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Regulatory Affairs Scientist

BE-Herentals 2 weeks ago

Job ID 2018-5208 **# Positions** 1 **Category** Regulatory **Position Type** Regular Full-Time

Overview

The Regulatory Affairs Scientist will be involved in designing and monitoring animal trials related to the safety for the animal, consumer, user and environment. She/he will also be responsible for maintaining product registration approvals by ensuring compliance with legal requirements and implementing post-approval changes required, as well as registering new products and ensuring compliances with regulatory requirements in the EMENA region.

Responsibilities

- Design, Planning, Follow-up and analysis of animal trials, review trial reports
- Writing and co-ordination of registration dossiers for both EU and other countries in the EMENA region
- Building a network throughout the EMENA region with research institutes and other parties involved in animal studies for product registration process
- Conducting regulatory research including locating regulations (Regulatory Intelligence)
- Understanding regulatory requirements and relevant government regulations in the EMENA region, as well as stay current on regulatory issues affecting Kemin products in these countries
- Working with the Sales & Marketing organizations in implementing the regulatory strategy to achieve timely filing and approval of new and existing products for each country in the EMENA region in accordance with business objectives
- Focus and prioritize activities of assigned projects and assume responsibility for their success
- Assist with regulatory submissions, and prepare product registration dossiers to obtain and maintain regulatory approvals for Kemin products under supervision
- Serve as regulatory liaison with marketing and research department for the development of regulatory plans in conjunction with new product development.

Qualifications

- University degree (Master or PhD depending on experience) in a relevant scientific field, preferably in animal nutrition, biochemistry, biomedical science or comparable discipline, preferably with some working experience in a regulatory or related position

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- Proven experience related to safety trials (lab animals and/or farm animals)
- Fluency in English is required
- Thorough knowledge of working with Excel spreadsheet preferable
- Familiarity with regulations in EU and non-EU countries is a plus
- Familiarity with REACH, CLP or EFSA guidelines is a plus
- Experience in reviewing and evaluating scientific literature with demonstrated ability to analyze and assemble/synthesize scientific information from many sources, including identification of information gaps and future research needs
- Excellent attention to detail required, reliable, highly motivated, ability to work independently and interacts well in a team environment
- Possess excellent verbal, written and interpersonal communication skills, demonstrated good technical writing skills, ability to present ideas effectively
- Excellent organizational and time management skills, demonstrated prioritizing, planning and project management skills

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