

PERSONAL INFORMATION

Olimpia Neagu

WORK EXPERIENCE

January 2010–Present

Senior Clinical and Pharmacokinetic Assessor at European Procedures Department

National Agency for Medicines and Medical Devices (Romania)

- Clinical assessment for to grant European Marketing Authorization by decentralized, mutual recognition, repeat-use applications for new medicinal products which include the pharmacokinetics and bioequivalence assessment and efficacy and clinical safety data respectively
- Clinical assessment for approval the clinical variations to existing licensed medicinal
- Clinical assessment for obtain scientific opinion required of National of the Medical Devices
- COMP member from Romania at European Medicines Agency since March 2016

November 2009–January 2010

Head of Medical Service

National Agency for Medicines and Medical Devices (Romania)

- Coordination of the assessment activity of non-clinical safety, efficacy and clinical safety and also the clinical protocol for approval the clinical trials performed in Romania
- Assessment of clinical dossier for approval a new therapeutic indication.

May 2003–November 2009

Head of Efficacy Evaluation Service

National Medicines Agency (Romania)

Coordination of the following issues:

- Assessment of the clinical documentation received from the applicant in order to grant the Marketing Authorization.
- Assessment of the clinical protocol for approval the bioequivalence studies performed in Romania.
- Assessment of clinical dossier for approval a new therapeutic indication.
- Participation in NMA Scientific Committee when have approved the clinical national regulations in accordance with European legislation.

June 2003–June 2010

Efficacy Working Group Member

National Medicines Agency (Romania)

Representation at EWP of CHMP the Romanian Agency position.

January 1999–June 2003

Medical Doctor

National Medicines Agency (Romania)

- Assessment of the non-clinical and clinical part of the Marketing Authorization Application

November 1995–January 1999

Medical Doctor

Ionescu-Stoian Sate Institute for Drug Control (Romania)

- Assessment of the non-clinical and clinical part of Marketing Authorization Application.
- Pharmacological and toxicological control of chemical substances - animal testing

EDUCATION AND TRAINING

January 2003–December 2008

PhD in Medicine Science (Clinical Pharmacology)

University of Medicine and Pharmacy (Romania)

October 2006–June 2008 **Master of Science in Biostatistics-medical field**
University of Bucharest - Faculty of Mathematics and Computer Science (Romania)
(Romania)

May 2008– **Senior Family Medicine Physician**
Universitary Center from Bucharest (Romania)

January 2001–May 2003 **Specialist Family Medicine Physician**
University of Medicine and Pharmacy (Romania)

September 1981–September 1987 **Medical Doctor Degre (BA)**
University of Medicine and Pharmacy (Romania)

ADDITIONAL INFORMATION

Expertise Clinical Pharmacology
Pharmacokinetics
Bioequivalence/Bioavailability
Pharmacological and Toxicological Control Testing
Regulatory Affairs

Publications

Projects

Memberships Member of the National College of Physicians of Romania

Other Relevant Information