

Curriculum Vitae

Personal information Karen De Smet

Work experience

1. Employer: Vrije Universiteit Brussel
 - Start date: 101994
 - End date: 032000
 - Position: Research Scientist
 - Activities: _ Collagen gel cultures of rat hepatocytes as in vitro tools in pharmacology _ An evaluation of phase I biotransformation.
 - _ Organisation of Practical Courses in Toxicology (4th year pharmacy students)
 - _ Co_promotor of several theses in Life Sciences (Pharmacists, Bio_Engineers)
 - Country: Belgium
2. Employer: R.E.D. Laboratories
 - Start date: 042000
 - End date: 102002
 - Position: Research Associate
 - Activities: Biotechnological research situated in the field of chronic immune diseases (MS and CFS).
 - Country: Belgium
3. Employer: FPS Health Food chain security and Environment, DG Medicinal Products
 - Start date: 112002
 - End date: 122006
 - Position: Non_Clinical Assessor
 - Activities: Assessment of non_clinical data (pharmacology, pharmacokinetics and toxicology) for the purpose of medicine registration for European and national registration procedures, European and national scientific advices and clinical trial approval.
 - Country: Belgium
4. Employer: Federal Agency for Medicinal and Health Product
 - Start date: 012007
 - End date:
 - Position: Senior Non_Clinical Assessor
 - Activities: Evaluation of the non_clinical efficacy and safety data of human medicinal products for the purpose of marketing authorizations, clinical trials and scientific advice.
 - Country: Belgium

Education and training

1. Subject: Vrije Universiteit Brussel
 - Start date: 101989
 - End date: 061994
 - Qualification: Pharmacist
 - Organisation:
 - Country: Belgium
2. Subject: Vrije Universiteit Brussel, Department of Toxicology, Faculty of Medicine and Pharmacy
 - Start date: 101994
 - End date: 062000
 - Qualification: PhD in Pharmaceutical Sciences
 - Organisation:
 - Country: Belgium
3. Subject: University of Surrey
 - Start date: 062004
 - End date: 042011
 - Qualification: Master in Applied Toxicology
 - Organisation:
 - Country: United Kingdom

Additional information

Publications

- Full papers
1. De Smet K, Callaerts A, Vercruysse A and Rogiers V (1997) Effect of phenobarbital on 7_ethoxycoumarin_O_deethylase and microsomal epoxide hydrolase in collagen gel cultures of rat hepatocytes. Toxicology In Vitro 11, 459_463
 2. Niki T, Rombouts K, De Bleser P, Rogiers V, De Smet K, Schuppan D, Yoshida M, Gabbiani G and Geerts A (1998) A histone deacetylase inhibitor, trichostatin A, suppresses myofibroblastic differentiation of rat hepatic stellate cells in primary culture. Hepatology 29, 858_867
 3. De Smet K, Beken S, Depreter M, Roels F, Vercruysse A and Rogiers V (1999) Effect of epidermal growth factor in collagen gel cultures of rat hepatocytes. Toxicology In Vitro 13, 579_585
 4. Beken S, Slaus K, De Smet K, Depreter M, Roels F, Vercruysse A and Rogiers V (1999) Effect of extracellular matrix composition on the expression of glutathione S_transferase isoenzymes in organotypical hepatocytes cultures. Toxicology In Vitro 13, 571_577
 5. Depreter M, Tytgat T, Beken S, Espeel M, De Smet K, Rogiers V and Roels F (2000) Effects of extracellular matrix on the expression of peroxisomes in primary rat hepatocyte cultures. Journal of Hepatology 32, 381_391
 6. De Smet K, Brüning T, Blaszkewicz, Bolt H, Vercruysse A and Rogiers V (2000) Biotransformation of trichloroethylene in collagen gel sandwich cultures of rat hepatocytes _ cell cycle. Archives of Toxicology, 74,

