

Senior QA officer

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

Candidate Specifications

- To ensure the batches are produced in accordance with the EU GMP and approved dossier
- Verification of batch record review before sending to QP for batch release
- To train the batch review team on manufacturing processes and document review process as per the standard procedures.
- Management of validation activities with respect any approved quality system document which have impact on the product quality
- Management of stability tasks where required in coordination with the finished product manufacturer
- Ensure allocation of task within the team

- Management of quality system tasks related to complaints, deviations and change controls related to batch record review process
- To ensure the computerized system and its operation complies and fit for intended use.
- To coordinate for AMT
- Responsible for compliance of internal audit observations at India Office
- Provide support to CMO and Bluefish cross functional team for any technical issues
- Planning of the product Quality review
- Ensuring training of new employees and ensure to identify training needs for the team.
- Assist functional head on required task

Education and Experience

- Post Graduate in life science with atleast 10 years of relevant experience of working in a OSD manufacturing facility with minimum 2-3 years of experience in management of team with 3 to 4 members
- 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

Email: hr@bluefishpharma.com