Eurofins Regulatory AG

STRONGER TOGETHER

eurofins | Regulatory AG

eurofins | Regulatory AG

Eurofins Regulatory AG

Your integrated, fluid provider for trouble free solutions

Offering a complete portfolio registration service, we are your integrated provider for a cost effective and efficient service for regulatory compliance. Eurofins Regulatory AG provides a full range of services leading to the compilation of registration documentation for agrochemicals, biopesticides, REACH and biocides.

Regulatory Affairs

We have a wealth of experience covering all disciplines of active ingredient and product registration dossier submissions.

We possess extensive experience in negotiating with regulatory authorities pre and post submission, task force representation, consumer and environmental risk assessments, stewardship of dossiers throughout the evaluation process and much more.

With strength in depth, our highly experienced team of experts can cover all aspects of your registration portfolio.

Eurofins Regulatory AG offers a 'one stop shop' tailored service including management of multi-site and multi-disciplinary projects; a combination of in-house testing and, where necessary, sub-contracted phases are supported by specialist project management and dedicated logistics. We have the capability to advise and identify a regulatory strategy for successful registration. Undertaking data gap analysis and project management from start to finish, the group also has in-depth experience with the organisation and planning of regulatory projects and CADDY dossiers. Be confident knowing that our regulatory capabilities span EU/E-EU, NAFTA, RSA, LATAM and ASEAN.

Eurofins Regulatory AG

regulatory@eurofins.com
www.eurofins.com/agroscienceservices/regulatory-affairs

eurofins | Regulatory AG

Our Promise

As a global service provider and market leader, Eurofins Regulatory AG can promise unparalleled expertise and a commitment to excellence. We can fully support large development projects as well as local regulatory projects.

You can expect:

- Provision of sound regulatory advice and strategy
- Project management for all or part of your testing programmes
- Scientific experts with specialised areas of expertise
- A 'One stop shop' for all aspects of registration

Portfolio of capabilities

We offer full consulting services which include:

- Advice on data requirements
- Review of protocols in order to guarantee compliance with all relevant guidelines
- Cost-effective strategies to support proposed product registration criteria
- Peer review / critical gap analysis of existing data sets

A complete registration service

Regulatory services include:

- Data gap analysis
- Preliminary risk assessment
- Proactively engaging with regulatory authorities at an early stage of project definition
- Strategic regulatory advice
- Scoping out the studies required and likely timelines to submission and market
- Task force management
- Authority contacts
- Annex III dossiers for new products or to support label and / or formulation changes
- Annex III dossiers for re-registration of products post-Annex I inclusion
- Biocide and REACH dossier generation and submission
- Compilation (including CADDY format) and submission of the completed dossier
- Compilation of Annex II and IIl (EU) compliant dossiers for agrochemicals and biopesticides
- EU and EPA compliant dossier preparation for agrochemicals and biopesticides
- Post- evaluation dossier stewardship
- Problem solving
- Project management from outset to completion
- Proposing appropriate countries for initial submissions
- Protocol design and study monitoring
- Risk assessments to current guidance documents
- Technical equivalence checks
- Writing of biological assessment dossiers as a stand-alone

Eurofins is shaping its regulatory services to meet new, global challenges by offering complete support to the agrochemical and chemicals industry. We have the expertise to provide a tailored strategy for the successful worldwide registration of agrochemicals, biopesticides, biocides and pharmaceuticals (ERA).

Our Expertise

At Eurofins, we have technical experts in all disciplines who constantly keep their knowledge up to date on all the evolving technical data requirements and guidance documents. Maintaining and developing this expertise is our priority, enabling us to identify and address specific technical issues that may arise. We offer strategic advice to our clients on the best way to proceed by identifying data requirements best suited to the client's regulatory objectives through support to full life-cycle-management.

We are confident in our knowledge of recent developments and changes to the current regulation. This allows us to update Eurofins study directors on new developments directly in-house.

Eurofins Regulatory AG can liaise with regulators to help answer any questions that may arise during the evaluation of your dossier. The team are closely linked to the major markets and can ensure all regulatory requirements are met, with local and national requirements taken into consideration.

There is no doubt that the regulatory environment and continually evolving legislation will remain a constant challenge.

Our Team

Eurofins Regulatory AG comprises of the largest regulatory risk assessment and modelling group within the CRO sector. With extensive study monitoring experience, the team have worked under a range of partnership models over many years of active operation.

Regulatory Expertise

- Environmental risk assessment
- Ecotoxicology (aquatic & terrestrial)
- Efate, behaviour & environmental modelling
- Environmental metabolism
- Biocides
- REACH

Committed to providing the best possible service to you, Eurofins Regulatory AG is here to assist you at any point of the regulatory process.

Working with Eurofins

Eurofins

- Strong financial position – stability is assured
- Network of established Eurofins labs and partners
- Experienced regulatory team across Europe
- Sites in Europe, US and RoW
- Client focused project managers
- Investments in the future
- People – hiring the best to meet and exceed client expectations
- Ongoing investments in state of the art equipment and IT
- Continued enhancement of procedures

Benefits

- Long term commitment
- Being able to offer a one stop shop
- Ensuring studies meet regulatory requirements
- Being able to manage multisite projects
- Providing global coverage wherever you have your research needs
- Qualified professionals who can fulfil your requirements
- Providing a high quality service

Eurofins Regulatory AG

regulatory@eurofins.com
www.eurofins.com/agroscienceservices/regulatory-affairs