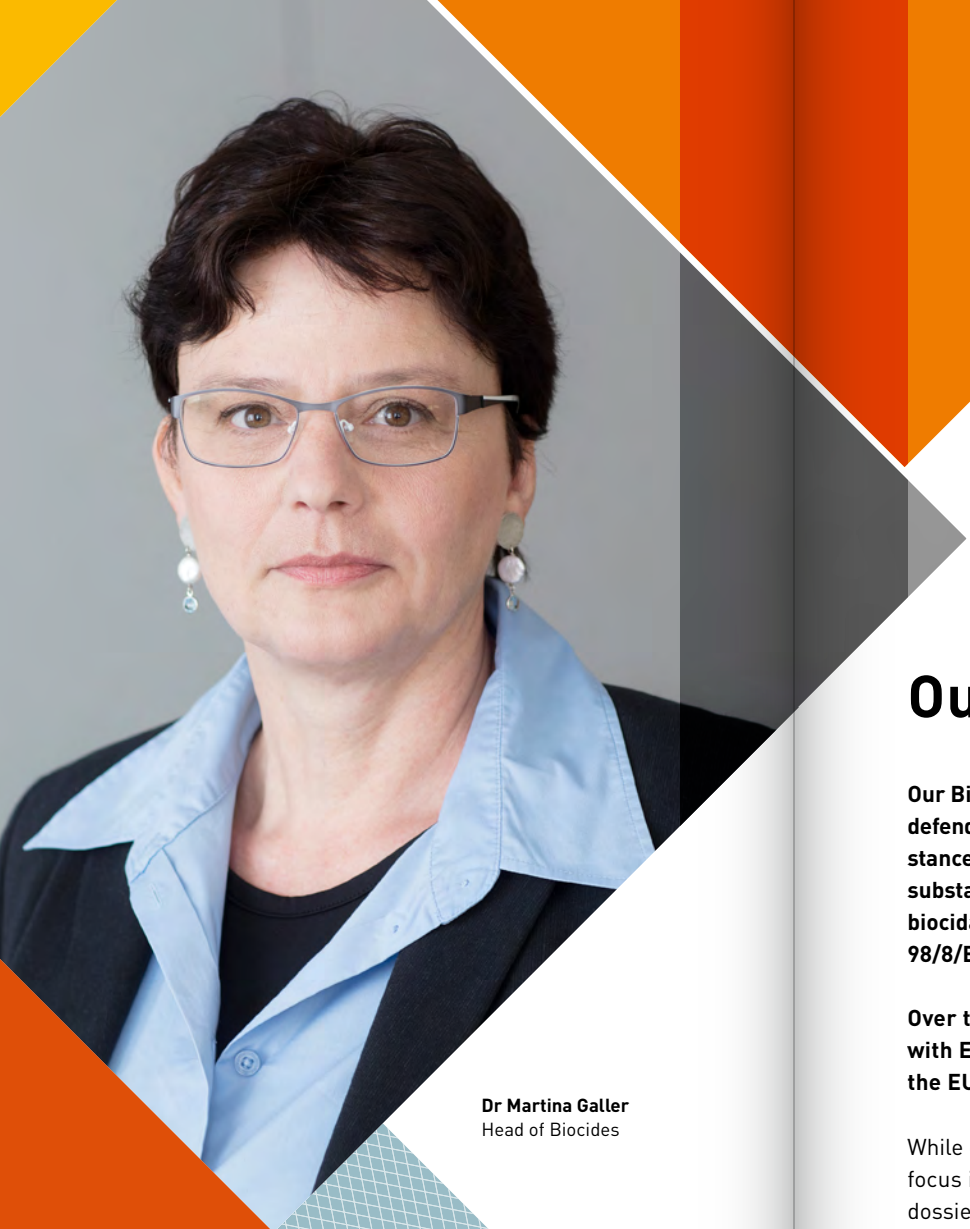
DISCOVER
OUR SEGMENT

BIOCIDES

SCC
WE CARE FOR YOUR SUCCESS



Dr Martina Galler
Head of Biocides

Our focus

Our Biocides experts have successfully submitted and defended dossiers for more than 20 biocidal active substances in nearly all product types (more than 70 active substance dossiers) as well as numerous dossiers for biocidal products and product families in line with BPD 98/8/EC or BPR (Regulation (EU) No 528/2012).

