



Curriculum Vitae

Personal information **Marialessia Marvulli**

Work experience

1. Employer: AIFA_
 - Start date: 112023
 - End date: present
 - Position: Full time contract _ GMP Inspector
 - Activities: _ conducting/leading domestic GMP inspection for medicinal products, with autonomy; inspection follow up; GMP Certificate issuance; Manufacturing Authorisation issuance
2. Employer: AIFA_Signal Management Office
 - Start date: 022021
 - End date: 112023
 - Position: Full time contract _ Signal Management Unit
 - Activities: _ Monitoring National Adverse Drug Reactions (ADRs) and literature; _ Monitoring EVDAS/eRMR monitoring; _ Assessment Report of regulatory documents; _ Risk_benefit evaluation; _ Update of Product Information _ Renewal Assessment
 - Country: Italy
3. Employer: Di Renzo Regulatory Affairs
 - Start date: 052020
 - End date: 012021
 - Position: Apprenticeship contract
 - Activities: For client companies I have dealt with: _ preparation of applications for variation and renewal of medicinal products with national, decentralized and mutual recognition MA; _ preparation of price and reimbursement dossiers; _ of marketing authorization applications with national procedure; _ of parallel import; _ preparing Due Diligence (DD), dossiers in eCTD format; _ communication of shortages of medicines to AIFA; _ gap analysis evaluations; _ support client companies in the activities of Medical Scientific Information (IMS).
 - Country: Italy
4. Employer: Di Renzo Regulatory Affairs
 - Start date: 102019
 - End date: 052020
 - Position: Intern
 - Activities: For client companies I have dealt with: _ preparation of applications for variation and renewal of medicinal products with national, decentralized and mutual recognition MA; _ preparation of price and reimbursement dossiers; _ of marketing authorization applications with national procedure; _ of parallel import; _ preparing Due Diligence (DD), dossiers in eCTD format; _ communication of shortages of medicines to AIFA; _ gap analysis evaluations; _ support client companies in the activities of Medical Scientific Information (IMS).
 - Country: Italy
5. Employer: Eguaglia (formerly Assogenerici)
 - Start date: 042019
 - End date: 102019
 - Position: Intern
 - Activities: Internship in the technical_scientific, industrial production and quality area. I supported the contact person of the Area for the implementation of the directive on falsified medicines in the European Union; the evaluation of the problems reported by the member companies / Executive Council and analysis with the competent authorities; the study and analysis of current legislation and related support to member companies.
 - Country: Italy
6. Employer: AGENAS _ AIFA agreement project
 - Start date: 102018
 - End date: 122018
 - Position: Project worker AGENAS _ AIFA agreement project
 - Activities: At the Post Authorization Procedures Office, I assessed requests for variation and renewal of the MA for medicinal products for the safety profile
 - Country: Italy
7. Employer: AIFA
 - Start date: 072017
 - End date: 072018
 - Position: Intern
 - Activities: At the Risk Management Measures Office, support in the assessment of the Risk Management Plan, the Risk Minimization Measures, the applications for Renewal of the MA of medicinal products, the analysis of the National Pharmacovigilance and Eudravigilance Network.
 - Country: Italy

Education and training

1. Subject: Post graduated in Clinical Pharmacology and Toxicology
 - Start date: 2022
 - End date: present
 - Qualification: Post graduated in Clinical Pharmacology and Toxicology
 - Organisation: Università La Sapienza - Rome
 - Country: Italy
2. Subject: School of Management of Univesity LUM Jean Monet

- Start date: 2017
 - End date: 032018
 - Qualification: Postgraduate specialisation diploma in management, organization and marketing of clinical and community pharmacy. Stock management.
 - Organisation: School of Management of Univesity LUM Jean Monet
 - Country: Italy
3. Subject: Università degli Studi di Bari "Aldo Moro"
- Start date: 102011
 - End date: 072016
 - Qualification: Degree in Pharmacy
 - Organisation: Università degli Studi di Bari "Aldo Moro"
 - Country: Italy

Additional information

Publications

Projects

Memberships

Other Relevant Information

_ Very good communication skills, including clearly expressing ideas and understanding others _ Excellent knowledge of computer systems based on Windows and Mac using software such as Microsoft Office (full package including Word, Excel, Exchange, Publisher, PowerPoint and Access). Using and managing databases (Office 241, Queries, Front End AIFA, BDUF, National Network Of Pharmacovigilance, EVDAS _ EudraVigilance, EudraGMP, CTS Client, Leaflet Database AIFA).