

Regulatory Strategy Support in Europe (EEA/UK)



Award-Winning Consultancy Providing Innovative Solutions to Meet Regulatory and Environmental Challenges

Our staff are experts in their respective fields and come from previous positions in the academic, chemical or contract research industries or government, giving us a unique perspective on regulatory requirements and scientific approaches.

We have extensive experience dealing with US, European, and global challenges across the chemical sector. Our strength has come not only from being able to adapt to industry trends, but by anticipating and applying new regulatory and scientific strategies to add value to client product

EEA & UK Regulatory Affairs

- Regulatory and environmental strategies for plant protection products including biopesticides, biocides, specialty and industrial chemicals, cosmetics, fertilisers and biostimulants, and animal health products.
- Liaison with European regulatory agencies including European Chemical Agency (ECHA), European Food Safety Authority (EFSA) and the European Commission, in addition to UK and European Economic Area (EEA) (EU27 plus Iceland, Liechtenstein and Norway) national regulatory authorities.

Dossier Development & Submission

- Preparation and submission of active substance dossiers for EEA and UK registrations.
- Preparation and submission of product dossiers for EEA Member States (including zonal and mutual recognition) and the UK.

Data Development, Study Placement & Monitoring

- Identification of required studies to support registration, data gap analysis, placement and monitoring of studies at contract research organizations, review and interpretation of study results, and Good Laboratory Practice (GLP)/Good Efficacy Practice (GEP) compliance consulting.

Technical Expertise

- Expert guidance on product and residue chemistry, toxicology and endocrine disruptors, ecotoxicology, environmental fate, and efficacy.

Risk Assessment

- Hazard identification, effects analysis, exposure assessment, and risk characterization.

Regulatory & Scientific Insights

- Advice on emerging regulatory and scientific developments that may impact current and future registrations.
- Recommend approaches to bring client products into compliance with new legislation.

Task Force Representation & Administration

- Extensive experience in co-ordination of industry task forces.
- Undertake both administrative and technical roles for task forces and consortia.

Litigation Support & Expert Witness Testimony

- Services include data compensation evaluation and expertise in supporting arbitration or settlement in lieu of litigation.
- Comprehensive due diligence support to companies and investors prior to mergers, acquisitions, joint ventures and other activities.
- In-depth expertise to support attorneys with case development.
- Qualified trial depositions and expert witness testimony including support for data valuation, crop damage assessment, pesticide use or misuse and regulatory compliance.
- Advice on emerging regulatory and scientific developments that may impact current and future litigation proceedings.

Literature Review

- Evaluation of public domain scientific literature and data to support client requests including in support of plant protection product registration dossiers in accordance with EFSA guidance.



Global Regulatory and Environmental Strategies since 1988

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