

## Quality Assurance Officer (Stockholm)

### 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 Quality Assurance Officer, contributing to the accomplishment of the Quality Assurance function objectives. As a QA Officer you are responsible for review and approve batch records, complaint investigations, and CAPA investigations. The role would be involved in the below mentioned areas:

- Review of batch documentation
- Deviation and CAPA management
- Handling of complaints, change control and review of quality reports
- Management of sampling
- Continuous improvements of the quality system and internal procedures, SOPs
- Contribute with GMP and GDP expertise in cross functional teams
- Other Quality Assurance related task

## Candidate Specifications

### Education and Experience

- University degree in Pharmacy or at least four years of theoretical and practical studies.
- At least 3 years of working experience in Quality Assurance within pharmaceutical industry and specific experience from finished product manufacturing of oral solid dose, OSD. Solid knowledge about cGMP and GDP is required
- Fulfilment of Qualified Person according to LVFS 2004:7 requirements or certified auditor will be an added advantage

### Skills & Abilities Requirements

- The person needs to be a good team player and willing to take on a wide range of tasks and responsibilities.
- Should be fluent in Swedish and English
- Should be very meticulous and structured as well as highly efficient
- Should enjoy working in a dynamic and fast-moving environment where he/she will have great opportunities to influence and learn new things

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