

Curriculum Vitae

Personal information **Maryam Mehmandoust**

Work experience

1. Employer: ANSM
 - Start date: 102012
 - End date: present
 - Position: Senior Quality assessor and Reference person for quality aspects of medicinal products of chemical origin.
 - Activities: In charge of harmonisation and peer review of assessments, tutoring of junior assessors, moderator of the pharmaceutical board in 2018-2019 and then since Dec 2021, elaboration of internal policies for assessment of dossiers Module 3/quality part. Assessment of quality section of clinical trials (IMPDs), scientific advices, quality defaults. Expert assessor to the EDQM Certification scheme
 - Country: France
2. Employer: AFSSAPS
 - Start date: 021999 then 112009
 - End date: 022007 then 092012
 - Position: Quality assessor
 - Activities: _ assessment of quality part of MAA and MAV within national and EU procedures, ASMFs, Clinical trials. Expert assessor to the EDQM Certification scheme
 - Country: France
3. Employer: World Health Organisation
 - Start date: 022007
 - End date: 112009
 - Position: Technical Officer within WHO Prequalification medicine programme
 - Activities: Assessment of API Master Files, implementation of the APIMF procedure within the programme, organisation of assessment sessions with external experts, review of assessment reports for sake of harmonisation and quality assurance, communication with manufacturers regarding dossier submissions, training of national authorities on regulation of medicines (WHO Member States)
 - Country: Switzerland

Education and training

1. Organisation: Paris XI University, Orsay
 - Start date: 091985
 - End date: 091989
 - Qualification: PhD in Organic Chemistry
 - Subject: asymmetric synthesis of heterocycles
 - Country: France
2. Organisation: Paris XI University, Faculté de Pharmacie de Chatenay Malabry
 - Start date: 091995
 - End date: 091996
 - Qualification: Master in pharmaceutical regulatory affairs
 - Subject: Requirements for development and international registration of medicines
 - Country: France

Additional information

Publications

M. Mehmandoust, Synthèse de dihydro-1,2 pyridines et d'équivalents de sels de dihydro-2,5 pyridinium chiraux. Application à la synthèse stéréosélective d'isoquinuclidines et de pipéridines 2-substituées, optiquement actives. **PhD thesis**, Université Paris XI, centre d'Orsay, France, September 1989.

10 publications in the field of organic chemistry when I was in research laboratory.

Projects

Memberships

- QWP member (end 2013-present), QWP Core Team member (May 2020-June 2023)
- ICH M7 (R2) EWG quality member from EC and M7(R3) Maintenance
- ASMF WG member (2010-present)
- EDQM Certification Technical Advisory Board (TAB) member (from 2010 to 2019), EDQM Certification INSP ad hoc committee member

Other Relevant Information

Field of expertise

- Organic chemistry, asymmetric synthesis
- Manufacture, characterisation and impurities of small molecules used as active substance obtained from chemical synthesis, semi-synthesis, extraction and/or fermentation including peptides and oligonucleotides, novel excipients
- CMC assessment including control strategy and stability of active substances and drug products
- Excellent knowledge of EU regulatory framework for pharmaceutical products (of chemical origin) including variations, regulatory procedures for active substances (ASMFs and CEPs)

