cGDP is required.
- Previous work with developing QA processes is an added advantage.

Skills & Abilities Requirements

- As part of the QA team you are expected to be a good team player and be willing to take on a wide range of tasks and responsibilities.
- Fluent in Swedish and communicate efficiently in English as you work in close cooperation with the QA team members in Bangalore, India.
- As a person, you need to be very meticulous and structured as well as highly efficient.
- You enjoy working in a dynamic and fast-moving environment where you will have great opportunities to influence and learn new things.

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