Anna Bottomley, Ph.D.

SENIOR SCIENTIST II

CONTACT INFORMATION

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PROFESSIONAL PROFILE

Dr. Anna Bottomley is a Senior Scientist II in ToxStrategies' Pharmaceuticals practice, with 16 years of experience in both the pharmaceutical and contract research industries. She practices in the United Kingdom and has nonclinical experience with biologic and small-molecule products in all species and multiple routes of administration.

Dr. Bottomley has served as a Study Director for a leading Contract Research Organization (CRO) in the UK, where she directed nonclinical acute, subchronic, chronic, and carcinogenicity studies to assess the general toxicology of a variety of pharmaceutical, biological, and chemical compounds in support of regulatory agency submissions. She was responsible for the technical conduct of nonclinical studies, as well as the study design, interpretation, analysis, and reporting of results. Dr. Bottomley developed particular expertise in conducting non-human primate (NHP) studies with monoclonal and bispecific antibodies and designing novel studies to support specific regulatory requests.

Dr. Bottomley recently served as an Alliance Manager for a global pharmaceutical developer. She was responsible for the key alliance with the main international CRO that delivered the majority of nonclinical studies, representing the firm at governance meetings, measuring key performance indicators, and improving/simplifying processes while maintaining delivery schedules. She held regular meetings with internal and external stakeholders from the toxicology, reproductive toxicology, and safety pharmacology teams focused on objectives for the relationship, implementation of any new techniques/processes, study prioritization, and resolving study issues. She had a close working relationship with multiple international CROs to help the pharmaceutical developer identify the most appropriate CRO to place studies based on a balance of cost, schedule, and scientific expertise. She also served as a Study Monitor for a small-molecule project, delivering the studies required to support the Investigational New Drug (IND) submission.

Dr. Bottomley earned her Ph.D. in Child Health from University College in London; her research focused on using proteomics to find evidence of protein nitration in the cerebral spinal fluid of children diagnosed with acute

lymphoblastic leukemia. Her undergraduate work included a year-long study of the effects of radiofrequency radiation on the rat heart and diaphragm function. In 2015, she served as a program manager (1-year sabbatical) for the National Centre for Replacement, Reduction, and Refinement (NC3Rs), a UK-based scientific organization dedicated to replacing, refining, and reducing the use of animals in research and testing. In 2015, Dr. Bottomley chaired a workshop at the Safety Pharmacology Society meeting on the housing of non-rodents during telemetry studies.

EDUCATION AND DEGREES EARNED

2001 Ph.D., University College, Institute of Child Health, London

1998 B.Sc., Neuroscience, Nottingham University (*with honors*)

SELECTED PROFESSIONAL EXPERIENCE

Alliance Manager, Global Pharmaceutical Company, UK

Managed a large number of GLP and non-GLP toxicology studies in most species and dose administration routes, in compliance with appropriate SOPs, GLPs, and regulatory guidelines, with a focus on NHP studies for monoclonal antibodies. Supported protocol development and in-life updates, managed urgent study issues and changes to design, reviewed data and wrote reports. Worked with clients to design and implement bespoke study designs to address specific regulatory requirements.

Study Director, Contract Research Organization, UK

Evaluated genomic, epigenomic, transcriptomic, metabolomic, and proteomic responses to environmental chemical exposures using *in vitro* models, animal models, and human cohort data.

Developed systems biology-based strategies to prioritize biological pathways that play key roles in disease progression. Implemented strategies to identify important canonical pathways (using DAVID, KEGG, and Ingenuity Pathway Analysis pathways) involved in bladder cancer, leukemia, and cancer of the upper respiratory tract that are under epigenetic regulation. Results were used to propose novel molecular targets for cancer inhibition and to prioritize molecular events that could be used in setting chemical safety criteria.

Program Manager, Government Organization, UK

One-year sabbatical as a Program Manager at a UK government body. Set up and chaired an international working group with members from the pharmaceutical/CRO industry and regulatory groups. Established best practices in the housing of non-rodents during telemetry recording on both safety pharmacology and toxicology studies, disseminating the information through publications and a workshop at the Safety Pharmacology Society meeting. In addition, active participant in working groups on adverse-outcome pathways (AOPs) and microsampling.

Scientific Officer, Government Organization, UK

Three-year research project involving three laboratories studying the effects of radiofrequency radiation on learning and memory. Conducted *in vivo* studies in the mouse that included assessing the behavioral model to be used, experimental planning, data analysis, and reporting.

MANUSCRIPTS

Prior H, **Bottomley A**, Champeroux P, Cordes J, Delphy E, Dybdal N, et al. 2016. Social housing of non-rodents during cardiovascular recording in safety pharmacology and toxicology studies. J Pharmacol Toxicol Methods 81(Sep-Oct):75–87; doi: 10.1016/j.vascn.2016.03.004.

Rasmussen CE, Nowak J, Larsen JM, **Bottomley A**, Rowles A, Offenberg H. 2016. Evaluation of nonacog beta pegol long-term safety in the immune-deficient Rowett nude rat (Cro:NIH-Foxn1rnu). Toxicol Pathol 44(5):726–737; doi: 10.1177/0192623316633311.

Bottomley AL, Rowles A, Mitchell DJ, Rasmussen AD. 2015. Detection of mild and reversible neurohistopathological changes in the brain of juvenile (preweaned) beagle dogs treated with vigabatrin for up to 91 days. Toxicol Pathol 43(7):1015-24; doi: 10.1177/0192623315591838.

PRESENTATIONS

Bottomley A, Prior H, Cordes J. Global cross-company data-sharing on the housing of non-rodents during the recording of cardiovascular telemetry data on safety pharmacology and toxicology studies. Poster presented at Safety Pharmacology Society, Prague, September 2015.