



**LKC Switzerland Ltd**

Registration and Development

**Plant Protection Products**

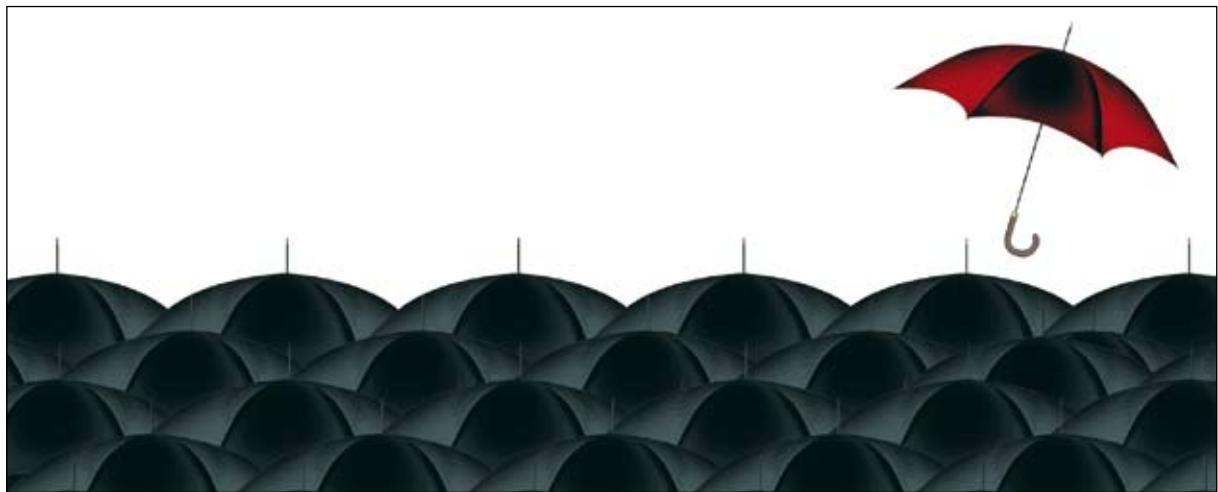
**Veterinary Medicines**

**Biocides**

**Chemicals**



"Branch out and  
broaden your  
horizons"



## About LKC Switzerland Ltd

LKC Switzerland Ltd (LKC) is an independent company founded in 2001 (as Landis Kane Consulting) to provide Registration and Development (R&D) management services to the international specialty chemicals industry.

LKC has a positive track record in Europe and a global vision with affiliates in the USA and Japan. Our core strength is our experienced multi-national and multi-disciplined staff.

LKC's head office is near Basel in Switzerland, a safe country with excellent infrastructure. The Basel area is home to many large and small companies with links to the chemical industry. Reputable universities such as Basel, Bern, Freiburg and Zürich are close by and provide a pool of expertise for businesses and services. In the triangle between Switzerland, France and Germany people are multi-lingual and open-minded, with world-wide connections.

## About LKC UK Ltd

In 2008, LKC UK Ltd. was created as a separate and wholly-owned legal entity to enable LKC to offer clients the capability for EU submissions and notifications on their behalf and especially as "Only Representative" under REACH regulations.





## LKC Activities

LKC provides a full range of regulatory services to achieve the registration of client's products in the fields of plant protection, biocides, veterinary and industrial chemicals.

LKC offers competent, comprehensive, confidential and custom tailored solutions to consortia, lead registrants, manufacturers & importers (both EU and non-EU) and downstream users either as direct interface with regulators or simply trusted advisor.

A comprehensive network of contacts within regulatory authorities allows LKC to continuously monitor progress and changes to the regulations to keep one step ahead of the field and to keep our clients one step ahead of their competition.

## LKC Areas of Expertise

LKC's team has scientific know-how in diverse areas of biology, agronomy, toxicology, environmental sciences, chemistry, project management and business administration. LKC is a steadily growing business with sound foundations and a positive vision for the future.





## LKC offers clients:

### Development and Regulatory Strategies

To bring a new innovative chemical product to the market is expensive and time consuming.

 LKC provides independent expert opinion to develop innovative regulatory strategies tailored to specific situations. Our experience is a significant benefit when timelines and cost are critical factors. LKC interfaces with Authorities on product review and EU Evaluations for Plant Protection Products, Biocides, Veterinary products, Industrial Chemicals and for Work Share e.g. OECD and JMPR

### Registration Dossiers

Compilation of documents for authorisation applications requires a detailed knowledge of the regulations and of the specific paper and electronic submission formats.

 LKC prepares complete or part dossiers including environmental and human risk assessments, for the registration of plant protection products, biocides, veterinary medicines and industrial chemicals. LKC offers dossiers in print and in electronic format (e.g. CADDY-XML, IUCLID, etc.)





## **Project Management and Study Monitoring**



Development projects become increasingly complex. Individual studies must fulfill current guidelines and GLP/GEP/GMP requirements, when personnel resources in producing companies are focused on innovative research. Dedicated project management and thorough study monitoring are significant success factors for seamless transition through the registration process.

 LKChas experienced project managers and study monitors in-house. We are multidisciplinary, fully independent and can select contractors best suited to successfully complete each study within the imparted budget and timelines. Additionally LKC works closely with regulatory authorities and experts worldwide to design and manage non-guideline higher tier studies.





## Business and Marketing

To register a new product is one half of the process. Success is complete when the product provides adequate profit for a healthy business. Key factors are to understand the market opportunities and constraints, to know competing products & companies and to find the right licensing partners for new products.



LKC helps manufacturers define major targets for business activities, to contact potential partners and to source experts for special issues. We advise on business plans and provide the necessary resources to convert the plans to reality.

## “Only Representative” in EU

Non European based Manufacturers are affected by REACH regulation which covers the registration of industrial chemicals.



As a specific service under REACH regulation, LKC will act as Only Representative for non-European based manufacturers. LKC focuses on new molecules under REACH and the construction of data packages and Chemical Safety Assessments for companies that require registration of new materials.





## Multi-site GLP Studies

Multi-site field studies are difficult, long lasting and expensive. However, they are often key elements of a registration strategy. They are governed by complex GLP procedures and require good coordination between the various testing sites and the sponsor.



LKC has GLP accreditation from the Swiss Authorities and provides study directors for multi-site studies and GLP archiving of test items and raw data.

Facility and study audits are part of our business which we conduct on behalf of study sponsors. We have expertise in auditing efficacy, residue, environmental fate and eco and mammalian toxicology facilities.





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