

PERSONAL INFORMATION **Inmaculada Corrales**

WORK EXPERIENCE

- December 2017- Present** **Quality Pharmacovigilance System Coordinator**
Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) (Spain)
- Responsible for the development, implementation and improvement of the Quality System within the Pharmacovigilance System.
- Liaison with the IT Department for the development and implementation of applications to enhance pharmacovigilance activities.
- Liaison with the Quality Unit of the AEMPS contributing to the overall Quality System of the Agency.
- Pharmacovigilance Training Coordinator.
- Coordinator of the Spanish Safety Committee (CSMH)
- Member of the CMDh Pharmacovigilance WP
- Member of the HARP group
- October 2011-August 2017** **Pharmacovigilance Assessor - PhV-QMS Coordinator**
Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) (Spain)
Member of the European PhV Audit Facilitation Group (since 2015)
Member of the European PSUR-Repository Advisory Group (2014-2016)
Active participation in European Joint Action SCOPE (starting November 2013)
Pharmacovigilance QMS Coordinator (since 2013)
Pharmacovigilance SOPs development and implementation (since 2011).
Quality management of the safety evaluation reports and process improvement (since 2008)
Assessment of product safety dossiers (DDPS, PSUR, RMPS, safety variations, others) (since 2006)
Spanish representative in the PSUR-worksharing group (since 2007)
- June 2011-October 2011** **Scientific and Technical Support**
Instituto de Salud Carlos III working for Quality Agency of the Spanish National Health System Ministry of Health (Spain)
Providing support to: design dissemination, implementation, assessment and follow-up of the Health National Strategies focused on Rare Diseases.
Management of databases and information related to Rare Diseases.
Collaboration in several international projects related to National Health Strategies: The European Joint Action on Rare diseases
- July 2006-March 2011** **Pharmacovigilance assessor (since 2006)**
Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) (Spain)
Pharmacovigilance SOPs development and implementation (since 2011).
Assessment of product safety dossiers (DDPS, PSUR, RMPS, safety variations, others) (since 2006)
Quality management of the safety evaluation reports
Spanish representative in the PSUR-worksharing group (since 2007)
- December 2001-May 2005** **Senior Outsourcing and Contracting Manager**
Pfizer S.A. (European Biometrics Centre, Pfizer World Wide Development Operations) (Spain)
Leading a group of Outsourcing Consultants and a Biometrics Project Coordinator.

Developing Request For Proposals, negotiating prices with CROs and establishing contracts
Conducting CRO evaluation visits, organizing Kick off and lessons learned meetings
Monitoring the CRO performance in conjunction with the biometrics teams
Managing the partnership with selected CROs. Acting as the key point contact between CRO, Clinical and Biometrics teams

October 1996-November 2001 **Senior Clinical Auditor /European Clinical Quality Assurance**
Pfizer Ltd (UK) (United Kingdom)
Coordinating the European System Audits Local Plan: Managing resources, reporting process and generating an agreed action plan.
Evaluating and ensuring the quality of clinical development projects: Review of procedures, data and facilities and working with colleagues to develop corrective action steps
Proficiency in different types of audits: systems, central laboratory, investigator site, database, regulatory documents, Pre-contract CRO, CRO oversight, facilities, Phase I Units.
Providing GCP and other country regulations advice within the audit group, other departments and investigators meetings.

February 1994-October 1996 **Clinical Research Associate**
Pfizer S.A. (Spain) (Spain)
Monitoring GCP and regulatory compliance by the study sites on Clinical Trials Phase I, III b and IV from initiation to closure.
Organizing the kickoff meeting between the Project team and investigators and review meeting during the conduct of the study.
Providing support to Marketing, Training and Pharmacovigilance Departments

June 1993-February 1994 **Contract Researcher**
Consejo Superior de Investigaciones Científicas (C.S.I.C.) (Spain)
Basic research on cell-membrane-receptor

July 1989-August 1990 **Lecturer in Microbiology**
University School for Nurses, Physiotherapists and Podiatrics (Spain)
Teaching microbiology in the University school of Nurses: theory and practice.

EDUCATION AND TRAINING

June 2020-June 2020 **Lean Management - Officer**
TCM - Tecnicas de Control Metrologico SL (Spain)
Techniques for improvement of quality, productivity, services and cost.
Mapping the value stream, creating a better flow in work processes and development of continuous process improvement culture.
Change management.

October 2016-October 2016 **Management of software development projects. Coordinator**
CAS Training SL. (as part of the AEMPS ongoing training program) (Spain)
- Management principles of the software development project
- Understanding software development from IT perspective to better liaise with an IT group within a common project.
- How to liaise with the IT team to achieve the software needed for the PhV activities: identification of responsible people, clear objectives and scope, planning, monitoring the progress, finalizing the project and further follow-ups for improvements.

October 2014-June 2015 **Six Sigma, Technician**
SEAS, Estudios Superiores Abiertos S.A.U., Zaragoza (Spain)
Six Sigma Methodology, Process optimization, identification and implementation of organizational improvements.

