DISCOVER
OUR SEGMENT

REGULATORY SCIENCE

SCC
WE CARE FOR YOUR SUCCESS

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Pharma Pre-Clinical

Our focus

In the demanding regulatory environment of the EU and worldwide also, expert knowledge is essential to gaining approval for substances and products. That is why the scientific expertise concentrated in our Regulatory Science Business Unit is the backbone of our company, and a key to our success.

Our experience and in-depth knowledge form the foundation of the professional registration service we provide to our clients. Based on detailed analysis of your database and the resulting data gap analysis, we design, contract and scientifically monitor all studies necessary for dossiers. We know exactly how the dossier needs to look; how to perform state-of-the-art risk assessments; and which studies and expert statements need to be included. Our specialists have a long history of successfully submitting dossiers and defending compounds in the different regulatory areas SCC offers services in.

Our services

With SCC, you have a highly competent team of committed experts at your disposal. Our services provide orientation and guidance in the quickly changing landscape of EU and global regulations. Well versed in the latest methods and with long-standing contacts at authorities, laboratories and research institutions, we are proud to offer a level of scientific support that few others can provide.

- Detailed analysis of databases and resulting data gap analysis
- Establishment of testing programmes/designing and scientific monitoring of all studies, including non-standard higher-tier studies
- Screening for endocrine disrupting properties and proposal of related testing
- Human and environmental exposure modelling, covering dietary, occupational, residential exposure, as well as all environmental compartments (*e.g.* soil, surface water, groundwater, air)
- Risk assessments for human health and the environment based on state-of-the-art exposure modelling
- *In silico* analysis (*e.g.* QSAR) and resulting assessments
- Addressing scientific/regulatory questions in physico-chemistry, analytics, toxicology, residues, environmental fate and ecotoxicology
- Performing literature searches and selecting relevant publications
- Compilation of relevant documents and dossier preparation
- MRL/import tolerances, as well as Codex MRLs, including dossier preparation and application
- Classification and labelling, including CLH dossier preparation
- Preparation and/or submission of electronic dossiers
- Task force and consortium management as a neutral adviser

Expertise in regulatory science

Environmental exposure assessment
Our experts have profound experience with all relevant regulatory models providing predicted environmental concentration (PEC). We use advanced server-distributed simulation and automated reporting solutions to assess a broad range of scenarios and parameter sets in a short time and with high reliability.

Ecotoxicological risk assessment
We develop strategies in line with current guidance documents and regulations and also take into account recent developments in the regulatory framework of EU and other areas in the world.

Human risk assessment
We use all current models available for the prediction of acute and chronic consumer, operator, worker, bystander and resident exposure. We have the necessary experience to refine risk assessments if required.

Study monitoring
We design and contract studies for physico-chemistry, analytical methods, toxicology, residues, environmental fate and ecotoxicology, including higher-tier studies.

Expert statements
We prepare expert statements to answer all potential scientific / regulatory questions.

Pharma / pre-clinical
We are well versed in study monitoring and professionally prepare expert statements regarding questions on mammalian toxicology and ecotoxicology as well as environmental fate and behaviour. One of the services we are particularly skilled in is supporting the environmental risk assessment (ERA) of pharmaceuticals.

Study monitoring

We offer study monitoring in the fields of:

- Physico-chemistry
- Analytics
- Toxicology
- Residues
- Environmental fate
- Ecotoxicology
- Efficacy

We have extensive experience in designing and monitoring non-standard higher-tier studies (*e.g.* operator exposure, field dissipation studies, micro/mesocosm studies, studies on birds/mammals, focal species and effect studies, as well as NTA/bee semi-field and field studies).

We are used to cooperating with laboratories on an international level, be they contracted service providers or part of your own company.

Exposure modelling and risk assessments

Environmental / ecotoxicological risk assessments
In our environmental exposure assessments, we use various models, including those recognised by the FOCUS group, to characterise properties relevant to the environmental fate of substances, and estimate the predicted environmental concentration (PEC) in soil, groundwater, surface water and air.

These PEC calculations are conducted using a powerful server-based simulation environment together with efficient data extraction software, enabling us to investigate a huge number of combinations of substance properties, application timings, uses and scenarios.

