Kristina Ulrich, Ph.D., M.Sc., E.R.T.

DIRECTOR, PHARMACEUTICALS PRACTICE

SENIOR MANAGING SCIENTIST

CONTACT INFORMATION

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PROFESSIONAL PROFILE

Dr. Kristina Ulrich is a toxicologist practicing in the United Kingdom, with 20 years of expertise in pharmaceutical discovery, development, and regulatory science. She has nonclinical safety experience with biologic, small-molecule, and cell and gene therapy products in a wide variety of therapeutic indications, including rare diseases, pain/neurology, oncology, respiratory, ocular, dermatology, and renal/urinary diseases, as well as multiple routes of administration (oral, ocular, intravenous, subcutaneous, inhalation, and dermal).

Dr. Ulrich is a former nonclinical assessor at the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom. Dr. Ulrich was responsible for reviewing nonclinical data packages submitted with applications for clinical trials to be conducted in the UK and Europe. This included first-in-human and first-in-UK trials and involved all types of therapeutic indications and medicinal products. Dr Ulrich also acted as nonclinical rapporteur for centralized marketing authorization applications, where she reviewed nonclinical packages (pharmacology, pharmacokinetics, and toxicology, including ecotoxicology) for a variety of therapy areas. Dr Ulrich has provided scientific and regulatory advice to pharmaceutical companies regarding nonclinical development in support of clinical trials and marketing authorization and has presented to national expert advisory groups (e.g., Commission for Human Medicine).

During her career in the pharmaceutical industry, Dr. Ulrich has led the nonclinical safety strategy for products at various stages of development, from early discovery to late-stage development and post-approval. She has been responsible for the toxicology sections of regulatory documents, including nonclinical overviews, INDs, CTAs, PSP/PIPs, NDAs, briefing documents for health authorities, and risk management plans, and has provided toxicology input for pharmaceutical in-licensing opportunities.

As a consultant, Dr Ulrich specializes in the design and implementation of nonclinical safety strategies, nonclinical data review, problem solving and recommendations for future investigations, health authority interactions and regulatory document preparation. She provides support to clients working on a broad range of therapeutic modalities (small molecules, biologics, and cell and gene therapies).

EDUCATION AND DEGREES EARNED

2013 Master of Science in Applied Toxicology (with Distinction), University of Surrey, Faculty of Health & Medical Sciences, UK

2003 Ph.D. in Biomedical Science, Faculty of Medicine, National Heart & Lung Institute, Imperial College, London, UK

1999 Bachelor of Science in Genetics (with Honors), 1st Class in Genetics, University of York, UK

PROFESSIONAL MEMBERSHIPS AND CERTIFICATIONS

2012–present European Registered Toxicologist (ERT)

2012–present Member, American College of Toxicology

2009–present Member, British Toxicology Society

2012 Certified Cosmetics Safety Assessor, Vrije University, Brussels

SELECTED PROFESSIONAL EXPERIENCE

Pharmaceutical Toxicology Project Leadership

Held role as Head of Toxicology in UK-based biotech company: responsible for the entire nonclinical safety function for drug discovery programs, including nonclinical strategy, operation, resourcing, budget, and timelines. Advised discovery programs and supported exploratory non-GLP studies.

Served as Strategic Toxicology Lead for the neuroscience portfolio in a global pharmaceutical company: developed the strategy for projects across all phases of development, guided and mentored other toxicologists in all aspects of delivering nonclinical safety plans, critically reviewed pivotal toxicology and safety pharmacology data, reports, and high-level summaries ahead of internal governance interactions and regulatory submissions.

Served as toxicology representative on project teams in a number of global pharmaceutical companies: led the development and execution of nonclinical safety drug discovery and development (small and large molecule) plans in accordance with appropriate regulatory guidelines, guided nonclinical safety strategies in alignment with other functions and senior management, and liaised with study monitors and functional project managers during planning and conduct of toxicology studies.

Key therapy areas of expertise included neurology/pain, oncology, dermatology, urology, cardiovascular/metabolic disease, allergy, and respiratory.

Regulatory Toxicology and Risk Assessment

At MHRA, provided nonclinical regulatory approval of clinical trial applications for trials to be conducted in the UK, including first-in-human and first-in-UK trials and all other trial types. This covered all types of investigational medicinal products, including biologics and advanced therapy medicinal products (e.g., gene therapy products).

Reviewed nonclinical data to ensure that the proposed clinical study is supported from the nonclinical perspective (e.g., clinical dose setting, safety margins, stopping criteria, and clinical monitoring of nonclinical findings).

Provided nonclinical scientific and regulatory advice to pharmaceutical companies regarding nonclinical development in support of clinical trials.

