Belgium Jobs Expertini®

Regulatory Affairs Consultant

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Company: Akkodis

Location: Puurs

Category: other-general

Position description

Category

OPERATIONS - ENGINEERING/PRODUCTION

Job title

Regulatory Affairs Consultant

Contract

Permanent contract

Job description

ABOUT US

Akkodis is an international engineering consulting and R&D services company. As an innovation accelerator for its clients, Akkodis supports leading industry players in the automotive, aerospace, rail, space, defense, energy and life sciences sectors throughout the life cycle of their products with cutting edge digital technologies

With more than 55.000 experts in over 30 countries, the Akkodis Group is one of the leaders in its field. In Belgium, we have close to 1000 experts active in different technical fields.

Job description

As a Regulatory Affairs Consultant, you will be part of a team that will be interpreting federal, state and international regulations as they apply to products, processes, practices and procedures. In this role you will be responsible for product registration activities of the assigned products and will report to the Regulatory Strategy Sr Manager. You will 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.

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 Pfizer 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.

Business Industry
Life sciences
Profile
Experience:
Master degree in Life sciences (. industrial pharmacist, biomedical sciences, bio-engineer,

Minimum 3 years of experience in the pharmaceutical sector (or equivalent by acquiring a PhD), with experience in regulatory (authoring CTD, BLA) and quality.

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

CMC experience is a real asset

OUR OFFER

As an Akkodis consultant, you will be:

In charge of diverse transversal and empowering projects

Supported in your career by your Akkodis Manager

Actor of your training plan and your personal and professional development

Member of a dynamic and collaborative community of engineers

Benefiting from a permanent contract

Benefiting from a competitive salary packages including several extra-legal benefits.

Position location

Job location

Europe, Belgium, Flanders, Antwerp

Location

Puurs

Candidate criteria

Minimum level of education required

6. Master Degree

Level of experience

3 to 5 years

Languages

English (3 : Advanced)

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