Bluefish Pharma GmbH is a subsidiary of the pan-European company Bluefish Pharmaceuticals AB. Founded in Sweden, with its long tradition of industrial entrepreneurship, Bluefish Pharmaceuticals has become one of the most progressive generics pharmaceuticals companies.

For our office in **Griesheim /Darmstadt** we are looking for a qualified:

Manager RA, PV & QA (f/m/d)

Germany /Austria

Essential Duties and Responsibilities:
In your role as Manager RA, PV & QA you are responsible for the Follow-up & feedback to Bluefish how new legislation is implemented nationally on the following areas:

Regulatory Affairs:
As local RA Manager you will assist with submission of variations and new MAAs, follow-up the process with BfArM and AGES and make reimbursement applications in Austria. Translation of product information into German or English. Additionally, you will act as "Informationsbeauftragte(r)" according to § 74a of the German drug law (AMG).

Pharmacovigilance:
In your role as local PV Manager you will work as "Stufenplanbeauftragte(r)" according to § 63a of the German drug law (AMG) and national PV responsible person in Austria. This role includes handling of local adverse reaction reports from healthcare professionals and consumers (translate into English and perform follow-up requests) as well as responding to medical enquiries, interacting with Bluefish PV department, performing pharmacovigilance training to local sales and marketing staff and local literature search. It also includes the qualification, interaction and training of stand-in consultants for Germany and Austria as needed and to support the EUQPPV on local level.

Quality Assurance:
As local QA Manager you will handle customer complaints, act as local recall administrator, be the contact point for the national authorities regarding quality matters, act as the contact point for logistic partners for quality matters, including storage and distribution information during a recall, evaluate returns, perform audits of European logistics partners, review and update of respective technical agreements and conducting change controls.

Your Qualifications:
State examination or master's degree (or equivalent) in Pharmacy (preferred), Biology, Chemistry or related Life Science and at least 2 years of experience each in Regulatory Affairs, Pharmacovigilance including Medical Affairs and Quality Assurance in pharmaceutical industry in Germany or Austria. A combination of similar experience and/or education will be taken into consideration.
You must have a very good command of the German and English language and be familiar with common MS-Office programs (Word and Excel in particular). You will integrate particularly well into our small team if you are ready to work independently, accurately, and reliably. You must have a high degree of organizational talent and enjoy working in a team.

Please apply by submitting your expressive application documents (incl. date you could start working and desired salary) to:

Bluefish Pharma GmbH
Daniela Stoppel
Im Leuschnerpark 4
64347 Griesheim Email: daniela.stoppel@bluefishpharma.com