



knoell

worldwide
registration

THINK GLOBALLY – ACT LOCALLY

BIOCONTROL REGULATORY SERVICES

Biocontrol regulatory services – we have the regulatory expertise to successfully support you in placing your products on the market!

The request for more sustainable use of our environmental resources in combination with an ever increasing global population triggered the demand for more eco-friendly but still efficient alternatives to complement the use of conventional plant protection products – the answer to these needs are biocontrol agents.

As a company dealing with biologicals, you may have questions such as

- ▶ Which regulations apply to my active substance or product?
- ▶ What are the options to classify my active substance or product as low risk?
- ▶ Does a “fast-track” registration option exist for my active substance or product?
- ▶ Are there any specific fees or regulatory processes to be considered?
- ▶ What are the minimum data requirements?
- ▶ Are local efficacy trials needed?
- ▶ How to address global data requirements with a minimum set of information?

Or do you face any other challenges with your products? Our team of experienced microbiologists, agronomists, toxicologists and ecotoxicologists as well as e-fate and residue specialists will be happy to develop appropriate solutions for you.

The broad expertise in regulatory affairs and study monitoring for microorganisms, semiochemicals, plant extracts and botanicals was gained by our team by supporting the registration and renewal of a large number of biocontrol active substances and products. Some of these were based on *Trichoderma*, *Metarhizium*, *Akanthomyces*, *Metschnikowia*, *Streptomyces*, *Pseudomonas*, *Bacillus thuringiensis*, *Bacillus subtilis*(*ssp.*) or baculoviruses.

Our services

- ▶ Regulatory services including registration strategy, development, and communication with authorities on behalf of clients
- ▶ Assessment and identification of data gaps to efficiently address requirements from region/country specifications
- ▶ Customized literature searches
- ▶ Efficacy assessment
- ▶ Study concept management and monitoring
- ▶ Specific local regulatory services, also including translation into local language, compilation and submission of dossiers locally
- ▶ Post-submission support

Due to our broad scientific network, we can facilitate the contact between you, as a client, and leading contract research organisations to help address any technical problems, as well as to advise the most appropriate regulatory approaches for your products.

Individual solutions

One source for your regulatory, product and business development needs – we can assist with the entire go-to-market strategy tailored to your product, or help with individual steps towards your commercialization objectives.

knoell as your go-to partner for registration – worldwide

Regardless whether you are looking for support in Europe, Asia, North and South America, or any other region, our biocontrol experts together with our local partners will be happy to answer all your questions and provide scientific and regulatory support for you.

For further information on biocontrol and our services, please contact us:

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www.knoell.com