

PERSONAL INFORMATION **Cornelia Nopitsch-Mai**WORK EXPERIENCE

July 1991- Present **Senior Quality Assessor**

BfArM (Germany)

- Evaluation of marketing authorisation applications like national, mutual recognition, centralised and decentralised procedure including variations and renewals; ASMFs- Synthetic and semi-synthetic drugs particularly in the field of anaesthesiology, algesciology, rheumatology/ and pneumology,
- Immediate and modified release dosage forms (tablets, capsule); parenteralia; inhalander

October 1999- Present **Chemical Expert**

EDQM (France)

Certification of dossiers submitted for the Certification of Suitability to monographs of the European Pharmacopeia (Chemical evaluation)

March 2001-July 2010 **Member of Technical Advisory Board (TAB)**

EDQM (France)

August 2005-March 2010 **Chairperson of TAB of EDQM**

EDQM (France)

November 2007-January 2012 **Member of QWP**

EMA (United Kingdom)

July 2013- Present **Member of Inhalander Working Party**

EMA (France)

EDUCATION AND TRAINING

October 1979-August 1983 **Third State Examination for Pharmacy**

Freie Universität Berlin (Germany)

August 1984-March 1990 **Dr. rer. nat. in Pharmaceutical Biology (equivalent to PhD)**

Freie Universität Berlin (Germany)

ADDITIONAL INFORMATION

Expertise Centralised Procedures (Rapp/CoRapp):

- Thalidomide
- Relistor
- Trimbow

DCP (RMS):

Synthetic and semi-synthetic drugs in particularly in the field of anaesthesiology, algesciology, rheumatology/ and pneumology

Scientific Advice:

- Oxycodone
- Morphine

- Paracetamol
- Tapentadol
- Formoterole
- Beclometasone

Publications S. Belz, U. Wippo, C. Nopitsch-Mai
Anforderungen an Referenzstandards chemisch definierter Substanzen aus regulatorischer Sicht
Pharm. Ind. 72 (12) 2037 - 2043 (2010)
Nopitsch-Mai, C.; Nachtsheim, C.; Wippo, U.
Regulatorischer Umgang mit genotoxischen Verunreinigungen
Pharm. Ind. 75, Nr. 1, 56 - 62 (2013)
Pharm. Ind. 75, Nr. 2, 218 - 222 (2013)
A guide to the EU variation procedure from a quality viewpoint
Regulatory Rapporteur - Vol 12, No 4, April 2015
Nopitsch-Mai, Cornelia; Winterscheid, Susanne
Patient Focus and Regulatory Considerations for Inhalation Device Design: Report from the 2015
IPAC-RS/ISAM Workshop
Journal of Aerosol Medicine and Pulmonary Drug Delivery

Projects CSA PerMed, Project regarding personalised medicine in cooperation with Federal Ministry of
Education and Research, Germany
Drafting Group for Evaluation of OIP Guideline

Memberships Member of Planta medica (Society in the Field of Phytochemistry)

Other Relevant Information