587_592

7. De Smet K, Cavin C, Vercruysse A and Rogiers V (2001) Collagen type I gel cultures of adult rat hepatocytes as a screening model for cytochrome P450 dependent enzymes. *ATLA* 29, 179_192
8. De Smet K, Loyer P, Gilot D, Vercruysse A, Rogiers V and Guguen_Guillouzo C (2001) Effects of epidermal growth factor on CYP inducibility by xenobiotics, cell cycle progression and caspase activations in collagen I gel sandwich cultures of rat hepatocytes. *Biochemical Pharmacology* 61, 1293_303
9. Beken S, De Smet K, Depreter M, Roels F, Vercruysse A and Rogiers V (2001) Beken S, De Smet K, Depreter M, Roels F, Vercruysse A and Rogiers V (2001) Effects of L_proline on phase I and phase II xenobiotic biotransformation capacities of rat and human hepatocytes in long_term collagen gel cultures. *ATLA* 29, 35_53
10. Roelens S, Herst CV, D'Haese A, De Smet K, Frémont M, De Meirleir K and Englebienne P (2001) G_actin cleavage parallels 2_5A_dependent RNaseL cleavage in peripheral blood mononuclear cells _ Relevance to possible serum_based screening test for dysregulations in the 2_5A pathway. *Journal of Chronic Fatigue Syndrome* 8, 63_82
11. Englebienne P, Herst CV, De Smet K, D'Haese A and De Meirleir K (2001) Interactions between RNaseL ankyrin like domain ABC transporters as a possible origin for pain, ion transport, CNS and immune disorders of chronic fatigue immune dysfunction syndrome. *Journal of Chronic Fatigue Syndrome* 8, 83_102
12. Demettre E, Bastide L, D'Haese A, De Smet K, Herst CV, De Meirleir K, Englebienne P and Lebleu B (2002) Ribonuclease L proteolysis in peripheral blood mononuclear cells of chronic fatigue syndrome patients. *Journal of Biological Chemistry* 277, 35746_51
13. Depreter M, Walker T, De Smet K, Beken S, De Prest B, Kerckaert I, Rogiers V and Roels F (2002) Hepatocyte polarity and the peroxisomal compartment. *The Histochemical Journal* 34: 139_151
14. Depreter M, Walker T, De Smet K, Beken S, Papeleu P, Tytgat T, Espeel M, Rogiers V and Roels F (2003) Modified peroxisomes in primary hepatocyte cultures. *Adv Exp Med Biol* 544: 255_264
15. van der Valk J., Brunner D., De Smet K., Fex Svenningsen Å., Honegger P., Knudsen L.E., Lindl T., Norberg J., Price A., Scarino M.L. and Gstraunthaler G. (2010) Optimization of chemically defined cell culture media – Replacing fetal bovine serum in mammalian in vitro methods, *Toxicology in Vitro*, 24 (4), 1053_63.
16. Weise M., Bielsky M._C., De Smet K., Ehmann F., Ekman N., Heim H._K., Heinonen E., Ho K., Narayanan G., Thorpe R., Vleminckx C., Wadhwa M, and Schneider C. K, (2011), Biosimilars – why terminology matters, *Nature biotech*, 29 (8), 690_3.
17. Weise M., Bielsky M._C., De Smet K., Ehmann F., Ekman N., Heim H._K., Heinonen E., Ho K., Narayanan G., Thorpe R., Vleminckx C., Wadhwa M, Moreau A, Van Aerts L, Kruse N, Gravanis I, Giezen T, Reichmann G and Schneider C. K, (2012), Biosimilars – what clinicians should know, *Blood*, 120 (26), 5111_5117.
18. Van Aerts A., De Smet K., Reichmann G., van der Laan J.W. and Schneider C. K., Animal studies in non_clinical development of biosimilars – a paradigm shift in the EU (2014), *mAbs Journal*, 6(5), 1155_1162.
19. Defays L., Van Malderen K., De Smet K., Verlinden V., Hamdani J., Sawchick J., Dogné J._M. and Dan B. (2015) Paracetamol use during pregnancy and child neurodevelopment, *Dev Med Child Neurol*, 57(8), 718_24.
20. Chapman K., Adjei A., Baldrick P., da Silva A., De Smet K., DiCicco R., Hong S.S., Jones D., Leach M., McBlane J., Ragan I., Reddy P., Stewart D., Sutters A. and Sims J. (2016) Waiving in vivo studies for monoclonal antibody biosimilar development: National and global challenges, *mAbs Journal*, 8(3), 427_45.

