Lee Smith PhD

Director & Principal Consultant

Education

Ph.D. - School of Biology & Biochemistry, University of Bath, UK (1999) Protein Engineering of a monoclonal antibody.

B.Sc. (Hons) – 2(i) – Biotechnology, UWE Bristol, UK (1993)

1 year exchange scholarship, University of Cincinnati, USA (1992)

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About

Dr. Lee Smith, a principal consultant and director of GRA, has a passion for biotech & data driven results but above all, helping people and companies achieve their objectives and grow. He has been working in the biotech area for almost 30 years and has worked with large multinational organisations, small & medium sized enterprises (SMEs) as well as with virtual start-up biotech companies.

Skills & Impact

Product Development: Have worked in senior roles on a variety of investigational medicines for infectious disease, oncology and cardiovascular disease, including over 20 developmental vaccines. Have worked closely with clinicians in performing trials and manage multiple international CROs & CMOs. Strong network.

Technical Expertise: A 'hands-on' individuals with experience in biopharmaceutical sector including R&D, product development & characterisation, manufacturing & clinical development on both early and late-stage products.

Compliance: Experience of working in GxP, HACCP and ISO environments for both development and manufacturing to European,American and ASEAN standards.

Regulatory: Familiarity with FDA, EMA & MHRA regulations for medicines including dossier submissions, BLAs and regulatory interactions.

Training: Have performed training internationally on CMC related activities including process, formulation, analytical development and QbD for a variety of organisations

Corporate & Financial: Responsibility for budgeting, P&L and balance sheet. Management of board meetings. Have previously been responsible for over 80 staff. VC network.

Business Strategy: Review of revenue generation strategies to improving both the top and bottom lines through business development and operational adjustments. In licencing activities & supporting patent filings.

Project Management: Demonstrated ability to manage projects and programmes to ensure forward momentum and value addition. Managed collaborations and relationships with industry, academia, regulatory bodies and NGOs

Lee Smith

Director & Principal Consultant

Areas of Expertise

- Strategic Planning & Due Diligence
- Assay & Quality Control
- CMC & Manufacturing
- Preclinical, Non-Clinical & Toxicology
- CDMO Management
- Formulation Development & Stability
- QA, Auditing & Regulatory Affairs
- Clinical Development & Monitoring

Languages: English (Fluent)

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Experience

Principal Consultant & Director – GreyRigge Associates Ltd, United Kingdom 2010 - Current

Founded GreyRigge Associates Ltd. in 2010, providing consultancy services to the biopharm & biotech sectors, Contributing to over 20 vaccines, including COVID (Vaxzevria), Dengue (QDENGA), Influenza & Chikungunya. Supported large MNCs including Gates Foundation, Takeda Vaccines, Merck, Ipsen. Negotiated in-licensing technology (patent WO 2011 117579 A1) from Cambridge Enterprise Ltd and in-licensed monoclonal antibody from National Institute of Health (NIH).

Chief Executive Officer – Davos Life Science Pte Ltd, Singapore Nov 2008 to April 2010

Directly involved in product sales & marketing – increasing average sales from £15K to £125K p.m., Operational & fiscal responsibility incl. P&L, balance sheet & budgeting: overheads reduction by 20%, Managed Manufacturing, QA, RA, QC, R&D, Pre-clinical & Clinical Dev., Finance, Admin and HR Depts. Developed BOM for manufacturing of various product types to facilitate costs and price points.

VP, Product Development – SingVax Pte Ltd, Singapore December 2007 to Oct 2008, CMC Function Director – SingVax Sept 2006 to Nov 2007

Directly responsible for the product development of three vaccines: EV71, JE & Chikungunya, managing pre-clinical, process & manufacturing, quality (GxP), method development and clinical testing. Worked directly with CEO in the design and implementation of company strategy, budgeting and project plans and Target Product Profiles (TPP).

Director of Development – Emergent Biosolutions Ltd, United Kingdom July 2005 to Aug 2006, Programme Director – Microscience Ltd July 2004 – June 2005– Head of Analytical Development - Microscience Ltd May 2002 – June 2004

Biopharmaceutical Group Leader – GlaxoSmithKline Ltd, UK Oct 1997 to April 2002

Application Specialist (P/T) – Igen Inc. Oct 1996 to Sept 1997