EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

Personal information

Roxane Fornacciari

Work experience

1. Employer: ANSM
   - Start date: 052000
   - End date: 042001
   - Position: INTERNSHIP AT THE ANSM
   - Activities:

Assessment of the clinical aspects of MAA and therapeutic applications (line extensions, new indications), within the framework of the European and national registration procedures, writing assessment reports and/or comments (in English for European procedures), reassessment of the benefit to risk ratio of "old" products still on market, participation to scientific advice meetings on clinical development programs, management of working groups in collaboration with experts.

Internal scientific collaboration with colleagues specialized in methodology of the clinical studies, interactions with other medicinal products, fertility, pregnancy and lactation, preclinical aspects as well as collaboration with public health authorities, other health authorities or pharmaceutical companies.

   - Country: France

Education and training

1. Subject: ANSM
   - Start date: 052001
   - End date:
   - Qualification: clinical assessor
   - Organisation: From Sept 2017 ANSM Clinical assessor _ NEUROLOGY Main allocated domain: alcohol dependence, familial amyloid polyneuropathy, Charcot_Marie_Tooth disease, Friedreich's ataxia, mitochondrial cytopathies, leukodystrophy, centro_nuclear myopathy epilepsy. 2012 to 2017 ANSM Clinical assessor _ GENERICS Scientific and regulatory assessment of marketing authorization applications (MAA) and variations for generic products, initial assessment of risk management plans, similarity and market exclusivity assessment in all therapeutic areas for generics compared to brand leaders. 2001 à 2012 AFSSAPS Clinical assessor – CARDIOLOGY _ INFECTIOLOGY _ GASTROENTEROLOGY Assessment of the clinical aspects of MAA and therapeutic applications (line extensions, new indications), within the framework of the European and national registration procedures, writing assessment reports and/or comments (in English for European procedures), reassessment of the benefit to risk ratio of "old" products still on market, participation to scientific advice meetings on clinical development programs, management of working groups in collaboration with experts. Internal scientific collaboration with colleagues specialized in methodology of the clinical studies, interactions with other medicinal products, fertility, pregnancy and lactation, preclinical aspects as well as collaboration with public health authorities, other health authorities or pharmaceutical companies.
   - Country: France

Additional information

Publications

Projects

Memberships

Other Relevant Information