SENIOR EXECUTIVE (FORMULATION RESEARCH AND DEVELOPMENT)

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 Executive (Formulation Research & Development), contributing to the accomplishment of the Formulation R&D function objectives. The position will report to Manager / Senior Manager Formulation Research and Development. The role would be involved in the below mentioned areas:

- Technical assessments of projects (Screening, pipeline and FR&D), Literature search.
- Technical screening of API sources & in-house development strategies.
- Preparation and review of development proposal & clearance to CDO.
- Timely completion of development activities at in-house R&D lab, CDO's (Pre-formulation studies, formulation development, stability studies etc.,)
- Preparation and finalisation of scope of activities for project executions.

- Assisting and executing formulation development and technology transfer activities at CDO and CMO.
- Planning of activities and project follow-ups (Procurements, formulation development activities).
- Preparation of technical data for milestone assessments.
- Preparation, Review of formulation development protocols, reports.
- Preparation, Review of technical documents leading to dossier batches executions.
- Providing technical clarifications to CMO during scale up and technology transfer execution.
- Assisting in development activities for technology transfer products (Portfolio).
- Preparation & practise of formulation development guidelines, SOP's
- Establishing in-house systems and procedures to ensure cGMP practices & regulatory requirements.

Candidate Specifications

Education and Experience

- Master of Pharmacy, with 3 - 5 years of relevant experience in Formulation Research and Development for regulatory market
- Expertise in scale up technology transfer
- Excellent computer skills, including Word and Excel in a Microsoft Windows environment
- Excellent interpersonal skills

Skills & Abilities Requirements

- Strong conceptual and formualtion, scale up, technology transfer 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 technologies like hot melt extrusion process, Particulate coating process etc.,
- Adequate Job knowledge and exposure to different Formulations like modified release, delayed release, sustained release, prolonged release formulations etc.,
- Adequate Job knowledge and exposure to QbD, DoE and statistical interpretation etc.,
- Willingness and ability to travel approximately 20-30% of time.

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