Acted as nonclinical rapporteur for centralized marketing authorization applications in various therapeutics areas, including respiratory, endocrine, ophthalmology, and dermatology (Orkambi, Truberzi, Skilarence, Cystadrops). Conducted nonclinical assessments (pharmacology, pharmacokinetics, and toxicology, including ecotoxicology) of new types of applications for marketing authorization (centralized procedures, national and mutual recognition procedures, and decentralized procedures).

Provided nonclinical advice to expert advisory committees (including the Commission for Human Medicine), as well as national and European (CHMP) scientific and regulatory advice to pharmaceutical companies.

Within several global pharmaceutical companies, prepared toxicology summary sections and integrative assessments for pre-INDs, IND/CTAs, and NDA/BLA submissions. Supported toxicology documentation of other regulatory documents (e.g., DSURs, RMPs, PSPs/PIPs, and Rest-of-World submissions).

Led scientific interpretation of study results in collaboration with internal and external subject-matter experts; also developed appropriate risk assessment recommendations and approaches.

Oversight of Toxicology Studies

Contracted and monitored GLP and non-GLP toxicology/safety pharmacology studies in rodents and non-rodents: established timelines, selected CROs, negotiated contracts, prepared and reviewed protocols, made in-life updates, responded to urgent study decisions, and reviewed and finalized reports.

In a global pharmaceutical company, acted as the single point of control (Study Director) for non-GLP and GLP studies to support repeat-dose toxicity studies in rodents and dogs in compliance with appropriate SOPs, GLPs, and regulatory guidelines. Responsible for technical conduct, study design, interpretation, analysis, documentation, and reporting of study results. Directed technical staff, collaborated across departments, and outsourced laboratories for multisite studies.

External Activities

2022-present	Member of the UK Register of Toxicologists (UK RT) Selection Panel
2017-2022	Education, Training and Career Development subcommittee member (British Toxicology Society)
2017-2019	Basic Training in Toxicology E-Learning Webinar subcommittee member (joint American College of Toxicology and British Toxicology Society)

MANUSCRIPTS

Thompson CM, Brorby G, Keig-Shevlin Z, Smith R, Franzen A, **Ulrich K**, Blanchette AD, Doepker C. 2023. Assessment of the in vivo genotoxic potential of three smoke flavoring primary product mixtures. Environ Mol Mutagen 64(8–9):420–431; doi: 10.1002/em.22576.

Gosset JR, Beaumont K, Matsuura T, Winchester W, Attkins N, Glatt S, Lightbown I, **Ulrich K**, Roberts S, Harris J, Mesic E, van Steeg T, Hijdra D, van der Graaf PH. 2017. A cross-species translational pharmacokinetic-pharmacodynamic evaluation of core body temperature reduction by the TRPM8 blocker PF-05105679. Eur J Pharm Sci 109: S161–S167.

Lamb DJ, Parker N, **Ulrich K**, Walsh R, Yeadon M, Evans SM. 2012. Characterisation of a mouse model of cigarette smoke extract-induced lung inflammation. J Pulmon Resp Med 2(3):open access, doi: 10.4172/2161-105X.1000125.

Ulrich K, Hincks JS, Walsh R, Caroline Wetterstrand EM, Fidock MD, Sreckovic S, Lamb DJ, Douglas GJ, Yeadon M, Perros-Huguet C, Evans SM. 2008. Anti-inflammatory modulation of chronic airway inflammation in the murise house dust mite model. Pulmon Pharmacol Therapeut 21(4):637–647.

Apfeldorfer C, **Ulrich K**, Jones G, Goodwin D, Collins S, Schenck E, Richard V. 2008. Object orientated automated image analysis: quantitative and qualitative estimation of inflammation in mouse lung. Diagnostic Pathol 3(1):S16.

Ulrich K, Stern M, Goddard ME, Williams J, Zhu J, Dewar A, Painter HA, Jeffery PK, Gill DR, Hyde SC, Geddes DM, Takata M, Alton Show EWFW. 2005. Keratinocyte growth factor therapy in murine oleic acid-induced acute lung injury. Lung Cell Molec Physiol 288(6): https://doi.org/10.1152/ajplung.00450.2004.

ABSTRACTS AND PRESENTATIONS

Ulrich K. Adversity and risk assessment of respiratory tract findings — A regulatory perspective. Presentation to the 31st Annual Meeting of the British Society of Toxicological Pathology (BSTP) — Association of Inhalation Toxicologists Joint Conference, Alderley Edge, Cheshire, UK, 2016.

Ulrich K. Inhalation toxicology – Regulatory aspects for pharmaceuticals. Presentation to In Vitro Toxicology Society Annual Meeting, Birmingham, UK, 2015.

Ulrich K. Requirements of nonclinical inhalation studies for clinical development and registration. Presentation to British Society of Toxicological Pathologists (BSTP) — Continuing Education Symposium 4, Department of Pathology, Cambridge, UK, 2015.