Managing Consultant – Regulatory Affairs

Who we are:

Xendo, a Propharma Group company, is a leading consultancy and project management organisations in the fields of (bio) pharmaceutical products, medical devices and health care. Thanks to our multi-disciplinary and knowledge-driven approach, we deliver a broad palette of services to the life sciences industry. For over 25 years, we have successfully completed thousands of national and international assignments for start-ups as we as for the largest, established multinational companies and organisations. ProPharma Group combined with Xendo has more than 1.000 professionals worldwide providing an unmatched variety of compliance related services including medical information, pharmacovigilance, clinical safety, regulatory affairs and a continuously expanding range of compliance, quality assurance, validation and consulting services.

Your Responsibilities:

As a Managing Consultant, you will be the first point of contact for all questions of our clients´ questions and requests with regard to pharmaceutical regulatory requirements and strategies. Our client spectrum includes large and small companies in the pharmaceutical industry.

- You will be responsible for maintaining existing client relationships as well as establishing new business opportunities in line with the service portfolio.
- You will effectively lead and further develop your team to maintain a high level of service for our clients.
- You will be responsible for budget planning and ensure that revenue targets are achieved.

Together with your team, you will…

- provide regulatory advice in regards to pre- and post-marketing issues to clients
- prepare and submit applications for marketing authorisations and variations including handling of deficiency letters for human medicinal products
- provide strategic and CMC writing support for dossier module 3
- communicate with regulatory authorities
- prepare briefing documents for scientific advice procedures

Your Profile:

- You hold a university degree, preferably in Life Science, Chemistry, Pharmacy or related disciplines.
- You have an entrepreneurial mindset.
- You have extensive experience in Regulatory Affairs within the Pharmaceutical industry, with a sound knowledge of relevant national and international regulatory requirements. In addition, you are willing to continuously learn and expand your knowledge in this area.
- You have experience in managing projects and leading a team.
- You possess strong analytical and organizational skills as well as problem-solving and consulting competence.
- You have an excellent command of written and spoken German and English.

- You have very good MS Office skills.
- You have excellent communication and negotiation skills.
- You are willing to travel to clients and other business locations.

We Offer:

- A diversity of interesting projects and varying tasks
- The opportunity to work with different clients for the pharmaceutical industry
- A flexible, dynamic and pleasant work atmosphere
- Opportunities for learning and further development
- Good terms of employment

We are an equal opportunity employer. M/F/D/. If you are qualified and are interested in our position, please send us your complete application to hr.de@xendo.com. In case of any questions, please do not hesitate to get in touch with us. We are looking forward to your application.