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Global Regulatory Affairs PM

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Company: ADAMA

Location: Tel Aviv

Category: other-general

The primary responsibility of the Global Regulatory Affairs Project Manager is to develop and implement a regulatory strategy for the active ingredients and the respective products under responsibility to acquire new registrations and maintain the existing ones according to the registration national / zonal / regional requirements. This goal involves the development of regulatory data, preparation and submission of registration dossiers, support of the country teams and represent the company in all matters related to the active ingredient and the respective products.

Responsibilities:

Develop and implement a regulatory strategy for the active ingredients and the respective products under responsibility (e.g. GAP, harmonized risk assessment strategies) including preliminary risk assessments to highlight potential regulatory opportunities and risks

Manage the registration data package for the relevant active ingredients and the respective products including gathering of all available information from different disciplines (chemistry, development, toxicity, field residues, environmental, eco-toxicity etc.) and internal departments for the preparation of new registration files or the maintenance of existing registrations

Project Management of the data package generation under global regulatory considerations, especially to prevent duplication

Find contractors & consultants and manage the production of registration files according to

country/area specific registration requirements in cooperation with experts

Represent ADAMA as the registration manager on regional and global level

Respond to regulatory issues and timely inform business on potential business impacts

Support the existing registrations and acquire new registrations following the business needs.

Primary contact person for all regulatory aspects for the internal stakeholders (e.g. e.g. Development, Business, country organizations)

Provides strategic direction to align the needs of the business and the development functions in consideration of possible regulatory limitations

Represents the company as the expert on the AI and products under responsibility and represent the company in official meetings with authorities or cooperation partners

Qualifications:

Ph.D. or similar degree in Life Sciences (e.g. Chemistry, Biochemistry, Biology, Agriculture)

Advantage: experience as Regulatory Project Manager with full regulatory responsibility in a country / area with high regulatory requirements (e.g. Europe, Brazil, US), preferred with experiences on global level.

Strong knowledge on registration / re-registration of Active Ingredients in a country / region with high regulatory requirements

Good verbal and written communication abilities in English (concise summarization of technical material, reporting on developments).

Regulatory experiences with biologics - an advantage.

Good organizational skills with ability to multi-task on several projects and independent working

Strategic thinking

Interpersonal skills

Networking ability (both internal/external)

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