



Curriculum Vitae

Personal information **Monica Martinez Redondo**

Work experience

October 2022 - September 2025

PRAC Alternate member, AEMPS

- Representing the Spanish view on proposed regulatory actions by the European regulatory network
- Presenting results on the critically assessed safety procedures concerning rapporteur appointed drugs
- Training and mentoring on pharmacovigilance tools and procedures
- Updating and implementing pharmacovigilance guidelines and process improvement initiatives

December 2019 - September 2025

Pharmacovigilance and pharmacoepidemiology assessor, AEMPS

- Assessment and monitoring of safety of medicines within the area of oncology, dermatology, rheumatology, immunology, haematology, respiratory and advance medicinal products (ATMP)
- Assessment of safety related procedures (PSUR, RMP, signal, PASS, safety variations, referrals, new marketing applications, renewals and scientific advice)

October 2016 - December 2019

Pharmacovigilance scientist, Roche

- Overseeing the quality of the individual case safety report (ICSR) process
- Implementing the process of safety reporting in marketing departments
- Maintaining ICSR reporting guidelines in line with regulatory requirements (pregnancy reporting and blind breaks processes)

Education and training

2018 - 2019

Master in Pharmacoepidemiology and Pharmacovigilance

Alcala de Henares University

2009 - 2014

Pharmacy degree

Alcala de Henares University

Additional information

Publications

Projects

- GVP V Risk Management Plan revision 3
- Best practice for PSUR assessment
- REVAMP project
- Network capacity building
- PRAC Drafting group on the risks of dependence and addiction of opioids
- PRAC AI activities
- SmPC advisory group

Memberships

Other Relevant Information