

Toxicology at Barkwith Associates



Human health hazard assessment
& general Toxicology

Rachel Tilley joins us as **Senior Toxicologist**, bringing specialist human health hazard assessment into the same team that already handles dossier preparation and regulatory strategy. For clients, this removes a potential project bottleneck. Rather than relying on a separate toxicology consultancy with its own priorities and timelines, toxicology expertise is integrated into our project team, enabling faster decision-making, improved coordination, and more efficient delivery of your submissions.



Rachel Tilley
Senior Toxicologist at Barkwith Associates
rt@barkwithassociates.com

Specialist Areas

Rachel's particular strengths include general toxicology, but she has particular expertise in skin sensitisation and skin and eye damage, and particularly how those endpoints are handled under REACH.

Alongside this, she covers developmental and reproductive toxicity (DART), neurotoxicity, and Endocrine Disruption Assessments. Weight-of-Evidence assessments, data gap analysis (DGA), integrated testing strategies, read-across justifications developed with QSAR specialists and Literature review. The common thread to her expertise is evaluating complex toxicological datasets and turning them into a regulatory position that will hold up under scrutiny.

Hazard Assessment

Acute tox with specialism in skin sensitisation, skin and eye damage

Strategy

Weight-of-evidence assessments, data gap analysis, integrated testing strategies, read-across justifications developed with QSAR specialists

Documentation

IUCLID technical dossiers, endocrine disruptor assessments, CLP classification and labelling support

General Toxicology

Study monitoring, data review and interpretation, critical evaluation of the published literature, regulatory advice.

Acute Toxicology, Developmental and Reproductive Toxicology (DART), carcinogenicity, Neurotoxicity, Endocrine Disruption (ED) Assessment, Genotoxicity endpoints within dossiers and we recommend testing strategies.

What this looks like on a project:

Most work starts with a question about whether the toxicological data you hold is enough. We can review what data exists, identify the gaps a regulator will most likely challenge, and set out the most cost effective route to closing them. That might mean a read-across argument rather than a new study, a targeted in vitro package rather than expensive and large in vivo tests, or a weight-of-evidence case built from information already in your file. Where testing is genuinely needed, we will specify it. If needed, we can help you place it and we can study monitor it.

Why clients want to work with us:

Regulatory toxicology is easy to get technically right and commercially wrong. A defensible testing programme can cost far more than it needs to, and a cheap one can cost a year when the dossier comes back.

One strategy is to commission every study on the list and think nothing can be challenged, in this scenario you think you have paid for certainty, but often this certainty isn't given, and in fact can open yourself up to even more unnecessary scrutiny.

Conversely; don't supply enough data to back your claims and the dossier comes back with a request for further information from the regulator, and this causes significant time delays. The expert judgement is in knowing how far short of the maximum you can stop and still scientifically defend your position. Barkwith has always taken a pragmatic approach to regulatory support where we always have in mind the scientific justification, the timelines and the budget.

The endpoints in more detail:

Skin sensitisation

Sensitisation is where a lot of registrations lose time, because the non-animal methods generate data that still has to be interpreted rather than simply read off. We build the case from the available *chemico* and in vitro results, existing human and animal data, and structural analogues, then set out a defined approach that supports a classification decision under CLP. Where the picture is genuinely equivocal we explain what would resolve it.

Skin and eye damage

Corrosion and irritation questions are often answerable without new testing, from physicochemical properties, existing data on the substance, and read-across to close analogues. We assess what the data supports, prepare the justification, and identify the narrow cases where a study is unavoidable.

Developmental and reproductive toxicity

DART studies are among the most expensive in the package, so strategy matters more here than almost anywhere else. We review what the existing dataset already demonstrates, assess whether a lower tier study or an adaptation can be justified, and prepare the argument for it.

Neurotoxicity

Neurotoxicity signals often surface as incidental findings in repeat dose studies rather than as a dedicated endpoint. We evaluate whether those findings are adverse, whether they trigger further work, and how they should be reflected in the hazard assessment.

Endocrine disruption

ED assessment demands a structured weight-of-evidence approach across a wide evidence base, and the documentation burden is heavy. We assemble the assessment, identify where the evidence is thin, and set out a testing strategy proportionate to the level of concern according to the latest guideline requirements.

How we operate:

Data gap review

A fixed price review of an existing dataset against the requirements for your registration, ending in a list of gaps and a recommended route to closing each one.

Testing strategy

An integrated testing strategy with costed options, so the commercial decision is made with the scientific consequences visible

Dossier work

Preparation or review of IUCLID endpoint summaries, read-across justifications, CLP assessments and endocrine disruptor assessments. Add derivation of DNELs and preparation of toxicokinetic assessments

Second opinion

Independent review of a position you already hold, before it is submitted or after it has been challenged

Alongside the rest of the consultancy

The same team supports REACH & CLP, biocidal product authorisation, FPR & Biostimulant Authorisation plant protection and biopesticide submissions, efficacy work and wider regulatory strategy. This means one team, full coverage with confidence through compliance.



To discuss a substance, a dossier or a testing strategy, contact

John Parkes

Director of Business Development.



+44 (0)7951 141905
+44 (0)1673 885333



jp@barkwithassociates.com
info@barkwithassociates.com



Barkwith Associates Ltd, Orion House, Barn Hill, Stamford, UK PE9 2AE