We perform ecotoxicological risk assessments in line with current guidance documents and regulations. We also take into account recent developments in the regulatory framework of the European Union.

Human health risk assessments
We perform risk assessments for all population groups. We use all current models available for the prediction of acute and chronic consumer, operator, worker, bystander and resident exposure (*e.g.* EFSA models for dietary and non-dietary exposure, WHO models, various national models including combined risk assessments).

International maximum residue limit (MRL) setting

We handle all types of MRL applications. These include MRL applications for crops traded within the EU; MRL applications for imported products to meet the needs of international trade, such as import tolerance applications; and applications for worldwide MRLs, *e.g.* Codex Alimentarius MRLs.

SCC is a recognised partner for industry in the EU, USA and Asia, with contacts in the competent authorities for the EU and Codex MRL setting. We have successfully submitted and defended numerous dossiers.

Our customers benefit from high-quality regulatory and scientific expertise, which we offer in all disciplines relevant for MRL setting (analytics, toxicology, residues).

Our MRL services

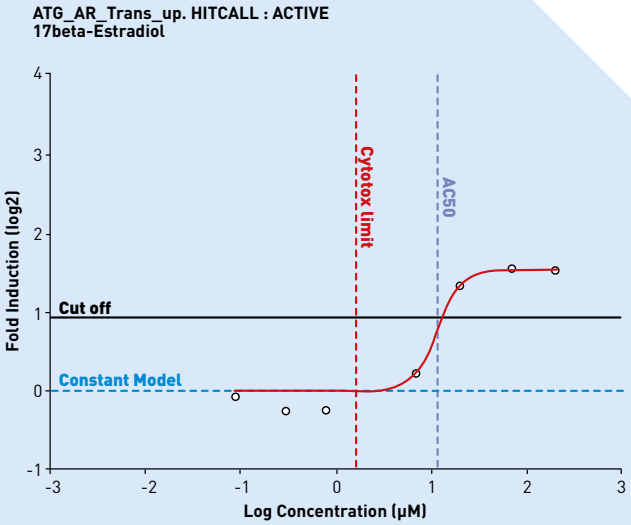
- Detailed analysis of databases and resulting data gap analysis
- Planning and monitoring of studies (analytics, toxicology, residues)
- Preparation of pre-submission meetings
- Risk assessments based on state-of-the-art models
- Compilation of regulatory documents and dossier preparation
- Communication and data management
- Dossier submission and follow-up

Our special services and expertise in toxicology, keeping sight of future perspectives

We offer **high-quality regulatory and scientific support** for specific demands, staying up to date in continuously developing areas. This includes new toxicity testing methods, the use of predictive toxicity models and the evaluation of complex toxicological demands such as the assessment of endocrine disrupting potential.

Our special services include:

- Weight of evidence (WoE) assessments: *in vitro*, *in vivo* and *in silico* data
- Predictive *in silico* toxicology:
  - » Conducting (Quantitative) structure-activity relationship ((Q)SAR) analysis
  - » Grouping of chemicals
  - » Data gap filling approaches, such as read-across and trend analysis
- Mode of action (MoA) analysis: adverse outcome pathway (AOP) concept
- Substance-specific and customised (testing) strategy development



Computational chemistry: *in silico* (eco)toxicology

Due to the increasing efforts to reduce *in vivo* tests for active substances, metabolites and impurities to a minimum, computational testing methods are quickly gaining in importance.

Computational methods are used to group chemicals and estimate or predict the (eco)toxicity of compounds. They are also employed to model toxicodynamic and toxicokinetic properties.

We routinely generate *in silico* data and perform knowledge- and statistically-based QSAR models (*e.g.* Toxtree, Vega and U.S. EPA T.E.S.T.) to fulfil regulatory hazard information requirements regarding metabolites and impurities. The OECD QSAR Toolbox is used by trained SCC experts for profiling and data-gap-filling approaches such as read-across. Detailed descriptions of the models used and the reliability and applicability domains are provided. SCC experts interpret and discuss the data in a weight of evidence (WoE) approach based on expert judgement.

We have in-depth expertise in the evaluation of specific toxicity endpoints such as genotoxicity or endocrine disruption. For the latter, effects on specific targets as receptors are predicted and evaluated using state-of-the-art models and databases (*e.g.* ToxCast Pathway Model Prediction, Danish (Q)SAR Database, Endocrine Disruptome).

