

PERSONAL INFORMATION

Sol Ruiz

WORK EXPERIENCE

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- 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

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- 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

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- 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 Clínica) 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 Tsiftoglou, 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 Tsiftoglou, 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 Tsiftoglou, 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 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 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.

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)