



PROF. PIETER NEELS

CURRICULUM VITAE

Personal details

Name: Pieter Neels
Education: MD
Vaccines Expert

Professional experience

Current position:

- Member, NDA Advisory Board
- Associate Professor for Vaccinology at the University of Namur, Belgium
- Independent consultant , Vaccine-Advice BVBA, Belgium

Previous positions:

- 1997 – 2013: Engaged by the Belgian Competent Authorities for registration of Medicinal Products. First “General Inspectorate for Pharmaceuticals” later transferred to the new Federal Agency for Medicinal and Health Products (FAMHP; FAGG; AFMPS)
- 1994 - 1997: Medical Director pharmaceutical industry: Byk Belga (Altana)
- 1992– 1994: Freelance medical expert of the Ministry of Public health
- 1986 – 1994: General Practitioner

Area of Expertise

- Clinical background in general medicine with a special interest and in-depth knowledge of vaccines
- Detailed knowledge of the European approval system including European Medicines Agency (EMA).
- Clinical documentation requirements to support European Clinical Trial Applications (CTA) and Marketing Authorisation Applications (MAA)
- Design of clinical development plans: Scientific and strategic aspects

Scientific regulatory speciality

Vaccines, Cardiology, Nephrology, Diabetes, Psychiatry, Clinical pharmacology,

Major projects

As Regulator:

- 1997 – 2013: Clinical Assessor involved in the evaluation of registration of new medicinal products in many different areas such as cardiology, nephrology, diabetes, psychiatry and vaccinology at the European and national level
- 1997 – 2013: Clinical Assessor involved in the evaluation of scientific advice both at the European and national level
- 2001 – 2013: CPMP/CHMP Member, EMA
- 2003 – 2013: WHO EU vaccine expert, Temporary advisor for WHO, facilitator and presenter at many WHO meetings on vaccines (AVAREF/DCVRN/Ad Hoc meetings)
- 2003 – 2008: Observer of EMA/CHMP Vaccine Working Party
- 2008 – 2013: Vice-Chair of EMA/CHMP Vaccine Working Party
- 2008 – 2013: EMA/CHMP observer at WHO SAGE meetings
- 2007- 2013: Vaccine - coordinator at the Belgian Federal Agency for Medicinal Products
- 2010 – 2011: WHO appointed member of the Immunization Practices Advisory Committee (IPAC)

In Industry:

- 1994 – 1997: Medical monitor of clinical studies in gastroenterology, oncological haematology and pneumology

As Consultant

- 2013 – now: WHO EU vaccine expert, Temporary advisor for WHO

Associations

Board Member of (International Alliance for Biological Standardisation) IABS - EU

Publications

Publications and conference presentations on aspects of Regulatory and clinical aspects during development and assessment of Vaccines.

The complete list can be provided upon request.