



Curriculum Vitae

Personal information **Marco Di Girolamo**

Work experience

1. Employer: AIFA Italian Medicines Agency
 - Start date: 2009
 - End date: 092011
 - Position: Pharmacovigilance Assessor
 - Activities: _ Monitoring National Adverse Drug Reactions (ADRs) and literature; _ Monitoring EVDAS; _ Assessment Report of regulatory documents; _ Risk_benefit evaluation; _ Update of Product Information _ Renewal Assessment _ PSUR Assessment _ PSUSA Assessment _ Writing/Editing/Translation of Safety Communication Documents
 - Country: Italy
2. Employer: AIFA Italian Medicines Agency
 - Start date: 102011
 - End date:
 - Position: Pharmacovigilance manager
 - Activities: _ Monitoring National Adverse Drug Reactions (ADRs) and literature; _ Monitoring EVDAS; _ Assessment Report of regulatory documents; Risk_benefit evaluation; _ Update of Product Information _ Collaboration with other European Agencies and EMA _ RMP Assessment _ Educational Material Assessment _ Renewal Assessment _ PSUR Assessment _ Writing/Editing/Translation of Safety Communication Documents
 - Country: Italy

Education and training

1. Subject: Università degli Studi di Urbino
 - Start date: 102002
 - End date: 032009
 - Qualification: Degree Pharmacist
 - Organisation: Pharmacology, legislation, pharmaceutical technology.
 - Country: Italy

Additional information

Publications

Natural rubber (latex) and risk of allergy or anaphylactic reactions. Abstract ISOP_ Drug Safety 2013–Title: Analysis of the ADRs of medication error in EudraVigilance: impact of the implementation of the new European Union pharmacovigilance legislation. Abstract ISOP_ Drug Safety 2010, Vol 33, No 10 (pp.805_962) – 86 Title: Drug Induced Rhabdomyolysis: Reports from the Italian Database of Spontaneous Reporting of Adverse Drug Reactions.

Projects

Joint Action SCOPE WP8

Memberships

Other Relevant Information

_ Competent in GMP, ICH, CTA's, Regulatory agencies requirements (AIFA, EMA, FDA). _ 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, NSIS, BDUF, National Network Of Pharmacovigilance, EVDAS _ EudraVigilance, EPITT European Pharmacovigilance Tracking Tool, EudraGMP, CTS Client, Leaflet Database AIFA).