Endocrine disruptors

The EU is currently in the process of implementing harmonised and legally binding criteria to identify substances as endocrine disruptors (EDs).

As part of this process, the EU Commission has adopted criteria to be used in plant protection legislation as well as for biocides. These hazard-based criteria originate from the World Health Organisation's (WHO) definition of EDs.

Furthermore, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA) have developed a guidance document for applying the new criteria to EU-wide pesticide and biocide legislation.

However, even with the enforced EU ED criteria and the ED guidance on hand, expert work and judgement will be needed to evaluate the putative ED properties of compounds.

SCC has a wide spectrum of expertise in the assessment of potential endocrine disruption. This allows us to successfully anticipate regulatory challenges and confidently guide our clients through the difficulties in developing target-specific strategies. To keep up to date with every new requirement, we continuously monitor the current regulatory and scientific developments in this field, both in the EU and worldwide.

Our expertise covers the entire range of methods that can be used in the development of an appropriate assessment strategy, including mode of action (MoA) analyses and adverse outcome pathway (AOP) concepts as well as weight of evidence (WoE) approaches.

SCC will serve you as a dedicated and highly experienced partner when it comes to assembling the lines of evidence. We will support you in gathering, evaluating and putting together all relevant information required for establishing whether the ED criteria are fulfilled.

Our expertise

Complying with international chemical regulations is not a matter of choice – but picking the right partner for this crucial task is. SCC will be with you through every step of the regulatory process and expertly guide your products to EU-wide and global success.

- **Outstanding knowledge of registration processes** and associated data requirements
- **Vast experience in designing, monitoring and evaluating higher-tier studies,** *e.g.* operator exposure studies, micro/mesocosm studies, birds/mammals or NTA/bee semi-field and field studies
- **Extensive experience in the efficient use of simulation models** needed for environmental and human health risk assessment, including *in silico* analysis (QSAR)
- **Numerous successful dossier submissions and defence** of compounds at EU and national level
- **Addressing scientific/regulatory questions** from all disciplines
- **Assessing endocrine disrupting potential** based on existing data and **providing testing proposals** where necessary
- **Excellent contacts** at the competent authorities within the entire EU
- **Professional handling** of various electronic submission formats
- **Management of task forces and consortia** since 1989
- **Recognition as a knowledgeable partner for industry** in the field of agrochemicals/biopesticides, biocides, chemicals and other regulatory areas

Who we are

SCC – Scientific Consulting Company – was founded in 1989 by Dr Friedbert Pistel. Since then, we have risen to become one of Europe's largest privately owned and independent scientific consulting companies, supporting global customers in the regulatory affairs business.

Our headquarters are located in Germany in the culturally rich Rhein-Nahe region, less than one hour's drive from Frankfurt Airport.

We have a second German office in Berlin, opened in 2014, and in 2018 also established SCC Japan in Tokyo, after 10 years of running a liaison office in Japan.

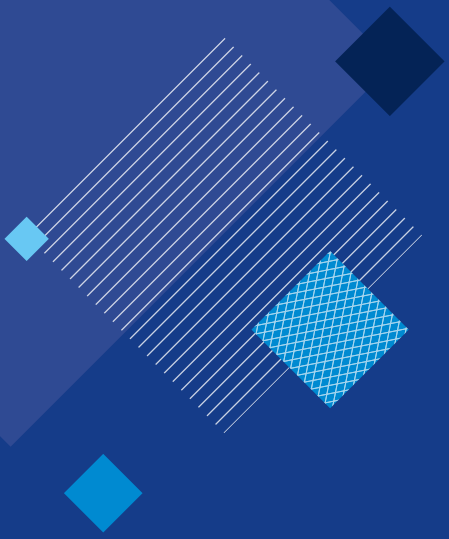
At SCC, you will find an open-minded, innovative entrepreneurial spirit backed by the expertise and commitment of a strong team. This winning combination has played a significant role in the rapid development of the company. We offer our customers high quality, flexibility, reliability and versatility, coupled with vast knowledge and a wealth of experience. Their success is what drives us forward.

85%
with a university degree

in **19** different disciplines

from **10** nations

130
SCC employees



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