Stephen Kirk

Senior Preclinical Consultant

Education

M.Sc – Biopharmaceutical Drug Development – University of Leeds, UK

contactus@greyrigge.com

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+44(0) 118 979 1169

About

A senior nonclinical development expert with over 30 years' experience supporting and leading global drug development programs. Specialist in toxicology, immunology, and regulatory strategy, with a strong track record of successful IND and CTA submissions. Experienced in guiding complex biologics and vaccine programmes from early research through to first-in-human clinical studies.

Skills & Impact

Nonclinical Development Strategy: Over 30 years as a Study Director, designing, implementing and interpreting non-clinical strategies and studies across a wide range of therapeutic modalities, including biologics, vaccines, and small molecules.

Good Laboratory Practice: With decades of compliance leadership, Steven has proved an ability to direct CROs, monitor study conduct, and maintain the highest standards of data integrity and regulatory readiness.

Immunotoxicology Expertise: Experienced SME in immunotoxicology, with significant to assay development and validation aligned with regulatory guidance (including ICH S8).

Regulatory Submission: extensive experience in leading and preparing regulatory submissions across IND,CTA, IB, ODD, PSP/PSP and more.

Project Management: Experienced in leading multidisciplinary teams and collaborating across research, clinical, and CMC functions. Adept at integrating diverse data streams into cohesive development narratives, supporting informed decision-making at project and portfolio level.

Biopharmaceutical & Vaccine Development: Specialist experience in the development of immunomodulators, biopharmaceuticals, and vaccines, including first-in-human programmes. Successfully contributed to the advancement of innovative therapies through early and late-stage development, with a strong focus on translating complex science into viable clinical strategies.

Stephen Kirk

Senior Preclinical 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

Stephen Kirk Nonclinical Drug Development Services
Consultant / Director
Dec 2025 – Present

Scendea
Principal Consultant
Sep 2023 – Dec 2025
Lead on regulatory submissions on behalf of clients, including IND, CTA, IB, ODD and PIP/PSP. Review of Non-clinical protocols, study reports, and CRO selection as part of early-stage drug development strategy. Preparation of Drug development plans, gap analyses, and regulatory strategies.

Allergy Therapeutics
Head of Nonclinical Science
Apr 2022 – Sep 2023
Successful IND submission for first-in-human trials for novel therapeutic vaccine for peanut allergy.

KalVista Pharmaceuticals
Senior Manager, Toxicology
Aug 2019 – Mar 2022
Designed and implemented nonclinical safety study packages, supporting lead candidates across development stages in Phase 1 and 2 trials. Managed relations with FDA, and provided regulatory documentation across CTD, IND, CTA, IB and more.

Covance/Labcorp
Study Director and Principal Investigator
Aug 2009 – Aug 2019
SME with an overarching view of all aspects of acquisition, analysis, reporting and interpretation of immunotoxicology data from repeat dose studies, biodistribution research, PK, PD and TK studies. Designed, implemented, and interpreted non-clinical safety studies, ensuring compliance with FDA and OECD GLP guidelines.

Aptuit Ltd
Study Director, Toxicology
Aug 2006 – Aug 2009

Charles River
Study Director, Immunotoxicology
Aug 2006 – Aug 2009