Senior Executive – Packaging Development Cell

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 – PDC (Regulatory Affairs), contributing to the accomplishment of the Packaging Development Cell function objectives. The position will report to Lead-PDC (Regulatory Affairs). The role would be involved in the below mentioned areas:

- Overall management of Artworks process.
- Responsibility for review and approval of artworks in line with the current EU local legislations, applicable to Artworks and packaging.
- Personally accountable for dedicated manufacturers for the life cycle management of Artworks.
- Building and maintaining an optimal dialogue and relationship with CMOs.
- Keep up to date knowledge in the requirements and regulations with respect to Artwork and packaging process.
- Thorough understanding of e-label system and its maintenance.

Artwork

- Initiation of e-label errands for applicable changes and PDC impact assessment.
- Co-ordinate with manufacturer/ CMO for blister layout & cutter guide/key line.
- Tracking the artwork development/ Revision in e-Label system.
- Ensure closure of change control process where applicable for the artwork revision or manufacturer change controls affecting the artworks.
- Maintaining the VNR applications & withdrawal as per requirement
- Sharing the approved artwork source files with CMO & follow up for print proofs
- Review & approval of print proof against approved artwork where applicable.
- Review and approval of artworks in line with the current local legislations, applicable to Artworks and packaging.

Quality Management System (QMS)

- Initiation/review of deviations, CAPA (corrective & preventive action), Action plan, complaints and any other non-conformity with respect to Artwork.
- Perform Bluefish investigation where required for the deviations or complaints with respect to Artwork.
- Extend support for audits at manufacturer/supplier facility with respect to Artwork.
- Preparation/revision/approval of SOP for the responsible activities.
- Co-ordination for relabelling/ repacking activities with respect to Artwork

Serialization

- Product Master Data creation/updation (GTIN code, new combination, launch products).

General

- Archival/retention of documents based on written procedure.

Candidate Specifications

Education and Experience

- Minimum of a Life Sciences or Pharmacy graduate with 6 + years of relevant experience in Pharma Industry bulk of which is in PDC (Regulatory Affairs).
- Excellent computer skills, including Word and Excel in a Microsoft Windows environment
- Excellent interpersonal skills
- Experience in Artwork process required for European and global market.

Skills & Abilities Requirements

- Good Team-worker
- Collaborative cross functional working
- Good, clear and transparent communicator (both written and oral) with acceptable command over English
- Assertive
- Positive and “can do” attitude
- Must have good problem-solving skills- Striving for win-win solutions
- Safety of the workforce
- Personal development through self-learning

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