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Regulatory Affairs Consultant (candidate pool)

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Company: Keyrus Life Science

Location: Belgium

Category: other-general

Job Description

Keyrus Life Science is looking on **a regular basis for Regulatory Affairs Consultants** to join our consulting team for clients (from big pharma to small biotech) projects based in **Belgium.**

This job description is an example on how your job could look like. Once we have a specific project and client you will be informed and you will have of course the choice to be presented at our client.

Your potential challenges could be:

Guide our client by interpreting federal, state and international regulations as they apply to products, processes, practices and procedures.

Be responsible for product registration activities of the assigned products and will report to the Regulatory Strategy Senior Manager.

Work in cross-functional teams with different departments (manufacturing, labs, QA, supply,…) and collaborate with R&D, global regulatory colleagues (Global Chemistry, Manufacturing & Controls (GCMC)) in order to support the introduction of new products at our client's site.

It is your hard work and dedication that will make our client ready to achieve new milestones and help patients across the globe.

Scope of work:

Support regulatory submissions (CTD, BLA, NDA,…) of the products by informing site

colleagues of regulatory requirements and by authoring the dossier.

Liaise with regulatory colleagues to communicate and resolve potential issues.

Collaborate across the network of other stakeholders to deliver high quality CMC submission and ensuring compliance of our client's portfolio.

Manage timely responses to Board of Health requests resulting from lifecycle submissions in markets or products under responsibility.

Assess post approval changes at the manufacturing site and the associated regulatory variations. You are responsible for authoring the impacted sections of the dossier.

Contribute to the completion of projects, manage own time to meet agreed targets and develop plans for work activities within a team to support operational goals.

Profile

Master degree in Life sciences (e.g. industrial pharmacist, biomedical sciences, bio-engineer,..).

Experience in the pharmaceutical sector (or equivalent by acquiring a PhD), with experience in regulatory (authoring CTD, BLA) and quality.

CMC experience is a real asset.

Scientific knowledge, analytical skills associated with technical writing skills to issue RFT regulatory documentation.

Knowledge of drug regulations and regulatory guidance of leading agencies (EMA, FDA).

Ability to communicate effectively verbally and in writing, good negotiation and influencing skills.

Dynamic, flexible, enthusiastic and eager to learn.

Ability to work under minimal supervision and in a team.

Fluent in written and spoken English and French or Dutch .

What we offer

Joining our consulting team means giving your career a step forward. Thanks to the privileged

partnership we have with our well-established clients, leaders in their domain, we offer our consultants unique projects to develop their skills, and put their professional experience in the pharma industry on the fast track.

As an expert **on the client side in Belgium**, you can count on us to support you at each step of your project thanks to regular touch points with our Key Account Manager. We then also carefully choose with you what would be your next assignment that is matching your career goal whether it is in Consulting or in one of our Functional Services Platforms.

We invest considerable time and resources in training our staff (technical and non-technical courses) to continuously support you in your personal and professional growth. On top of this, you will receive a complete salary package including attractive extra-legal benefits (company car, petrol card, meal vouchers, group insurance, hospitalization…) based on your background and experience.

Who we are

Keyrus Life Science is an international Consulting, Contract Research Organisation and Functional Services provider with a reputation for transparency and integrity, highly focused on being able to deliver with excellence. Our ‘human’ approach to service provision is what differentiates us from our competitors. Combined with our high caliber staff, this approach has allowed us to become a key player in clinical research.

At Keyrus Life Science we’re proud of our commitment to delivering services of the highest quality, not only skillfully, efficiently and reliably, but also with sincerity and genuine care for our clients’ projects, priorities and reputation. Thus we maintain and advance our vision and our standards, all the while ensuring that we serve your interests better

From early- to late-stage drug development, our range of services includes: Project Management, Clinical Operations, Pharmacovigilance, Quality Assurance (GxP), Regulatory Affairs Strategy & Support, Data Management, Medical Review & Coding, Biostatistics, Medical Writing & Medical Information, Real World evidence services.

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