Curriculum Vitae

PERSONAL INFORMATION

Sol Ruiz

WORK EXPERIENCE

1998- 2000 **Biotechnology Section Head**
Institute of Health Carlos III, Madrid (Spain)

2000- 2008 **Biotechnology, Head of Service**
Spanish Medicines Agency (Spain)

January 2013-April 2013 **Instructor in Pharmaceutical Biotechnology**
European University of Madrid (UEM) (Spain)

2008- 2015 **Biotechnology and Advanced Therapies, Head of Sector**
Spanish Medicines Agency (Spain)

2015- Present **Head of Biologics, Biotechnology and Advanced Therapies**
Spanish Medicines Agency (Spain)

EDUCATION AND TRAINING

1982- 1987 **BSc Science, Biology**
Universidad Complutense Madrid (UCM) (Spain)

1988- 1989 **MSc Biology**
Universidad Complutense Madrid (UCM) (Spain)

1991- 1994 **PhD Immunology**
Fundación Jiménez Díaz, Madrid (Spain)

1994- 1997 **PhD Immunology**
University of California Irvine (UCI) (United States)

ADDITIONAL INFORMATION

Expertise: Biologics - Biotechnology - Biosimilars - Advanced Therapies - Transmissible spongiform encephalopathies

Publications:

Ruiz, M.S., F. Carbonell, C. Platas, A. Padilla (1990). An enzyme-linked antiglobulin test for assessing anti-D immunoglobulin preparations. Biologicals 18: 89-95.

Marques, G., L.C. Anton, E. Barrio, A. Sanchez, S. Ruiz, F. Gavilanes, F. Vivanco (1993). Arginine residues of the globular regions of human C1q involved in the interaction with immunoglobulin G. Journal of Biological Chemistry 268: 10393-10402.

Anton, L.C., S. Ruiz, G. Marques, E. Barrio, A. Sanchez, F. Vivanco. (1994). C3 binds with similar efficiency to Fab and Fc regions of IgG immune aggregates. European Journal of Immunology 24: 599-604.

Ruiz, S., A. Henschen-Edman, A.J. Tenner (1995). Localization of the site on the complement component C1q required for the stimulation of neutrophil superoxide production. Journal of

Biological Chemistry 270: 30627-30634.

Nepomuceno, R.R., S. Ruiz, M. Park, A.J. Tenner (1999). C1qRP is a heavy O-glycosylated protein involved in the regulation of phagocytic activity. Journal of Immunology 162: 3583-3589.

Ruiz, S., A.H. Henschen-Edman, H. Nagase, A.J. Tenner (1999). Digestion of C1q collagen-like domain with matrix MMPs-1, -2, -3 and -9 further defines the sequence involved in the stimulation of neutrophil superoxide production. Journal of Leukocyte Biology 66: 416-421.

Ruiz, M.S. (1999). Biotechnological Products and Gene Therapy. What are we talking about? Methods and Findings in Experimental and Clinical Pharmacology 21, suppl.B: 7.

MA Serrano, S. Ruiz (2004): "Terapia Genica." Chapter 8 (Parte VII. Farmacologia Clinica) of the book Medicina Interna Vol. I y II, 2ª Ed., J. Rodes, J. Guardia. Ed. Masson.

D.A. Fraser, S.S. Bohlson, N. Jasinskiene, N. Rawal, G. Palmarini, S. Ruiz, R. Rochford and A.J. Tenner (2006). C1q and MBL, components of the innate immune system, influence monocyte cytokine expression. Journal of Leukocyte Biology 80:107-116.

Timon M, Ruiz S. (2007). Bases regulatorias de los medicamentos de origen biotecnologico. Revista Espanola de Economia de la Salud. 2007; 6 (6): 346-351.

JS Robertson, J Blumel, K Brorson, A Groner, TR Kreil, S Ruiz, H Willkommen (2009). Meeting report Virus & TSE safety forum 2008. Biologicals 37(5): 345-354.

The Committee for Advanced Therapies (CAT) (2010). Challenges with advanced therapy medicinal products and how to meet them. Nature Reviews Drug Discovery 9, 195-201.

Committee for Advanced Therapies and CAT Scientific Secretariat (2010). Use of unregulated stem-cell based medicinal products. Lancet 376(9740):514.

S Ruiz, F Abad-Santos (2010). Regulacion y Evaluacion de los ensayos clinicos de terapia celular. Medicina clinica (Barc) 135(1): 35-39.

S Ruiz, G Calvo (2011). Similar biological medicinal products: Lessons learned and challenges ahead. Journal of Generic Medicines 8: 4-13.

S Ruiz, E Sulleiro, G Calvo (2011). Medicamentos biotecnologicos: from dream to reality. FAP 9(3)

S Ruiz, A Groner (2012). Pharmaceuticals. Chapter III.5 of the book Decontamination of prions. D Riesner, J-P Deslys, M Pocchiari and R Sommerville (Eds.). Dusseldorf University Press.

F Salmeron, A Portela, S Ruiz, M Timon, S Lopez, R Hernaez, I Perez, A. Sagredo (2012). La importancia de la regulacion y el control de vacunas en la erradicacion de enfermedades virales. Chapter of the book Erradicacion y control de las enfermedades producidas por virus, R Najera Morrondo (coordinador). Ed. Centro de estudios Ramon Areces.

CK Schneider, JJ Borg, F Ehmann, N Ekman, E Heinonen, K Ho, MH Hoefnagel, RM van der Plas, S Ruiz, AJ van der Stappen, R Thorpe, K Tiitso, AS Tsiftsoglou, C Vleminckx, G Waxenecker, M Welin, M Weise, J-H Trouvin, BMWP & BWP (2012). In support of the European Union biosimilar framework. Nature Biotechnology 30: 745 - 748.