Over the years, we have established a direct dialogue with ECHA and many competent authorities across the EU.

While offering a broad spectrum of services, our special focus is on preparing and defending active substance dossiers as well as writing dossiers for biocidal products and product families. We have extensive knowledge and experience in performing standard and non-standard risk assessments, planning and monitoring any studies relevant for your dossiers, and preparing expert judgement (waivers) to replace studies, where applicable. As your experienced partner, we provide you with clear budgetary estimates along with fast-track, professional services.

Our services

The world of biocide regulation is highly complex and can be hard to navigate. Our experts provide competent and experienced support on all aspects of the registration process. Whether taking over specific tasks or preparing entire dossiers, they offer customers top-of-the-line services they can rely on.

- **Support on regulatory, scientific and technical questions** concerning any dossier-related issues for active substances and product applications for national and union authorisations
- **Definition of the appropriate regulatory strategy** in the defence of existing active substances, their renewal of approval, dossier preparation for new actives and product authorisations
- **Identification of data gaps**
- **Planning and monitoring of any type of studies** on analytics, physico-chemical properties, efficacy, e-fate, (eco)-toxicology
- **Performance of preliminary exposure and risk assessments** to find out whether all intended uses are safe or whether additional studies (e.g. leaching studies or worker exposure studies) are required
- **Identification of substances of concern** and definition of necessary regulatory activities
- **Clarification of possible critical issues** with the selected evaluating competent authority state
- **Preparation of complete dossiers for active substances and products**
- **Preparation of technical equivalence dossiers**
- **Dossier submission and follow-up** (i.e. timely and competent response to questions raised by the authorities)
- **Flexible service**
  We offer support for specific questions or take on overall responsibility for the preparation of complete dossiers
- **Task-force and consortium management**
  We are experienced in management of small and large task forces for active substances and products

Exposure and risk assessments

Rigorous assessment of potential exposures and risks is an essential requirement for gaining substance approval or product authorisation. We are familiar with all relevant testing methods and simulation models, as well as with accepted shortcuts that can save our customers time and money.

- **In all product types and for all uses**
- **Use of all relevant up-to-date environmental guidance/scenarios and models,** such as EUSES, SimpleTreat, FOCUS PELMO and PEARL as well as FOCUS surface water models (step 1–4)
- **Proven expertise** in adapting standard ESDs to non-standard applications and creating new ESDs
- **Fast and cost-effective**
- **Thorough knowledge** of all relevant human health exposure models, including TNsG, BEAT, ART, ConsExpo and RiskOfDerm
- **Assessment of livestock exposure and dietary risk**
- **Familiar with** HEEG Opinions, Headhoc recommendations, substance-of-concern guidance
- **Experienced in read-across** of dermal absorption studies to similar products

Our expertise

- **Successful submission of numerous BPD/BPR dossiers** on biocidal active substances, including substances of key importance for the biocide sector, **as well as biocidal products and product families**
- **We are experts in preparation and defending active substance and product (family) dossiers**
- **Dealing with critical issues** raised by competent authorities or ECHA (e.g. refinement of exposure and risk assessments as well as read-across argumentations)
- **All aspects of dossier preparation for new active substances** from data gap analysis, through planning and monitoring of studies, to dossier writing, including the performance of risk assessments
- **Broad experience in designing, monitoring and evaluating higher tier studies**, e.g. operator exposure studies (OPEX studies) and micro-/ mesocosm studies

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.

Our other offices in Berlin, established in 2014, and in Tokyo, opened in 2007, complement our headquarters in Bad Kreuznach and guarantee our international customers broader access to our services.

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. It embodies values such as high quality, flexibility, reliability and versatility, coupled with vast knowledge and a wealth of experience. And that is what drives us forward.

85%
with a university degree

in **19** different disciplines

from **10** nations

130
SCC employees

SCC – SCIENTIFIC CONSULTING COMPANY
Chemisch-Wissenschaftliche Beratung GmbH

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