Role title: Regulatory Affairs Freelancer – France, Belgium, Switzerland (Zug)

Area of expertise: Regulatory Submissions and/or Regulatory CMC

https://www.pharmalex.com/

Your responsibilities

- Provide a wide range of flexible regulatory affairs services for different clients on a range of product types (i.e. chemicals, biologicals, generics, medical devices) and therapeutic areas
- Planning and conducting authorization procedures in the EU (MRP, DCP, CP and purely national procedures, CTA) and in emerging markets as well as lifecycle management procedures (variations, renewals, MAH transfers, etc.) worldwide
- Review of approval documents and text management (labeling management)
- Expert support/leadership for CMC activities including CMC project management, review and writing of CMC gap analysis and CMC strategies, Change control
- QC review of documentation, compendial cross checking and report formatting
- Ensuring that regulatory affairs programs and projects are delivered to high standards.
- Communication in the project team, with clients, local partners and representatives in the international context
- Providing regulatory expertise to regulatory programs and projects
- Professional interaction with regulatory authorities
- Accurate time reporting.
- Given the nature of the role, some EU and international travel can be expected, including on site availability on clients' sites.

Your Profile

- Degree in natural sciences (preferably medicine, pharmacy, chemistry or biology)
- Required level of experience depending on client project
- Experience in drug licensing with a focus on EU or with admission procedures in non-EU countries and experience with Launch Management, Labelling Management, Clinical Trial Applications and admission procedures in non-EU countries.
- Knowledge of current drug and regulatory requirements (EU)
- Experience in a multi-task consulting environment
- IT affinity to databases and the handling of project management software
- Team-oriented, communicative, conscientious, accurate and responsible
- Home based, flexibility to travel and work on site
- Secure MS Excel and Word knowledge as well as confident English and French skills
- Structured, analytical, systematic thinker
- Strong communication skills
- Concentrated and high-quality work
- Ability to work in a team
- Strong sense of responsibility
- Excellent written and verbal communication skills, with a focus on client-facing interactions

Please, if you are interested in collaborating with PharmaLex and be part of our Associate Panel do not hesitate to contact us:

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