Curriculum Vitae

Personal information

Per Spindler

Work experience

1. Employer: Danish Medicines Agency
   - Start date: 112023
   - End date:
   - Position: Head of Unit Toxicology, Pharmacokinetic & Biologics (Non-clinical, Human pharmacokinetics & modelling, Quality assessment of biotech products)
2. Employer: Danish Medicines Agency
   - Start date: 122021
   - End date: 102023
   - Position: Team Manager GCP / GVP / GLP Inspections
   - Activities:
   - Country: Denmark
3. Employer: Region Zealand
   - Start date: 2020
   - End date: 2021
   - Position: Head of Research and Innovation
   - Activities: As the position was part of the regional government responsibilities included: clinical research and personalised medicine, innovation, research libraries, legal aspects of ethics committees, etc.
   - Country: Denmark
4. Employer: University of Copenhagen
   - Start date: 2011
   - End date: 2020
   - Position: Director of Biopeople, Denmarks Life Science Cluster
   - Activities:
   - Country: Denmark
5. Employer: University of Copenhagen
   - Start date: 2005
   - End date: 2011
   - Position: Director of BioLogue
   - Activities:
   - Country: Denmark
6. Employer: BioImage A/S
   - Start date: 2002
   - End date: 2005
   - Position: Vice President Preclinical Development
   - Activities: Biotech_spinn of Novo Nordisk A/S
   - Country: Denmark
7. Employer: H. Lundbeck A/S
   - Start date: 2002
   - End date: 2002
   - Position: Project Management (Corporate)
   - Activities:
   - Country: Denmark
8. Employer: Danish Medicines Agency
   - Start date: 2001
   - End date: 2002
   - Position: Chief Scientific Officer (Chefkonsulent)
   - Activities:
   - Country: Denmark
9. Employer: Novo Nordisk A/S
   - Start date: 2000
   - End date: 2001
   - Position: Regulatory Project Manager
   - Activities:
   - Country: Denmark
10. Employer: Danish Medicines Agency
    - Start date: 1995
    - End date: 2000
    - Position: Chief Scientific Officer (Chefkonsulent)
    - Activities: CHMP Safety Working Party. Preclinical safety assessment: CT, MAA, SA and guidelines.
    - Country: Denmark
11. Employer: H. Lundbeck A/S
    - Start date: 1992
    - End date: 1995
    - Position: Reproduction Toxicologist
    - Activities: Toxicology and pathology.
    - Country: Denmark
12. Employer: Institute for Toxicology
    - Start date: 1992
    - End date: 1992
    - Position: Pathologist
    - Activities:

- Country: Denmark

Education and training

1. Subject: University of Surrey
   - Start date:
   - End date: 2001
   - Qualification: MSc in Applied Toxicology
   - Organisation: Toxicology and safety assessment.
   - Country: United Kingdom
2. Subject: University of Copenhagen
   - Start date:
   - End date: 1991
   - Qualification: DVM, Doctor of Veterinary Medicine
   - Organisation:
   - Country: Denmark
3. Subject: Scandinavian International Management Institute (SIMI). Now: Copenhagen Business School.
   - Start date:
   - End date: 2005
   - Qualification: Executive Master of Business Administration (E-MBA)
   - Organisation: Business administration and leadership.
   - Country: Denmark

Additional information

Publications

Westergaard N, Krogsgaard R and Spindler P (2019) Fremtidens patient skal være en aktiv medspiller i egen sundhed. Ugeskr for Læger, 181/3: 270_271.

Spindler P and Lima BS (2018) Editorial: The European Patients Academy on Therapeutic Innovation (EUPATI) Guidelines on Patient Involvement in Research and Development. Front Med (Lausanne), 5:310.

Spindler P, Bach KF, Schmiegelow M, Bedlington N, Eichler HG (2016) Innovation of medical products: the evolution of regulatory science, research and education. Therapeutic Innovation & Regulatory Science. 50(1), 44_48.

Spindler P, van Cauteren H (2013) Duration of Acute and Chronic Toxicity Testing in Animals (ICH S4A and S4B). In Global Approach in Safety Testing: ICH Guidelines Explained (Eds. van der Laan JW and DeGeorge JJ) Springer (ISBN_10: 1461459494, ISBN_13: 978_146145949)

van Gool AJ, Spindler P, Harpur E, Bounous D, Olejniczak K, van de Klundert FAJ, Haenen B (2008) Biomarkers in the Drug Development Process: report from workshop discussions. Regulatory Toxicology and Pharmacology, 52(2), November: 75_76.

Gluud C, Dejgaard A, Krams M, Wallenbeck I, Tougas G, Wetterslev J, Burman C_F & Spindler P (2008) International Symposium on Adaptive Clinical Trials. Drug Information Journal (Therapeutic Innovation & Regulatory Science). 42(1):93–97.