October 2011-October 2012 **Master's degree in Epidemiology**
Universidad Autónoma de Madrid (Spain)

	Methods in Epidemiology, the use of different statistical packages, scientific publication skills
2005- 2006	European Expert on Quality Management Agencia Española para la Calidad (AEC) (Spain) Design and implementation of quality systems.
August 1990-February 1993	Post-doctoral graduate Academic Zuikenhuis Utrecht University, The Netherlands (Netherlands) Post-doctoral research, scientific publications, oral explanations,
August 1986-June 1990	PhD Universidad Complutense de Madrid (Spain) Scientific (basic) research, scientific publication skills, oral explanations
September 1981-July 1986	Bachelor in Science Universidad Complutense de Madrid () Science Degree

ADDITIONAL INFORMATION

Expertise	<p>Software development for PhV activities.</p> <p>Pharmacovigilance systems: quality management system</p> <p>Pharmacovigilance assessments (Scientific Assessor for the EMA, 2007-ongoing)</p> <p>Epidemiology methods and research</p> <p>Pharmacovigilance systems quality management</p> <p>Outsourcing and contracting - CROs focused on biometrics</p> <p>Clinical auditing</p>
Publications	<p>17. Catala-Lopez F, CORRALES I, de la Fuente Honrubia, Gonzalez Bermejo D, Martin-Serrano G, Montero D, Macias Saint-Gerons D. Risk of thromboembolism with thrombopoietin receptor agonists in adult patients with thrombocytopenia: An updated systematic review and meta-analysis of randomized controlled trials. <i>Med Clin (Barc)</i>. 2015 doi:10.1016/j.medcli.2015.03.014</p> <p>16. CATALA-LOPEZ F.,CORRALES I., MARTIN-SERRANO G., TOBIAS A., CALVO G. Risk of thromboembolism treated with thrombopoietin receptor agonists in adult patients with thrombocytopenia: systematic review and meta-analysis of randomized controlled trials" <i>Med Clin (Barc)</i> 2012; 139(10):421-9</p> <p>15. CORRALES I.,WEERSINK A.J.L.,VERHOEF J.,KESSEL K.P.M. "Serum independent binding of LPS to human monocytes is trypsin sensitive and does not involve CD14". <i>Immunology</i> 1993; 80:84-9</p> <p>14. MATO R.,CORRALES I.,PRIETO J. "Influence of lomefloxacin on phagocytic and killing activity of macrophages and neutrophils". <i>J Antimicrob Chemother</i> 1992; 30:558-9</p> <p>13. CORRALES I.,LIMA A.,SUAREZ A.,ANDRE J.,PRIETO J. "Effects of cefotaxime on antibody-producing cells of mice spleen. <i>J Chemother</i> 1989; (Suppl.4):604-5</p> <p>12. CORRALES I.,SUAREZ A.,LIMA A.,BALLESTERO S.,GOMEZ-LUS M.L.,PRIETO J. "Clindamycin and tetracyclin as immunomodulating agents: An in vivo study". <i>Drugs Clin Exp Research</i> 1989; 25(9):409-16</p> <p>11. CORRALES I.,SUAREZ A.,SANZ R.,MATO R.,GOMEZ-LUS M.L.,PRIETO J."Comparative effect of three beta-lactam antibiotics on anti-PC direct plaque forming cells". <i>Drug Clin Exp Research</i> 1989; XV(10):491-6</p> <p>10. PRIETO J.,MINGUEZ F.,ORTEGA P.,CORRALES I.,LEDESMA V. "Comparative study of the effects of roxythromycin and other macrolides on the polymorphonuclear white cells in vitro". <i>Brit J Clin Pract</i> 1988; 42(Suppl.55):38-9</p> <p>9. GOMIS M., BARBERAN J.,RAMON J.,CORRALES I.,PRIETO J. "Modelos experimentales en osteomielitis". <i>Rev Esp Quimioter</i> 1993</p> <p>8. CORRALES I. "Tazobactam / piperacilina". <i>Rev Esp Quimioter</i> 1992; 5(4):357-9</p> <p>7. GOMEZ-LUS M.L.,MINGUEZ F.,CABRONERO M.J.,ANDRE J.,CORRALES I.,RAMOS C.PRIETO J. "Etiologia microbiana de la infeccion del canal dental". <i>Rev Esp Microbiol Clin</i> 1992; 181-4</p> <p>6. CORRALES I.,SUAREZ A.,MATO R.,MARTIN M.,NIQUE R.,MINGUEZ F. "Influence of rifampicin and chloranphenicol an antibody-forming cells response". <i>Rev Esp Quimioter</i> 1991; IV:199-204</p>

5. CORRALES I.,MATO R., LIMA A.,NIQUE R.,MINGUEZ F.,GOMEZ-LUS M.L. "In vitro effect of ciprofloxacin and ofloxacin on C. albicans interactions with human neutrophils". Rev Esp Quimioter 1990; 3(1):75-82
4. CORRALES I.,BALLESTERO S.,LIMA A.,MINGUEZ F.,GOMEZ-LUS M.L. "Clindamicyn effect on macrophage and lymphocyte functions: Experimental study". Rev Esp Qumioter 1989; 2:56-60.
3. MINGUEZ F.,GOMEZ-LUS M.L.,REDONDO M.,CORRALES I.,PRIETO J. "Efecto postantibiotico de amoxicilina y netilmicina sobre cultivos puros y asociados de S. aureus y E. coli". Rev Esp Quimioter 1989; 419-24
2. MINGUEZ F.,CORRALES I.,GOMEZ-LUS M.L.,LURUENA S.,PRIETO J."Efecto postantibiotico de cinco antimicrobianos sobre S. aureus y E. coli. Rev Esp Quimioter 1989; 2(2):161-73.
1. MINGUEZ F.,REDONDO M.,APARICIO P.,CORRALES I.,PRIETO J. "Efecto postantibiotico de amoxicilina y acido clavulanico sobre E. Coli y S. aureus." Rev Esp Microbiol Clin 1988; 3:551-7

- Projects**
- o Member of the Spanish Presidency Team (2010) - Development of the European Pharmacovigilance Legislation
 - o Spanish representative in the European Joint Action SCOPE (Strengthening Collaboration for Operating Pharmacovigilance in Europe), under Work Package 7.

Memberships Spanish Society of Epidemiology (member since 2011)

Other Relevant Information Mother tongue: Spanish
Other languages: English (Proficiency), Italian (Elementary)