Exponent®
Engineering & Scientific Consulting

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Professional Profile

Mr. James Noakes is a Managing Scientist in the Chemical Regulation and Food Safety Practice at Exponent.

A highly experienced toxicologist with particular expertise in running complex studies as Study Monitor and previously Study Director spanning over 30-years of experience for a very broad range of *in vivo* and *in vitro* study types, including designing bespoke investigative studies across Pharmaceutical, Agrochemical and Industrial sectors. Mr Noakes additionally has an in-depth specialism in Inhalation toxicology.

At Exponent, James is providing toxicological support for multiple projects including completion of regulatory dossiers, regulatory responses and data gap analyses. He is providing expert study monitoring support and facilitating discussion with international CROs in relation to contracting out of toxicology studies.

His consultancy experience prior to joining Exponent has additionally covered:

- Proposing and implementing a successful strategy for monitoring isolated adverse changes on a dog toxicity study, with clear termination criteria, to satisfy both the CRO and Sponsor company.
- Leading client meetings to manage multiple projects to ensure prioritisation of activities and engagement with key stakeholders.

Academic Credentials & Professional Honors

M.Sc., Applied Toxicology, University of Surrey, UK, 2007

B.Sc., Biology, University of Sussex, 1988

Prior Experience

Consultant Toxicologist, Regulatory Science Associates (RSA) (April 2020 – 2023)

Managed a variety of projects including the toxicology review and compilation of regulatory documents, including assessment of endocrine disruption. Monitored studies on behalf of client organisations at CROs at a number of global locations, advising on study design, reviewing study documentation, issue resolution, report reviews. Organised, participated in and contributed to weekly client project meetings.

Associate Principal Scientist, Study Monitor, AstraZeneca, Clinical Pharmacology and Safety Sciences, daVinci building, Melbourn, Hertfordshire (Jan 2016-Mar 2020).

Provided Study Monitoring support for general and reproductively toxicology studies across multiple therapeutic areas (respiratory, oncology, cardiovascular and renal) with small molecules and well as a range of new biological modalities including mRNA, ASO and proteins, in a range of different species including combined efficacy and safety and juvenile toxicity models. Latterly more specialised on support for inhalation studies placed at several global CROs.

Key representative at fortnightly Issues and Improvements meetings with a partner CRO facilitating best practice and the sharing and resolution of issues for the whole of the Study Monitor Group.

Responsibility for revising and maintaining the High-Level Study Designs guidance documentation, interacting with key stake holders to facilitate change and simplification

Study Director/Project Scientist, Dermal Technology Limited , Keele University Science and Business Park, Keele, Staffordshire, ST5 5NL (Dec 2012 – Dec 2015).

Study Director/Project scientist for in vitro dermal absorption studies, delivering high quality and fast-tracked reports for international regulatory submission within a specialised small CRO. Responsibility for coordinating and delivering multiple projects for two major global agrochemical clients.

Company COSHH and risk assessor. Company first aider.

Associate Principal Scientist, AstraZeneca, Global Safety Assessment, Alderley Park, Macclesfield, Cheshire (2007-2012).

Successfully led cross-function teams to deliver high-quality studies for multiple projects across all therapy areas, including designing bespoke investigatory studies. Study Director for internal studies and Study Monitor for CRO studies at several European laboratories, for a range of rodent and non-rodent studies, focusing specifically on inhalation study support.

Customer focused and ensured a high level of compliance with GLP and relevant regulatory test guidelines. Delivered a very high standard of scientific report writing and able to interpret the results from an extensive range of complex regulatory and investigative toxicity studies.

Substantial experience with single to repeat dose studies, in a wide variety of species, including primates, covering a range of administration routes: inhalation, gavage and intravenous (including surgically prepared infusion model). Extensive interaction with surgical technical group.

MHRA inspection support. Pro-active involvement in pre-inspection preparation, extensive support of the MHRA inspections, ensuring successful outcome and delivery of post inspection improvements.

Training and mentoring less experienced Study Directors, including support to discovery toxicologists.

Multidisciplinary Study Director, Syngenta Central Toxicology Laboratory, Alderley Park, Cheshire (1998-2007)

Delivered a very high standard of scientific report writing and able to interpret the results from an extensive range of complex regulatory and investigative toxicity studies.

Substantial experience with single to repeat dose studies, carcinogenicity studies including transgenic mice, in a variety of species (predominantly rodents and dogs), including juvenile animals, and covering a range of administration routes: inhalation (aerosols, dusts and vapours), gavage, diet, intravenous, intranasal, dermal, intraperitoneal, subcutaneous implants, minipumps.

HUNTINGDON LIFE SCIENCES LTD, Eye, Suffolk (currently part of Labcorp Group).

Study Director, Toxicology (1994-8), **Study Supervisor** (1990-3), **Trainee Study Supervisor** (1989).

Publications

Prior H, Noakes J, Slater I, Kelly S, Smith M, Marks L, Kimzey A, Roberts R & Valentin J-P (2012). Inclusion of Microchip Transponder Body Temperature Measurements in Rat Toxicology Studies. Society of Toxicology (SOT) meeting poster session presentation, San Francisco, USA.

Green, Trevor & Toghill, Alison & Lee, Robert & Waechter, Felix & Weber, Edgar & Noakes, James. (2005). "Thiamethoxam Induced Mouse Liver Tumors and Their Relevance to Humans: Part 1: Mode of Action Studies in the Mouse." Toxicological sciences: an official journal of the Society of Toxicology. 86. 36-47.

Green, Trevor & Toghill, Alison & Lee, Robert & Waechter, Felix & Weber, Edgar & Peffer, Richard & Noakes, James & Robinson, Mervyn. (2005). "Thiamethoxam induced mouse liver tumors and their relevance to humans. Part 2: Species differences in response." Toxicological sciences: an official journal of the Society of Toxicology. 86. 48-55.

Horner, Steve & Gould, Sarah & Noakes, James & Rattray, Niccola & Allen, Sandra & Zotova, Elena & Arezzo, Joseph. (2004). "Lack of neurotoxicity of the vascular targeting agent ZD6126 following repeated i.v. dosing in the rat." Molecular cancer therapeutics. 3. 783-91.

Project Experience

- Successfully manages a portfolio of projects across various stages in the product life cycle.
- Completed a data gap analysis for a widely utilised chemical (food ingredient) proposed as a plant protection product active ingredient to enable a client to make key decisions on the viability and funding required for the project.
- Lead a client Task Force team to develop strategy and deliver ahead of a renewal for a plant protection product, including endocrine disruption.
- Coordinated a team delivering a complex dossier compilation to meeting challenging timelines for delivery.
- Monitors a wide variety of toxicology studies for a number of client companies and organisations utilising a wealth of experience as both a Study Director and Study Monitor.