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:

- Responsible and accountable for all regulatory activities supporting quality, safety, compliance of Bluefish Products
- Responsibility for compilation/submission/follow up of, variations, renewals and other relevant maintenance activities for allocated Bluefish products.
- Personally, accountable for allocated products to achieve product registration maintain the product lifecycle.
- Carry out all activities necessary to track and record RA activities and maintain compliance.
- Accountable for overseeing artwork generation and artwork readiness for all approved artworks for products allocated
- Carry out all activities necessary to track and record RA activities and maintain compliance.

- Share knowledge with the team and together learn and grow with the team
- Lead by example and demonstrate good teamwork and collaborative working in the team and cross-functionally
- Coordinate and submit allocated MA transfers and other life cycle maintenance activities
- Initiate and Review change controls
- Manage and deliver allocated task/projects
- Build and maintain optimal dialogue and relationship with dossier providers
- Follow all work instructions and processes laid down in the team.
- Keep up to date knowledge in national and European Union legislation and regulations.
- Work towards continual improvement of the Regulatory Affairs systems.
- Co-ordinate for renewal and variation submissions for Allocated Bluefish products.
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Marketing authorization applications

- Review of in licensed dossier for new MAA.
- Prepare common SPC, PIL and Labeling in line with the reference product and according to marketing requirements.
- Co-ordination with the country specific consultants for translations for required countries as per QRD template in local languages.
- Follow up of marketing authorization applications.
- Accurately managing fee remittance and reimbursement in a timely manner.

- Comments from Health Authorities and Response package

- 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 approval PIL/mock-up to all stake holders of cross functions.
- Get artwork, generated, reviewed and approved as per the defined workflows and processes.
  Be artwork ready at all times

Variations & Renewals

- Collection and review of required documents and information.
- Compilation and review of variation and renewal package.
- Accurately managing fee remittance and reimbursement in a timely manner.
- Ensure relevant checklists are completed timely
  Ensure tracking tools are updated

Change control

- Initiate and Review change controls
- Management of RA owned change controls till closure
- Ensure tracking tools are updated to ensure variation filing on time.
- Ensure proper change control logs are maintained and updated for RA owned changes and variations are filed according to the deadlines.
- Ensure change control procedures (SOP) followed are in regulatory compliance

Others

- Support cross-functions where they have dependencies.
- Technical review of packages and construction of variation packages
- Any other task allocated by the manager from time to time

Administrative activities:

- Invoice approvals
- Provide regulatory input to budget and other financial requests

Candidate Specifications

Education and Experience

- Pharmacy graduate or postgraduate with 2-3 years' experience in working with the Nordics in areas of new submissions and post marketing maintenance
- Excellent computer skills, including Word and Excel in a Microsoft Windows environment
- Excellent interpersonal skills
- Experience of Document Management System desirable
- Experience in Project Management desirable
- Experience in European and global new submissions and post marketing maintenance activities

Skills & Abilities Requirements

- DMS and ectd handling experience -Publishing experience -CESP submission experience
- Experience in correspondence, communication, and negotiation with the regulatory agencies
- Experience in managing Local Regulatory partners and consultants
- Good Team-worker
- Project management skills
- 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
- Knowledge about IDMP requirements
- CMC documents knowledge, understanding and interpretation
- Worked in QA and has a good understanding of evaluation of CMC documents.

Email: hr@bluefishpharma.com

Website: www.bluefishpharma.com