

Professional Biography

Graeme Ladds
PharSafer[®] Associates Ltd
29 Frederick Sanger Road
Guilford
Surrey
GU2 7YD

Contact Details:

Phone & Fax: +44 (0) 1483 685921

Mobile 07887 842935

e-mail: graemeladds@pharsafer.com

Professional Qualifications

Degree in Biochemistry & Pharmacology { B.Sc.(Hons) 2.1} 1977- 1981

PhD Influence of Cytochrome p450 systems on drug metabolism in pathophysiological disease states 1981 – 1984

Positions held

Head of Drug Safety & Medical Information Ashbourne Pharmaceuticals 1990 – 1999

Head of International Pharmacovigilance Shire Pharmaceuticals 1999 - 2003

PharSafer Associates Ltd 2003 –

Saphar Ltd 2003 -

Work Related Experience Pharmacovigilance experience 1990 – present date

SOP Writing	1993 - present date
GMP Procedures review	1995 – present date
Drug Safety system training	1996 – present date
Presentations on Safety (International)	1996 – present date
Product due diligence	1997 – present date
CRF design templates	1997 – present date
Pharmacovigilance Auditing	1997 – present date
GCP Auditing	1998 – present date
PSUR Writing	1998 – present date
EU QP PV Status	1998 – present date
Clinical Expert report writing	1998 – present date
International Protocol reviews	1998 – present date
Investigator Brochure reviews	1998 – present date
Auditing of Phase I units	1999 – present date
PSUR writing	1999 – present date
Training in MedDRA	1999 – present date
Auditing of CROs	1999 – present date
Due diligence Audits (Companies)	1999 – present date
Training in Pharmacovigilance	1999 – present date
Drug Safety system designs & development	2000 – present date
International Investigator presentations	2000 – present date
International Safety submissions (licence applications)	2001 – present date
Global Safety System deployment (Relsys, Argus)	2001 - 2002
Advisory Board IIR Safety Conferences	2002 – present date
Company Specific Pharmacovigilance Training	2003 – present date
Speaker at Univ. Hert. Post Grad PhV Course	2003 – present date
Medical Information System Designs	2003 – present date
Training Company (SaPhar Ltd) for PhV	2003 – present date
Multiple Safety system decision making & deployments	2003 – present date
Safety Database validation determinations	2003 – present date
Training for and appointment as contract EU QP for PV	2004 – present date
Pharmacovigilance Planning submissions	2005 – present date
Risk Management & Minimisation programmes	2005 – present date
e-learning courses for Pharmacovigilance (in prep.)	2006 – present date

Professional Associations

AIOPI (PIPA)– Association of Information Officers in the Pharmaceutical Industry 1996
SIGAR – Special Interest Group on Adverse Reactions 1996
DIA – Drug Information Association 1998 (SIAC Member)
ESRA – European Society of Regulatory Affairs 2000
ISOP – International Society of Pharmacoepidemiology 2002
ICR – Institute of Clinical Research 2003
BARQA - 2006

Published articles

Multiple published articles in PIPA; AIOPI; Journal of Biotechnology; PV Review
Editorial staff for Multinational PV Journal (PV Review) Jan 2006

Published Book

A Guide to Global Pharmacovigilance – A 10-part book on Global Clinical and Post-Marketing Pharmacovigilance June 2006

Last 6 months

Current Projects have involved Database selection and implementation (Global and National); MHRA Inspection Corrective Action Plans for Multinational Company; MHRA Preparation for Inspection; full Pharmacovigilance Service Provider; CCSI Development; GCP Inspection; Auditing;