**Manager-Pharmacovigilance, Quality Assurance and Regulatory Affairs** **(Griesheim Darmstadt, Germany)**

# 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 Manager-Pharmacovigilance, Quality Assurance and Regulatory Affairs, contributing to the accomplishment of the Pharmacovigilance, Quality Assurance and Regulatory Affairs function objectives. The incumbent will be:

* Local Drug Safety Officer (LDSO) / Local QA / Local RA for Germany and Austria
* Stufenplanbeauftragte/Informationsbeauftragte
* Acting as a point of contact on behalf of Bluefish Pharmaceuticals with regards to pharmacovigilance, quality assurance and regulatory activities towards patients, healthcare professionals and Competent Authorities in the territory
* Monitor and give feedback to Bluefish Pharmaceuticals on national legislation and its implementation regarding the areas of interest (i.e. RA/PV/QA)

The role would be involved in the below mentioned areas:

**Pharmacovigilance:**

* Monitoring local legislation, implementing changes and informing Bluefish of any relevant changes.
* Being available to support to the EU QPPV during working hours and support EU QPPV in any local safety matter
* Alerting the QPPV about any issue or potential issue related to the safety profile of products under Bluefish responsibilities.
* Informing the QPPV of any requests for PV-related information from CAs and of any ADRs concerning safety data provided to the CAs.
* Management of safety communication, if required and requested by the QPPV.
* Assisting in implementation of additional risk minimisation activities if required.
* Collecting, reporting and follow-up of AE reports from all sources, including local CAs along with source data.
* Maintain a tracking list of local ICSRs and non-valid cases in the territory
* Ensuring that ADRs received out-of normal office hours are handled to meet internal and regulatory reporting timelines.
* Quality checking of all literature cases and ICSR reports from the territory which are prepared by CMT before medical review step.
* Ensuring that pharmacovigilance activities are conducted in compliance with Bluefish internal procedures and local-, EU- and worldwide- PV legislation.
* Ensuring compliance to local and EU legislation relating to patient and reporter confidentiality (personal data act).
* Ensuring quality control of the English translation and accuracy of data against the source data.
* Submitting monthly reconciliation reports to the Bluefish PV department.
* Ensuring local scientific literature monitoring is performed according to Bluefish procedures and local legislation.
* Forwarding literature articles/abstracts concerning Bluefish Pharmaceutical’ products.
* Responding to medical queries with support from Bluefish Global PV department when required and ensuring the use of the latest approved national SmPC when responding to medical queries.
* Forwarding latest approved national SmPC to the marketing and sales personnel in their respective countries.
* Performing PV training within their territory.
* Participating/supporting in GVP audits/inspections when requested

**Quality Assurance:**

* Ensure that applicable SOPs are implemented as required by Bluefish QA.
* Receive and if applicable translate customer complaints and send to the corporate office. Reply to customers based on the information provided by Bluefish QA.
* Act as the point of contact for the national competent authority regarding quality matters on request from Bluefish QP.
* Act as the point of contact for logistic partners for quality matters, including storage and distribution information during a recall.
* Act as local recall administrator.
* Performing GDP audits of external partners

**Regulatory Affairs:**

* Assist with submissions of applications for new licenses and variations, following up the process and if needed negotiating with the national authority
* Translation of texts for labelling, PILs and SmPCs and review changes required to these by national authority
* Approval of information material aimed for Germany and Austria; ensure that the labelling, the package leaflets, the expert information and advertisements correspond with the content of the marketing authorisation
* Checking and approval of invoices from regulatory authorities and consultants in the territory.
* Keeping abreast with all EU and national regulations impacting activities in Bluefish
* Participating in monthly meeting conducted by RA and contributing meaningfully to the RA activities
* Monitoring the status of sunset clause for all registered Bluefish products in Germany/Austria as per the prevailing local laws and flagging up any actions well in time.
* Read, be aware and follow all RA SOPs and Work instructions as applicable
* Document, share with RA and follow any processes that are used for executing RA tasks
* Document any non-conformances with the RA WI/SOPS in the NRFT log and collaborate with RA on coining and implementing correcting and preventive actions.
* Train RA on any new regulations impacting Bluefish RA activities and any other agreed areas of expertise from time to time.
* Participate in RA training initiatives as and when applicable.
* Share knowledge and download information from any training courses or conferences attended that may directly or indirectly impact RA activities or improve overall efficiency
* Raise Change controls and process them for product discontinuation activities to progress once signed decision form is available after the approval of decision in the decision meeting.

**Others:**

* Reimbursement applications and communication with reimbursement authorities in Austria.

**Candidate Specifications**

**Education and Experience**

* Degree in Pharmacy or Medicine
* Minimum of 5 years of Pharmacovigilance, Quality Assurance and Regulatory Affairs experience
* Excellent computer skills, including Word and Excel in a Microsoft Windows environment
* Excellent interpersonal skills

**Skills & Abilities Requirements**

* Fluent language skills in English and German
* Good MS Office user knowledge, especially very good knowledge of Excel
* Independent, structured and careful way of working.
* Strong analytical and conceptual skills, high affinity for numbers and result-oriented work
* High level of cooperation and teamwork
* Strong personal responsibility, high degree of personal initiative and above-average commitment

**We are open to candidates who want to work part time upto 75%**

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