

KATHRYN LEE BSc BA PhD MICR

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PROFILE

Results-focused clinical research professional having held positions as a Clinical Research Associate, Project Manager and Compliance Manager working on phase II through IV clinical trials in a range of therapeutic areas within both CRO and global pharmaceutical company environments. Experienced in supervising both remote and in-house teams. A creative team leader, effectively motivating others to success, with excellent problem solving and communication skills.

CAREER

VENTRIX CONSULTING SERVICES LTD, *Principal Consultant*

SEP 2006 – present

Assignments: BIOGEN IDEC, Maidenhead, UK

Manager, Clinical Compliance (Mar 2008 – present)

- Providing GCP advice and compliance support to Clinical Operations; supporting R&D audits and regulatory inspections; using clinical trial and project management expertise to provide input into SOP review and process improvement programs.

Senior Clinical Trials Manager (Sep 2006 – Feb 2008)

- Project Management of a global phase 2 trial of a monoclonal antibody in relapsed Chronic Lymphocytic Leukaemia; responsible for study set-up and conduct ex-US including CRO management. Exceeded corporate First Patient In goal for ROW by one month.
- Led recruitment activities for the Oncology SBU whilst an Operations Manager was appointed; actively coached less experienced staff.

PAREXEL INTERNATIONAL, Uxbridge, UK

2004 – 2006

Senior Project Manager

- Project Management of late phase trials including an Oncology Expanded Access Programme and phase 3b/4 studies in osteoporosis and multiple sclerosis.
- Responsible for client liaison, leading and motivating a cross-functional team, project assessment and implementation, study budget management (revenue recognition & forecasts, client invoicing), resource planning and quality / timeline deliverables.
- Coaching / supervision of Associate Project Managers (APM) and new Project Managers.

WYETH, Taplow, Maidenhead, UK

2000 – 2004

Senior Clinical Project Manager, Wyeth Vaccines Research (2001 – Sep 2004)

- European Programme Manager for a new influenza vaccine consisting a programme of 10 paediatric and adult studies in the EU, Eastern Europe, Israel, South Africa and Asia. This was part of a larger global programme and involved working closely with US colleagues.
- Supervised 5-7 Clinical Project Managers (CPM) based in UK and Belgium. Ensured consistency across the clinical trial programme through study document review, team meetings and liaison with US counterparts.
- Member of Global Process Development Teams and SOP Development Working Groups contributing to a major process re-engineering project.

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- Contracted in a team of QC experts to conduct a review of study documentation for all studies in the programme as part of preparation for an EMEA / FDA inspection. This involved working closely with facilities, IS and HR to ensure adequate office space, computers etc in addition to line management / supervision responsibilities.

Clinical Project Manager, Wyeth Vaccines Research (2000 – 2001)

- Project Management of a phase 3, influenza vaccine trial which successfully recruited 1750 healthy paediatric subjects attending daycare within 6 weeks in four European countries and Israel.
- Selected and managed CRO and affiliate monitoring groups. Developed protocols, case report forms and study-specific manuals for multiple studies in the influenza vaccine programme; liaised with colleagues in the USA and Europe to ensure adequate support from other functional groups.

ClinTrials Research Ltd, Maidenhead, UK

1996 – 2000

Senior Clinical Research Associate (1999 – 2000)

Clinical Research Associate II (1998 – 1999)

Clinical Research Associate I (1996 - 1998)

- Lead CRA for a pan-European, phase 3 dermatology study.
- CRA / Lead CRA: Study set-up and monitoring of 3 UK hospital sites for a phase 2 blood substitute / high risk surgery study.
- CRA: Study set-up and monitoring of 2 hospital UK sites for a phase 2 oncology study (prostate and renal cell carcinomas); 3 UK hospital sites for a phase 2 hepatitis study; 5 UK hospital sites for a large global, phase 3, stroke study. Feasibility and qualification for a large phase 3 GP UTI study.
- Contributed to Clinical Monitoring Department activities: Interviewed prospective employees. Advised project teams / less experienced CRAs. Conducted co-monitoring training visits. Conducted feasibility studies and participated in proposal presentations to potential clients.

Dept. Molecular Pharmacology, University of Manchester

1995 - 1996

Post-doctoral Fellow

Institute of Cancer Research, Royal Marsden Hospital, London

1993 - 1995

Post-doctoral Scientist

Institute for Cancer Studies, Royal Hallamshire Hospital, Sheffield

1989 - 1993

Research Assistant (PhD research)

QUALIFICATIONS & PROFESSIONAL AFFILIATIONS

BSc (Hons) 1st Class

Life Sciences, University of Westminster (1989)

PhD

Molecular Biology / Oncology, University of Sheffield (1993)

BA (Hons)(Open) 1st Class

History, Open University (2000)

Institute of Clinical Research

MICR (2005). Full Member since 1996.

PERSONAL

Date of Birth: 19 October 1967

Interests: Cycling, skiing, family history, classical history & classical languages, gardening.