

Medwise International Consultancy Limited

Consultancy services to Pharmaceutical, Biotechnology and Medical Device industries including:

- Non-clinical overview section of Common Technical Document for worldwide licensing of medicinal products (drugs)
- Pre-clinical testing requirements for medicinal products, medical devices and tissue engineered medical products
- Preparation of pre-clinical expert reviews and statements for medical products and their component materials and chemicals
- Preparation of responses to regulatory authorities on safety / toxicology / drug metabolism and pharmacokinetics questions
- Guidance on drug metabolism and pharmacokinetic studies including design, monitoring, reporting and interpretation
- Design, monitoring, reporting and interpretation of preclinical studies for medicinal products, medical devices and tissue engineered medical products
- Regulatory developments and advice on proposed use of animal or human tissues or derivatives in medical products
- Developments and guidance in the use of technical standards relating to risk management and biological safety of medical devices and tissue engineered medical products (national, EN and ISO standards)
- Developments and guidance in the use of ISO 10993: Biological evaluation of medical devices, parts 1-20
- Establishment of allowable limits of leachable substances in medical devices using ISO 10993-17: 2002
- Training courses and workshops tailored to your needs on any of the topics above and delivered at your site or chosen venue.

Contact:

Dr John C T Lang DABT
Managing Director
Medwise International Consultancy Limited
P.O. Box 17 Wilberfoss
York YO41 5YY
UK

Tel: +44 (0)1759-380273
Mob: +44 (0)7977-994157
Fax: +44 (0)1759-380865
Email: johnlang@medwise-international.com
Website: www.medwise-international.com

John C T Lang, BSc, PhD, DABT
European Registered Toxicologist

Senior Manager with over 25 years experience and achievements in pre-clinical R&D, medical surveillance and regulatory support. BSc Hons Biochemist with PhD in Medicine and Board Certified in Toxicology (American Board of Toxicology) for 23 years. Fourteen years technical, strategic and lobbying experience with Trade Associations and International Standards Bodies. An excellent communicator, seasoned professional, effective leader and organiser, analytical and strategic thinker who adds value to every client.

Medwise International Consultancy Limited 2003 – to present

➤ **Managing Director & Principal Consultant**

Case Examples:

- Non-clinical Overview for CTD for a Dermal Application Pharmaceutical Product completed to customer deadline and exceeding customer expectation (delight)
- Secured 12 month service contract with multinational company to provide update and guidance on ISO 10993 developments, use of human and animal tissues and derivatives in products / TSE risks etc.
- Preclinical overview of literature (28 page report) completed in 2 weeks for an enzyme for potential pharmaceutical applications
- Contract awarded from BSI, and completed to deadline, to prepare major revision of ISO 10993-1, Biological evaluation of medical devices: Evaluation and testing within a risk management process. Submitted for approval by ISO/TC 194 in Norway, June, 2004
- Appointed by UK MHRA, in May 2004, as Toxicology Assessor for Clinical Investigations of Medical Devices and appointed by a Notified Body as External Assessor in February 2005
- Ongoing contract with multinational company to provide product safety evaluation and regulatory support service
- Review report (26 pages) on Metabolism and Pharmacokinetics Issues for an Inhaled Drug for an emerging pharmaceutical company
- Safety assessments, regulatory guidance and strategic advice to 12 start-ups and SMEs from UK, Europe, South Africa and New Zealand
- Tailored training courses delivered in UK and Europe at seven sites including two US multinationals, a FTSE 100 company, a Regulatory Authority and a Notified Body
- Leader of the British delegation to the annual (week long) meetings of ISO/TC 194 (ISO 10993 and 22442 standards): Alexandria, 2003; Tromso 2004; Utrecht 2005; and Chicago 2006

Experience

Corporate Product Safety Assurance Manager, Smith & Nephew plc, for 11 years with responsibility for Group medical, regulatory and product safety issues. Provided key support for regulatory submissions, including preparation of Expert Reports for pharmaceutical products and participation in hearings at US FDA and Japan Ministry of Health and Welfare. An active member of a wide range of professional bodies (including Eucomed Human Tissue Products Group; Regulatory Affairs Professional Society' Human Tissue Products Group; Convenor of ISO/TC 194 WG14, Biological Evaluation of Medical Devices: Material Characterization; and has participated in lobbying of international political bodies (including the European Commission). Served two years on the European Pharmaceutical Industry' Drug Metabolism Discussion Group (DMDG) Committee.

Previously, Head of Experimental Biology, Smith & Nephew, for 5 years; Senior Research Scientist, Department of Biopharmaceutical Sciences and Drug Metabolism, Upjohn Ltd. 5 years; and 3 years as Senior Research Scientist, Inveresk Research International.