EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

Personal information

Caroline Auriche-Benichou

Work experience

1. Employer: AFSSaPS
   - Start date: 111996
   - End date: 032010
   - Position: Clinical Assessor
   - Activities: Assessment of the Benefit/risk ratio (Marketing Authorisation dossiers). • Assessment of MA new demands or variations / national or EU procedures • Management of Working groups (ad hoc group « Orphan drugs » _ Immunology _ haematology _ Imaging –Thrombosis – Lipides _ Cardiology _ Diabetology _ Metabolism _ Metabolic rares inherited diseases _ Hepatology and Gastro_enterology _ diagnostic agents). Relationships with external experts / Management of conflicts of interest. • Assessment of clinical trials, cohorts "ATU", Risk Management Plans, PIP, Specific Missions : • Implementation /coordination internal workshops : Clinical trials in small populations, • Links between AFSSAPS and Health Ministry, other national agencies, EMEA, member of ANAES workgroups
   - Country: France
2. Employer: AFSSaPS then ANSM
   - Start date: 032010
   - End date:
   - Position: Head of scientific advices
   - Activities: Development plans/Protocol assistance/ absence of relevant guidelines National level • Part of support of innovation; Focus on SME, innovative drugs, unmet medical need (advanced therapies, rare diseases, internal medicine, immune disorders, borderline drug/medical devices..); 4 to 6 per month • Quality/efficacy/safety, non clinical, PK, PD, methodology and statistics. • Project mode (innovation referent, innovative projects carriers, internal experts, external • Resp. processes, business indicators Member of the Interface Committee with Pharmaceutical Industry/subgroup Innovation European level : delegate at the Scientific advice Working party, specially devoted to rare diseases (rare neurological and neuro_muscular diseases, inherited metabolic diseases, etc.), vaccines, immunology and auto_immune diseases, diagnostic agents
   - Country: France
3. Employer: FDM_PHARMA PARIS _FRANCE
   - Start date: 011996
   - End date: 101996
   - Position: Clinical Project Manager
   - Activities: Promotor for a foreign company, conception of the development plan_ design of phase II studies_ Project Management, production of scientific/regulatory documentation
   - Country: France
4. Employer: Henri Beaufour Institute_ Beaufour_Ipsen Group
   - Start date: 091990
   - End date: 121995
   - Position: Responible for Development Coordination
   - Activities: 1. Development coordination ☐ Implementation of development plans, Matching regulatory frame ☐ Participation into working_out of development budgets ☐ Links with the "in and out_licensing" 2. In charge of S.O.P.s
   - Country: France
5. Employer: AFSSaPS
   - Start date: 112007
   - End date: 032010
   - Position: Project manager MA dematerialisation processes
   - Activities: • Electronic submission _ document management system _ workflow☐ proposed for the « prix du Manager public de l'année 2009" • Interface : users/companies_LeEM/ other EU national agencies /EMA/IT /steering committees • CCTP /General and detailed specifications of processes/up to production/training
   - Country: France
6. Employer: Assistance publique hôpitaux de Paris
   - Start date: 111985
   - End date: 062013
   - Position: Biologist practionner
   - Activities: Biochemistry haematology (coagulation and cytology)
   - Country: France

Education and training

1. Subject: University of medical Studies PARIS-EST CRETEIL:
   - start date Nov 2021
   - En date set 2022
   - Qualification: master degree 2 in gene therapy, cell therapy and immune therapy
   - Country: France
2. Subject: Faculty of medicine PARIS VI Pierre et Marie Curie
   - Start date: 091991
   - End date: 061992
   - Qualification: Certificate of statistics applied to clinical investigations

- Organisation: Methodology Statistics Clinical trials Epidemiology
- Country: France

3. Subject: Faculty of medicine PARIS VI Pierre et Marie Curie
   - Start date: 091989
   - End date: 061990
   - Qualification: BS in molecular and cellular biology (metabolism/immunology/inflammation).
   - Organisation: Molecular and cellular biology Inflammatory and metabolism disease : obesity and T2DM, lipidse and atherosclerosis, allergy and inflammation
   - Country: France
4. Subject: Faculty of medicine PARIS VI Pierre et Marie Curie
   - Start date: 091988
   - End date: 061989
   - Qualification: Master in molecular and cellular biology.
   - Organisation: Cellular biology Molecular biology
   - Country: France
5. Subject: Faculty PARIS V René Descartes
   - Start date: 091985
   - End date: 061986
   - Qualification: Cerificate of haematology
   - Organisation: High degree in haematology (coagulation, cytology, anemias, haemato_cancerology)
   - Country: France
6. Subject: Faculty of Pharmacy PARIS V René Descartes
   - Start date: 091979
   - End date: 061984
   - Qualification: Doctor of Pharmacy (Pharm. D)=
   - Organisation: Pharmacist and biologist
   - Country: France

Additional information

Publications

Auriche C., Steru L., Thebault J and Conquet P. Performing clinical research in France. Insight; 1995. Guinot Ph., Auriche C. and Gunning M. Determination of the pharmacodynamic properties and the clinical and biological safety profile of a natural PAF_antagonist extracted from the Ginkgo biloba tree : ginkgolide B. Drug Invest., 1994. Duchier J., Auriche C. and Guinot Ph. Effect of BN 50730, a specific PAF_antagonist, on PAF_induced platelet aggregation and skin response in healthy human volunteers. Drug invest., 1994;8(2): 95_103

Projects

☐ Coordinator/Rapporteur for about 25 EU scientific advicse per year in SAWP, EMA Clinical Safety and efficacy Guidelines, EU assessment reports for marketing authorisation applications (> 50) ☐ Séminars (benefit/risk, drug development in small populations/rare diseases/paediatry/diagnostic agents) in « Ecole des Mines », in neuro_pediatry university level, as part of the tweening with Serbian Agency, speaker in several scientific and regulatory affairs congresses.

Memberships

_. Since January 2023: chairman of the Rhumato_Immuno Working party and Rapporteur for the Cystic Fibrosis Guideline revision/Chairman of the Cystic Fibrosis drafting group _ Since March 2010: Member of the CHMP Scientific Advice Working party (SAWP) at the European Medicines Agency (EMA) _ 2005 to 2010: Delegate at the CHMP Efficacy Working party (EWP) in EMA (efficacy and safety guidelines on drug development, all therapeutic fields) _ 2005 to 2010: Member of the Gene Therapy Working Party (GTWP) at EMEA _ 2007 to 2010: Delegate in EURS (EU electronic submission), TIGS (telematic implementation group), member of the TIGes subgroup « harmonisation topic group »

Other Relevant Information

_2004 : First at the intrance exam « Pharmacien Inspecteur de Santé Publique » (Health policies, regulatory, legislation) _ 1996 : admission to the intrance exam for Health economics in Ecole Supérrieure Commerce de Paris (ESCP)