europass 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.

Marqués, G., L.C. Antón, E. Barrio, A. Sánchez, 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.

Antón, L.C., S. Ruiz, G. Marqués, E. Barrio, A. Sánchez, 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 Génica.” Chapter 8 (Parte VII. Farmacología Clinica) of the book Medicina Interna Vol. I y II, 2ª Ed., J. Rodés, 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.

Timón M, Ruiz S. (2007). Bases regulatorias de los medicamentos de origen biotecnológico. Revista Española de Economía de la Salud. 2007; 6 (6): 346-351.

JS Robertson, J Blümel, K Brorson, A Gröner, 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). Regulación y Evaluación de los ensayos clínicos de terapia celular. Medicina clínica (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 biotecnológicos: from dream to reality. FAP 9(3)

S Ruiz, A Gröner (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 Salmerón, A Portela, S Ruiz, M Timón, S López, R Hernaez, I Pérez, A. Sagredo (2012). La importancia de la regulación y el control de vacunas en la erradicación de enfermedades virales. Chapter of the book Erradicación y control de las enfermedades producidas por virus, R Nájera Morrondo (coordinador). Ed. Centro de estudios Ramón 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 Blümel, K Brorson, D Chen, Q Chen, A Gröner, 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 López-Púa, S Ruiz, G Calvo (2013). Medicamentos biosimilares. Un concepto europeo exportado con éxito 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 España: calidad sostenible", Fundación 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-Gutiérrez, P. Díaz-Ramosa, E. Sulleiro-Avendaño, M. de Miguel-Marañón, M.E. Padilla-Gallego, A. Sancho-López, S. Ruiz-Antúnez, C. Prieto-Yerro (2015). Contribución de la Agencia Española de Medicamentos y Productos Sanitarios al Comité Europeo de Evaluación 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, Blümel J, Brorson K, Chen D, Chen Q, Gröner 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 Zaragozá (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 patologías musculares, articulares e inmunológicas; chapter 5 in the book "Trastornos osteoarticulares, musculares e inmunológicos". Consejo General de Colegios Oficiales de Farmacéuticos (ed.).

S Ruiz (2019). Regulación de medicamentos de terapia avanzada en la Unión 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). Autorización de biosimilares en la Unión Europea. El Médico 1205: 8-11

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)