Executive-Regulatory Affairs

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 Executive-Regulatory Affairs, contributing to the accomplishment of the Regulatory Affairs function objectives. The position will report to General Manager-Regulatory Affairs. The role would be involved in the below mentioned areas:

- Evaluate and co-ordinate submission strategy, submission and launch support for new products
- Submission of MAA applications till end of procedure
- Responsibility for planning and compilation/submission/follow up of marketing authorisation applications, variations, renewals and other relevant maintenance activities for dedicated products within EU.
- Personally accountable for dedicated products to achieve product lifecycle and maintaining licenses.
- Co-ordination of Export market activities.
- Administrative support to RA
- Building and maintaining an optimal dialogue and relationship with Health Agencies.
- Keep up to date knowledge in national and European Union legislation and regulations.

- Ensuring that appropriate Regulatory Affairs procedures are in place to cover all regulatory requirements.
- Working towards continual improvement of the Regulatory Affairs systems.
- Plan and coordinate MAA (MRP, DCP, national) and MA transfers

Marketing authorization applications

- Data base search for reference products in all EU markets.
- Prepare common SPC, PIL, Labelling and mock-ups in line with the reference product and according to marketing requirements.
- Translations for required countries as per QRD template in local languages.
- Follow ups for dossiers from providers and additional requirements required for filings.
- Checking of dossiers for any feasibility after receiving the dossier from provider.
- Preparation of Module 1 and rearrangement of dossier in module wise as per ICH-eCTD format and checking for accuracy as applicable for export markets.
- Overall calculation for regulatory fees to be paid.
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Comments from Health Authorities and Response package

- Evaluate and communicate the dossier comments and questions with the dossier provider and internal functions and set a timeline for the response documents.
- Preparation of Highlighted, Clean & track changed SPC, PIL & Labelling as per each authority's comments.
- Evaluate, compile and submit the response documents within the stipulated timeline.

National phase

- Ensure correct translations of SPC/PIL/Labelling and country specific mock-ups are submitted within 5 days from end of procedure.
- Follow-up on national submission and negotiate final approvals with health authorities.
- Forward approved PIL/mock-up to Quality assurance department.
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Variations & Renewals

- Collection and review of required documents and information.
- Preparation, review and compilation of variation and renewal package.
- Calculation for variation and renewal fees to be paid.
- Ensure completed relevant checklists
- Ensure tracking tools are updated
- Ensure deviation log is updated when relevant

Others

- Support to Marketing, BDv & SCM.
- Preparation and circulation of Launch triggers and update of product launch tracker
- Tender file updates & support to re-packing activities.
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Export market activities:

- Review of business cases : country wise/ product wise
- Management of registration process

Administrative activities:

- Keeping databases up to date at all times.

Candidate Specifications

Education and Experience

- Minimum of a Life Sciences or Pharmacy graduate fresher or up to 3 years of relevant experience in Pharma Industry bulk of which is in Regulatory Affairs
- Excellent computer skills, including Word and Excel in a Microsoft Windows environment
- Excellent interpersonal skills

- Experience in European and global new submissions and post marketing maintenance activities

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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