ASSISTANT MANAGER (DEVELOPMENT 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 – Development Quality Assurance, contributing to the accomplishment of the quality and regulatory compliance within R&D functions like Formulation, Analytical etc., . The position will report to Deputy General Manager (Research and Development). The role would be involved in the below mentioned areas:

- To establish and implement appropriate quality systems for generic formulation R&D activities for Europe, RoW and other regulated markets (USA, Brazil, etc.).
- To review development documents for regulatory submissions, including analytical method development/validation protocols and reports, Formulation product development reports, stability protocols and reports, dossier validation batch documents.
- To review Pilot and dossier batches execution records for release of batches for bio-studies.

- To monitor and ensure compliance to regulatory requirements in day to day analytical research and formulation research development activities.
- To perform technical and compliance audit of dossiers / documentation for regulatory submissions.
- Technical evaluations to support development stage vendor assessments
- To review and approve specifications and test methods for raw materials, packing materials, intermediates and finished product.
- To prepare, implement system SOP's in R&D facility to ensure compliance to regulatory requirements and update as required.
- To review, approve equipment qualification documents.
- To conduct internal audit of Analytical research, formulation research and clinical research activities as per periodic schedules.
- To support and ensure compliance to overall quality management system.
- To monitor and ensure necessary documentation of stability & Photo stability chambers, Deep Freezer, Hot air oven etc.,
- To control archival of development documents.

Candidate Specifications

Education and Experience

- Master of Pharmacy, with 7 - 9 years of relevant experience in Developmental Quality assurance, compliance in Analytical Research and Development, Formulation Research and Development for regulatory market.
- Expertise in quality systems and compliance in analytical and formulation development.
- Expertise in reviewing analytical data, validation reports, development reports etc.,
- Excellent computer skills, including Word and Excel in a Microsoft Windows environment.
- Excellent interpersonal skills.

Skills & Abilities Requirements

- Strong conceptual and formualtion, analytical skills
- Good communication (verbal, Writing) and presentation skills.
- Must have ability to meet deadlines, and work on multiple projects simultaneously.
- Must be a team player and be able to interact with staff at all levels of the company and with external parties as well.
- Must have ability to work independently.
- Adequate Job knowledge and exposure to different Analytical methods, instrumentations
- Adequate Job knowledge and exposure to different Formulation equipments, techniques etc.,
- Should have thorough understanding and familiarity with EU GMP regulations, including 21 CFR 210 and 211, ICH guidelines, FDA guidance documents; familiarity with GLP and GCP regulations
- Well versed with Pharmaceutical Formulation Development and analytical development activities with fair understanding of QbD and its tools (DoE)
- Willingness and ability to travel approximately 20-30% of time

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