

# Environmental Risk Assessments for Pharmaceuticals



## Regulatory Science at SCC

The specialists in SCC's Regulatory Science department are the backbone of the company and the key to its success. SCC unites experts from all registration-relevant disciplines, such as chemists, food chemists, geoecologists, e-fate specialists, ecologists, ecotoxicologists, toxicologists, biologists, and agronomists.

This access to a wide spectrum of expertise ensures that SCC's clients can take advantage of a highly efficient service.

The experts in SCC's Regulatory Science department know exactly how to perform state-of-the-art risk assessments, as well as knowing which studies and expert statements have to be included where, instead of running an expensive study, a more favourably priced expertise can often be used.

The experience and detailed knowledge of the Regulatory Science department means that SCC provides its clients with clear budgetary estimates along with fast-track service for registration. The benefit for SCC's clients: fast access to the marketplace.

Let SCC be your specialist for environmental risk assessments and pre-clinical study monitoring for your pharmaceutical active substances!

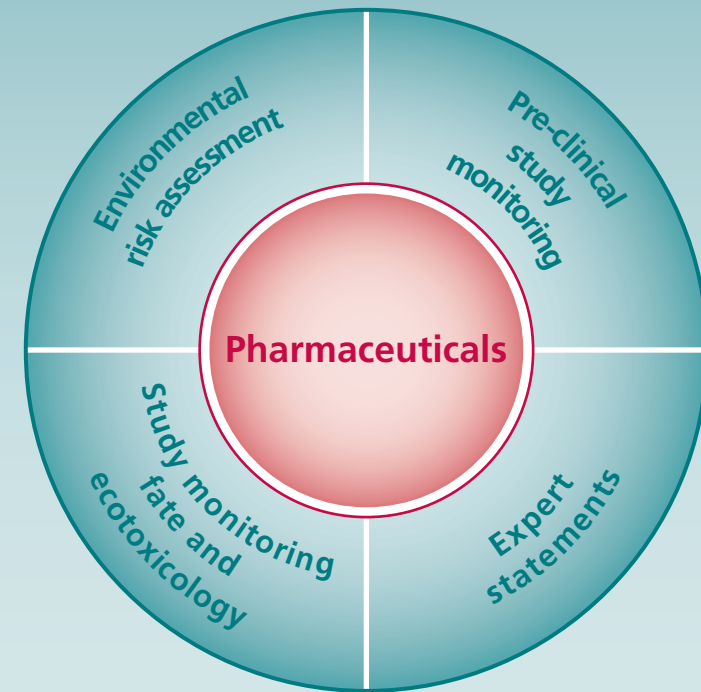
Scientific Consulting Company (SCC) was founded in 1989 by our president, Dr. Friedbert Pistel. SCC is today one of Europe's leading privately-owned and independent consulting companies for the registration of agrochemicals and biopesticides, biocides, chemicals, consumer products, feed & food additives and veterinary medicine. SCC is independent: it intentionally does not have laboratories of its own and is therefore free to co-operate with any laboratory which best suits the needs of its clients.

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## Environmental risk assessment and pre-clinical study monitoring

The “Guideline on environmental risk assessment of medicinal products for human use” refers to the guidelines and test protocols issued by the European Commission, OECD and ISO.

Based on the extensive experience which our experts have gained in the difficult field of plant protection with environmental risk assessments (fate, exposure, effects, risk), we can offer you full scientific and regulatory service.



## Risk Assessments and Modelling

Simulation models are a very useful tool for assessing and estimating the environmental, ecological and human health risk of pesticides, chemicals, biocides and pharmaceuticals.

SCC scientists perform ecotoxicological risk assessments according to current guidelines and regulations, and also take into consideration recent developments in the regulatory framework of the European Union and the United States, as well as available guidance documents.

## SCC provides scientific services to suit the needs of the pharmaceutical industry

SCC is well-versed in study monitoring – from planning, initiating through to monitoring – such studies as:

- pre-clinical studies on mammalian toxicology
- studies on the environmental fate and behaviour
- studies on effects to aquatic and terrestrial organisms

We can prepare expert statements regarding questions on mammalian toxicology, ecotoxicology, and environmental fate and behaviour.

Environmental risk assessments, comparing potential exposure with potential effects, is an integral part of our services.