Dr Menno van der Elst

Dr Menno van der Elst is the alternate PRAC member for the Netherlands. With a background as community pharmacist, he joined the Medicines Evaluation Board almost 10 years ago. Since then Menno has a special interest in PSURs and their assessment. First, as member of the former PSUR worksharing WP, and currently through his involvement in the PSUR roadmap project, the Granularity and Periodicity advisory Group (GPAG) that advises PRAC on changes to the EURD list and as an active member in the CMDh's Pharmacovigilance Procedure Worksharing Working Party.

Dr Craig Hartford

Dr Craig Hartford (MB BCh, MSc Med, PhD) is Vice President, Head of Safety Surveillance and Risk Management in worldwide Research & Development for Pfizer's established products, monitoring a portfolio of over 600 products including innovator products, biosimilars and generics. Dr Craig Hartford has extensive experience in major pharmaceutical company Pharmacovigilance and Medicines Benefit-Risk Management, and prior external experience as a Clinical Investigator for several major Pharmaceutical Companies plus direct clinical experience within underprivileged communities.

Dr Val Simmons

Dr Val Simmons (MB, BS, FFPM) is the European Qualified Person for Pharmacovigilance (QPPV) at Eli Lilly and Company Limited. Val is a registered physician from the University of London and specialised in Anaesthesia and Intensive Care Medicine. She joined the pharmaceutical industry in 1987, as a Medical Advisor for Janssen Pharmaceuticals Limited and, since 1991, has subsequently pursued a career in drug safety through senior management positions in Glaxo and Eli Lilly.

Val's intense passion for the field of pharmacovigilance and patient safety is reflected in her active involvement in various external committees and academic bodies including the EFPIA Pharmacovigilance Committee, and CIOMS VII and IX Expert Working Groups. She has acted as EFPIA Topic Leader on various ICH Expert Working Groups including ICH E2D, E2F (DSUR) and E2C(R2) (PBRER). More recently, Val was appointed Rapporteur for the ICH E2C (R2) Implementation Working Group that developed the supporting Q& A for the PBRER and which was finalised in 2014.

Dr Ulla Wändel Liminga

Ulla Wändel Liminga is a pharmacist and has a Doctoral thesis in Medical Sciences from Uppsala University in Sweden. In 1994, she started at the Medical Products Agency (MPA), Sweden, as a non-clinical assessor. She has since then worked with non-clinical as well as clinical efficacy and safety assessments. In 2007, she became scientific director of pharmacology and toxicology at the MPA and has from July 2012 been one of the Swedish members of the PRAC.

Dr Klaudija Marijanovic Barac

Safety physician with 15-year experience in pharmacovigilance and risk management, Klaudija, Director at Teva Periodic reports and risk management Centre (TPC) (MD), is head of unit responsible for preparation of periodic reports for EU and other regions, and development of risk management strategies for innovative and generic products worldwide. She received her MD degree from University of Zagreb, and postgraduate diploma in Pharmaceutical Medicine and Pharmacoepidemiology from Free University of Brussels. She is member of Pharmacovigilance Working Party in Medicines for Europe organization.

Dr David Lewis

Dr Dave Lewis joined Novartis in March 2007 following 20 years' pharmacovigilance at GSK and at Shire Pharmaceuticals. He was appointed EU QPPV at Novartis Pharma AG from April 2009 then moved to Global Head of Pharmacovigilance Systems and Data Management, followed by Global Head of Pharmacovigilance in February 2011. He was confirmed as Global Head of Pharmacovigilance (including vigilance for medical devices) for Novartis Patient Safety in June 2016. Dr Lewis has worked in country affiliates and in a variety of global safety & risk management functions with both investigational & marketed products, as well as in roles concerned with systems and processes. Dr Lewis is the author of papers on the safety of medicines as well as research papers on neuropharmacology. He has a number of academic links, including being named Visiting Senior Fellow, Faculty of Health and Human Sciences, University of Hertfordshire. Dr Lewis is Project Coordinator for the WEB-RADR consortium (@ http://www.web-radr.eu).

Dr Michael Richardson

Michael has worked in major multinational companies' across the globe both at a Regional management level and heading up Research and Development in Asia. Currently, Michael is International Head of Bristol Myers Squibb's Pharmacovigilance Function and EU QPPV. Prior to this role he headed BMS and Eli Lilly's Development and Medical Organisation across Asia Pacific. He also has experience in Japan heading Fujisawa Fisons Development and quality control organisations.

Michael practised in O&G and clinical research. He has been involved in Pharmacovigilance for the past 10 years on external committees including the EFPIA Pharmacovigilance Committee, and represented EFPIA on the ICH Expert Working Groups E2C(R2) (PBRER) and the ICH E2C (R2) Implementation Working Group that developed the supporting Q&A for the PBRER.

Dr Kora Doorduyn-van der Stoep

Dr Kora Doorduyn-van der Stoep (Pharm D, MSc in Pharmacy) has held various positions in regulatory and management at the Medicines Evaluation Board (MEB) in the Netherlands for more than 30 years and is a CMDh member/Senior Policy Adviser since 2009. Kora is also a member of several CMDh working parties for issues related to the Pharmacovigilance legislation (RMPs/PSURs/PSUSA) and variations. She has a very broad experience in coordinating/assessing national and European (Mutual Recognition/Decentralised/Centralised procedures) procedures.

Kora has coordinated/assessed a large number of procedures in the role as Concerned Member State/Reference Member State and/or rapporteur. From 2002 -2007 Kora has been managing both regulatory project leaders and clinical assessors in a Pharmacotherapeutic group. In this position she was also responsible for processing/scheduling all registration procedures within this Pharmaco-therapeutic group.