BIOCIDAL PRODUCT AUTHORISATION

AGREXIS propose a multistep regulatory approach, specifically tailored to each project, where independent contracts can be established for each step.

1 – Regulatory Strategy Development & Data-Gap Analysis

Under an open consultancy agreement, strictly based on actual time spent, highly experienced **AGREXIS'** regulatory and product safety experts will assist defining the most cost- and time-effective strategies among the various possibilities now proposed by Regulation (EU) 528/2012 (Product Families, Union Authorisation, Mutual Recognition…), based on market constraints and assumptions agreed upfront with our clients.

Full review of proprietary and unprotected data will lead to a clear identification of gaps and a list of data that need to be generated to fulfil the current requirements. It will also help to better estimate the overall costs – data generation, dossier preparation and authorities' fees – of the whole project and anticipate potential regulatory, scientific or technical issues.

AGREXIS' independence from any CRO is the best assurance that the proposed list of studies will be limited to the strictly necessary. Testing can be commissioned and supervised directly by our clients, or we can assist, from selection of the laboratories according to specific criteria, to design and monitoring of a complete study programme.

AGREXIS can guide you through the new regulations to tailor your dossiers to the latest requirements.

2 –Preparation and Submission of the Product Authorisation Dossier

Costs of dossier preparation may vary depending on the intrinsic properties of the product, the active substance(s) it contains, the Product Type, the methods and areas of application and on the regulatory strategies. Typically, an agreement is designed specifically for each project, covering the dossier preparation and, if the client wishes, its submission.

Biocidal Product Authorisation prepared by **AGREXIS** includes environmental, human health and dietary risk assessments, and can cover the totality of the Dossier (R4BP and national application, Document I, Document IIB, Document IIC, Document IIIB) or only parts of it, depending on specific needs.

Additional Product Types for the same product do not need the preparation of a completely new Dossier and therefore would be charged at significantly reduced cost. Grouping of different products into product families, based on composition, can also reduce costs.

3 – Post-submission work

AGREXIS offers follow-up agreement on a time-spent basis to assist our clients in any post-submission work, such as responding to questions, commenting authorities' assessment reports, and defending existing authorisations.

For further information please contact us
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