Book chapters

1. De Smet K, Beken S, VanhaeckeT, Pauwels M, Vercruysse A and Rogiers V (1998) Isolation of rat hepatocytes. In 'Methods in Molecular Biology vol 107 : Cytochrome P450 Protocols', Phillips IR and Shephard EA, eds, Humana Press, Totowa, pp 295_301
2. Beken S, VanhaeckeT, De Smet K, Pauwels M, Vercruysse A and Rogiers V (1998) Collagen gel cultures of rat hepatocytes : collagen gel sandwich and immobilisation cultures. In 'Methods in Molecular Biology vol 107 : Cytochrome P450 Protocols', Phillips IR and Shephard EA, eds, Humana Press, Totowa, pp 303_309
3. Vanhaecke T, De Smet K, Beken S, Pauwels M, Vercruysse A and Rogiers V (1998) Rat hepatocyte cultures : conventional monolayer cultures and co_cultures with rat liver epithelial cells. In 'Methods in Molecular Biology vol 107 : Cytochrome P450 Protocols', Phillips IR and Shephard EA, eds, Humana Press, Totowa, USA, pp 311_317
4. Depreter M, Walker T, De Smet K, De Prest B and Roels F (2000) Localization of ATP, ADP and AMP in hydrolyzing enzyme activities as a tool to assess hepatocyte polarity. In 'Ecto_AT_Pases and related ectonucleotidases, Vanduffel L and Lemmens R, eds, Shaker Publishing, Maastricht, pp 61_67
5. Englebienne P, Herst CV, Roelens S, D'Haese A, El Bakkouri K, De Smet K, Frémont M, Bastide L, Demettre E and Lebleu B (2002) Ribonuclease L : overview of a multifaceted protein, In 'Chronic fatigue syndrome, a biological approach', Englebienne P & De Meirleir K eds, CRC Press, Boca Raton, FL, USA, pp 17_54
6. Frémont M, D'Haese A, Roelens S, De Smet K, Herst CV and Englebienne P (2002) Immune Cell Apoptosis and CFS, In 'Chronic fatigue syndrome, a biological approach', Englebienne P & De Meirleir K eds, CRC Press, Boca Raton, FL, USA, pp 131_174
7. De Becker P, McGregor N, De Smet K and De Meirleir K (2002) Current Advances in CFS Therapy, In 'Chronic fatigue syndrome, a biological approach', Englebienne P & De Meirleir K eds, CRC Press, Boca Raton, FL, USA, pp 229_264
8. Papeleu P, De Smet K, VanhaeckeT, Henkens T, Vinken M, Elaut G, Snykers S and Rogiers V (2006) Isolation of rat hepatocytes. In 'Methods in Molecular Biology ', vol 320, Phillips IR and Shephard EA, eds, Humana Press, Totowa, USA, pp229_237.
9. De Smet K. and Van Aerts A., Non_clinical studies for biosimilars (2017) Eds Endrenyi, Declerck and Chow,Taylor and Francis.

Projects

Memberships

Member of the Biosimilar Medicinal Products Working Party (BMWP) at EMA, London, UK, 2007-2023

Expert of the Safety Working Party (SWP) at EMA, London, UK, 2003-2022

Expert of the Vaccine Working Party (VWP) at EMA, London, UK, 2009-2016

European Society of Toxicology In Vitro (ESTIV), since 1996 _ Belgian Toxicology Society (BelTox), since 2005

Registered as European Registered Toxicologist, Eurotox, since 2010

Other Relevant Information