J Camarero, S Ruiz (2012). Cancer immunotherapy products: Regulatory aspects in the European Union. Human Vaccines & Immunotherapeutics 8:9, 1-6.

J Camarero, S Ruiz (2012). Immunotherapy in renal cell cancer: the more the merrier? (editorial). Transl Androl Urol

H Willkommen, J Blumel, K Brorson, D Chen, Q Chen, A Groner, TR Kreil, JS Robertson, M Ruffing, and S Ruiz (2013). Meeting Report: PDA Virus and TSE Safety Forum. PDA J Pharm Sci and Tech 67: 81-97.

AS Tsiftsoglou, S Ruiz, CK Schneider (2013). Development and Regulation of Biosimilars: Current Status and Future Challenges. BioDrugs 27 (3): 203-211.

Y Lopez-Pua, S Ruiz, G Calvo (2013). Medicamentos biosimilares. Un concepto europeo exportado con exito a todo el mundo. BioPharmaceuticals 2 (3): 20-30.

S. Ruiz (2014): "Normativa legal europea sobre medicamentos biosimilares", chapter of the book "Libro blanco de los medicamentos biosimilares en Espana: calidad sostenible", Fundacion Gaspar Casal.

AS Tsiftsoglou, JH Trouvin, G Calvo, S Ruiz (2014). Demonstration of Biosimilarity, Extrapolation of Indications and Other Challenges Related to Biosimilars in Europe. BioDrugs 28 (6): 479-486.

Salmikangas et al. (2015): Manufacturing, characterisation and control of cell-based medicinal products: challenging paradigms towards commercial use. Regen Med 10: 909-922.

A. Alonso-Gutierrez, P. Diaz-Ramosa, E. Sulleiro-Avendano, M. de Miguel-Maranon, M.E. Padilla-Gallego, A. Sancho-Lopez, S. Ruiz-Antunez, C. Prieto-Yerro (2015). Contribucion de la Agencia Espanola de Medicamentos y Productos Sanitarios al Comite Europeo de Evaluacion de Medicamentos de Uso Humano. Rev Clin Esp 215(4): 230-235.

P Salmikangas, M Schuessler-Lenz, S Ruiz et al. (2015). Marketing regulatory oversight of advanced therapy medicinal products (ATMPs) in Europe: The EMA/CAT perspective; chapter in the book "Regulatory aspects of gene therapy and cell therapy products ". MC Galli and M Serabian (eds.). Springer Int Publ.

Willkommen H, Blumel J, Brorson K, Chen D, Chen Q, Groner A, Kreil TR, Ruffing M, Ruiz S, Scott D, Silvester G (2016). Meeting Report: 2015 PDA Virus & TSE Safety Forum. PDA J Pharm Sci Technol. 70(2): 177-88.

S Ruiz (2017). Biosimilars in the EU: Regulatory Guidelines; chapter in the book "Biosimilar Drug Product Development". L Endrenyi, P Declerck and Shein-Chung Chow (eds.). CRC Press, Taylor & Francis Group.

FJ de Abajo, J Albanell, O Delgado Sanchez, K Klein, JV Moreno-Muelas, S Ruiz, MJ Sanz Ferrando, R Thorpe, F Zaragoza (2017). Roundtable on biosimilars: pharmacovigilance, traceability, immunogenicity 15 November 2016, Madrid, Spain. GaBI J 6 (1): 31-37.

Mark Cilia, Sol Ruiz, Peter Richardson, Tomas Salmonson, Anthony Serracino-Inglott, Francesca Wirth, and John Joseph Borg (2017). Quality Issues Identified During the Evaluation of Biosimilars by the European Medicines Agency's Committee for Medicinal Products for Human Use. AAPS PharmSciTech 18: 1-23. (https://doi.org/10.1208/s12249-017-0892-0)

S Ruiz (2018). Terapias avanzadas en patologias musculares, articulares e inmunologicas; chapter 5 in the book "Trastornos osteoarticulares, musculares e inmunologicos". Consejo General de Colegios Oficiales de Farmaceuticos (ed.).

S Ruiz (2019). Regulacion de medicamentos de terapia avanzada en la Union Europea. PharmaTech 41: 52-57.

S Ruiz (2019). Vector characterization & validation (interview). Cell & Gene Therapy Insights 2019; 5(4), 471-475

S Ruiz, M Timon (2019). Autorizacion de biosimilares en la Union Europea. El Medico 1205: 8-11

A Portela, S Ruiz (2021). Evaluacion y autorizacion de vacunas frente a la COVID-19. RIECS 2021, 6, 1; ISSN: 2530-2787

S Ruiz, I Moreno, D Pernas (2021). Retos y oportunidades de las terapias avanzadas. Farmabiotec 000: 46-47.

S Ruiz, I Moreno, D Pernas (2021). Medicamentos de terapia avanzada; ¿el futuro ya esta aqui? Actualidad en Farmacologia y Terapeutica (AFT) 19(4): 240-241

Projects

Memberships

Other Relevant Information

Chair of the Biologics Working Party (BWP) of the EMA (March 2014-present), vice-chair of the BWP (September 2007-March 2014)

Co-opted member of the Committee for Human Medicinal Products (CHMP) of the EMA (September 2007-present)

Spanish/CHMP representative at the CAT (Committee for Advanced Therapies) of the European Medicines Agency (EMA) (January 2009-present)