Curriculum Vitae

Last name, First name: **…Jones, David R** **Gender**: **…Male**

Nationality/ies: **…**

UK

Overall Scientific Expertise:

My current role principally involves assessing nonclinical data for Clinical Trial Applications, both non-biological and biological. A further aspect of my job is to offer regulatory advice to companies on behalf of the MHRA or the EU's Committee for Human Medicinal Products (CHMP). I am one of the UK's accredited non-clinical experts to support the CHMP and am the UK representative on the EU's Safety Working Party (SWP). I represented the EU in the ICH revision of the M3 Guideline and on the ICH S10 Guideline. I am now EU Rapporteur on the new ICH S11 (Nonclinical support for Paediatrics) guideline and the Q&A document for ICH S3 (Toxicokinetics). I work closely with the NC3Rs and represent the MHRA on a Governmental body dealing with animal welfare.

I am also a guest lecturer on courses held at the University of Surrey, the University of Wales, the University of Leicester, the University of Copenhagen and the University of Lisbon and a frequent presenter at conferences around the world.

Professional Experience

Years employed from – to	Title of position	Employer – name and location	Areas of professional specialisation♠
1996 to date	Expert PharmacoToxicologist	MHRA, London, UK	Pharmaceutical Toxicology
1985 to 1996	Toxicologist	Fisons, Loughborough, UK	Pharmaceutical Toxicology
1978 to 1985	Study Director	HRC, Cambridge, London	Toxicology

Educational Background

Year	Degree awarded	Educational Institution – name and location	Areas of educational specialisation*
1986	MSc	University of Hertfordshire, UK	Pharmacological Biochemistry
1977	BSc	University of Wales	Biochemistry

Memberships in Scientific Advisory Bodies/Committees/Panels *(if any)***:**
EU's Safety Working Party; British Toxicology Society Committee member.

Memberships in Learned Societies *(if any)***:**

British Toxicology Society, Society of Biology, TOPRA, Association of Inhalation Toxicologists, Toxicokinetics Discussion Group,

Memberships in Editorial Boards *(if any)***:**
Toxicology Reports, Frontiers in Medicine

List of Publications:

Exploiting microphysiological systems to transform safety assessment and drug metabolism within drug discovery and development (Co-Author due to be published 2017)

Preclinical imaging methods for assessing the safety and efficacy of regenerative medicine therapies (Co-Author due to be published 2017)

D R Jones. Looking to the future of organ-on-chip and toxicity assessment. Future Science, OA. 2016; 2(4)

J W van der Laan, P Kasper, B Silva Lima, D R Jones and M Pasanan. Critical analysis of carcinogenicity study outcomes. Relationship with pharmacological properties. (2016) Critical Reviews in Toxicology, DOI: 10.3109/10408444.2016.1163664

A Holmes, F Bonne and D R Jones Assessing drug safety in human tissues — what are the barriers? www.nature.com/reviews/drugdisc (2016)

Chapman K *et al* Waiving *in vivo* studies for monoclonal antibody biosimilar development: national acceptance, global challenges. MAbs. 2016;8(3):427-35. doi: 10.1080/19420862.2016.1145331.

J A Heslop *et al* Understanding the risks of stem cell-based therapies. Stem Cells Transl Med. 2015 Apr;4(4):389-400. doi: 10.5966/sctm.2014-0110. Epub 2015 Feb 26.

F Sewel *et al*. Recommendations from a global cross-company data sharing initiative on the incorporation of recovery phase animals in safety assessment studies to support first-in-human clinical trials Regul Toxicol Pharmacol. 2014 Oct;70(1):413-29. doi: 10.1016/j.yrtph.2014.07.018. Epub 2014 Jul 29.

A P Valeri, M Beharry and D R Jones. Strategic Regulatory Approaches for the Qualification of a Biomarker Assay for Safety Use. Bioanalysis (2013); 5(4): 411-414

J G Sathish *et al* Challenges and approaches for the development of safer immunomodulatory biologics. *Nature Reviews Drug Discovery* **12**, 306-324 (April 2013) | doi:10.1038/nrd3974

D R Jones *et al.* A regulatory perspective of clinical trial applications for biological products with particular emphasis on Advanced Therapy Medicinal Products (ATMPs). British Journal of Clinical
Pharmacology, 2012. DOI:10.1111/bcp.12057

M Ceridono *et al*. The 3T3 Neutral Red Uptake Phototoxicity Test: Practical Experience and Implications for Phototoxicity Testing - The Report of an ECVAM-EFPIA workshop. Regul Toxicol Pharmacol. 2012 Aug;63(3):480-8. doi: 10.1016/j.yrtph.2012.06.001. Epub 2012 Jun 9

P S Jones and D R Jones. New regulatory framework for cancer drug. Drug Discov Today. 2012 Mar;17(5-6):227-31. doi: 10.1016/j.drudis.2011.12.015. Epub 2011 Dec 22.

K Park *et al* Managing the challenge of chemically reactive metabolites in drug development. *Nature Reviews Drug Discovery* 10, 292-306 (April 2011) | doi:10.1038/nrd3408