Curriculum Vitae

Personal information

Francesca Alteni

Work experience

1. Employer: Italian Medicines Agency
   - Start date: 112008
   - End date:
   - Position: Pharmacist_GMP Inspector
   - Activities:

     Currently performing GMP inspections in Italy and abroad (EMA, WHO, request by Companies for GMP certificate renewal).

     Conducted routine cGMP inspections at more than 400 manufacturing sites (all dosage forms, sterile and not sterile, included homeopathic products, blood products and blood establishments). Inspections at active substance manufacturers: manufacturing and purification of extracted substance from animal source (heparin and ursodeoxycholic acid, etc.), vaccines, production by cell culture/fermentation, and monoclonal antibodies and small molecules synthesis.

     Assessor of SMF, VMP and GMP-Follow Up activities, revision of GMP guidelines, technical documents and site variations submitted by API and dosage forms manufacturers.

     New inspectors training.

     GMP expert for Scientific Advice.

     Participation in joining inspections with FDA inspectors.

     WHO consultant as GMP Inspector for inspection at vaccines and snake antivenoms manufacturers since 2019.

     Included in EMA “Experts database”.
   - Country: Italy
2. Employer: Italian Medicines Agency
   - Start date: 052007
   - End date: 112008
   - Position: Quality Assessor
   - Activities:

     Quality Assessor: assessment of national variations (type IA_IB_II)
   - Country: Italy

Education and training

1. Subject: University of Perugia
   - Start date: 072007
   - End date:
   - Qualification: Diploma of Specialist in Hospital Pharmacy
   - Organisation: The logistic of a hospital warehouse.
   - Country: Italy
2. Subject: University of Ferrara
   - Start date: 032001
   - End date:
   - Qualification: Diploma of Specialist in Cosmetic Science and Technology
   - Organisation: Studies conducted to scale_up, optimize and validate the manufacturing process of cosmetic products.
   - Country: Italy
3. Subject: University La Sapienza
   - Start date: 031995
   - End date:
   - Qualification: Degree in Pharmaceutical Chemistry and Technology
   - Organisation: Synthesis, structural and conformational studies of peptides (cicloline peptide A).
   - Country: Italy

Additional information

Publications

Projects	Participation in the following international working groups: - IWG drafting group on the Guidelines on Good Manufacturing Practice for Advanced Therapy Medicinal Products. (2016); -TAIEX project (Technical Assistance and Information Exchange Instrument of the European Commission): Study Visit on Inspection in medicinal products and manufacturing of active substances, clinical trials and pharmacovigilance system, beneficiary: Bosnia and Herzegovina Regulatory Agency (2019); -IWG drafting group on the Guideline on the responsibilities of the sponsor with regard to handling and shipping of investigational medicinal products for human use under Good Clinical Practice and Good Manufacturing Practice (EMA/202679/2018 Committees and Inspections Department, 2021); -Workshop on Risk-benefit assessment of snake antivenoms (as relator), Dubai, 3-4 December 2024.
Memberships	
Other Relevant Information	