Webber K & Spindler P (2007) Environmental Assessment for Pharmaceuticals in the United States of America. Drug Information Journal, 41(2): 155_157.

Montfort M, Spindler P, Taylor D, Williams R (2007) Editorial. DIA/HESI/SAPS Conference on Environmental Risk Assessment of Human Medicines (Stockholm 22_23 May 2006). Editorial. Drug information Journal, 40(2):129_131.

Olejniczak K, Williams RT, Kühler T and Spindler P (2007) Use of Data Developed During Drug Development for "Read Across" to Environmental Analysis. Drug Information Journal, 41(2): 201_202.

Spindler P, Montforts M, Olejniczak K, Koschorreck J, Vidal J_M, Johansson A_K, Stemplewski H, Virtanen V, Rönnefahrt I, Kristensen S and van der Laan J_W (2007) Environmental Assessment for Human Medicines in the European Union. Drug Information Journal, 41(2): 149_153.

Kasper P, Kirkland D, Leblanc B, Sjöberg P, Spindler P (2004) Acceptability of Low Levels of Genotoxic Impurities in New Drug Substances. International Journal of Pharmaceutical Medicine, 18(4): 1_3.

Olejniczak P & Spindler P (2004) Environmental Risk Assessment of Medicinal Products for Human Use: Aspects of Its Regulations in the European Union, Canada and United States. Pharmaceuticals in the Environment, pp 269_287. In: Kümmerer K (ed.), Pharmaceuticals in the Environment, Springer_Verlag Berlin Heidelberg.

Spindler P & Seiler J (2002) Quality Management of Pharmacology and Safety Pharmacology Studies. Fundamental and Clinical Pharmacology, 16(2): 83_90.

Laan, van der J_W & Spindler P (2002) In Vivo Rodent Test Systems for Assessment of Carcinogenic Potential. Regulatory Toxicology and Pharmacology, 35(1): 122_125.

Cavagnaro JA & Spindler P (2000) Summary of roundtable discussion on methods for predicating tumourigenicity of immunomodulatory biopharmaceuticals. Human & Experimental Toxicology, 19: 213_214.

Black LE, Green JD, Rener J, Dayan A, Cavagnoaro JA, Spindler P, Bussiere JL, Bouchard P, Inoue T, Thomas PT, Essayn DM, Gillett NA, Hart TK, Hastings K, House RV, Latta D, Liminga U, Treacy G and Wierda D (2000) Safety evaluation of immunomodulatory biopharmaceuticals: can we improve the predictive value of preclinical studies? Human & Experimental Toxicology, 19: 205_207.

Spindler P, Van der Laan J_W, Ceuppens P, Harling R, Ettlin R & Lima BS (2000) Carcinogenicity Testing in the European Union: a Workshop Report. Drug Information Journal, 34: 821_828.

Spindler P, Sjöberg P & Knudsen L (2000) First Exposure in Man: Toxicological Considerations. Pharmacology & Toxicology, 86: [Supplement I] 8_12.

Knudsen LE, Spindler P & Renneberg J (1999) Preclinical/toxicological evaluation of drugs. Ugeskr. Laeger. 161 (30): 4312_4313.

Knudsen LE, Rau H & Spindler P (1999) Preclinical Safety Assessment of Clinical Trials in Denmark. Pharmacology & Toxicology, 85 (Supplement 1): 60.

Spindler P & Madsen C (1992) Subchronic Toxicity Study of Peppermint Oil in Rats. Toxicology Letters, 62: 215_220.

Projects

2007-2020: Active Member of Public-private Consortia of the EU Innovative Medicines Initiative (IMI):

PHARMATRAIN, training in pharmaceutical medicine (2007_2012),

SAFESCIMET, training in safety sciences (2007_2019)

and EUPATI, patient training (2012_).

2007-2014: Chair of the Board of SHARE's Cross Faculty PhD Initiative (Synergies between Human and Animal Research), University of Copenhagen.

Memberships

2020-2021: Member of the Regional Research Council of Region Zealand.

2020-2021: Member of the Board, Trial Nation (Denmark).

2020-2021: Member of the Board of the Biomedical Design Fellowship Programme (Novo Nordisk Foundation).

2018-2020: Member of the Board, Council of European BioRegions asbl. (CEBR).

2016-Present: Fellow of the DIA (Drug Information Association).

2016-Present: Associate Editor for Regulatory Science, Frontiers in Medicine (publication of Frontiers Media S.A.).

2015-2020: Chair of the Cluster Excellence Expert Group (CEEG), Berlin.

2015-2020: Partner and Member of the Scientific Advisory Board, Copenhagen Centre for Regulatory Science (CORS), University of Copenhagen.

2007-2016: Board Member of the Drug Information Association (DIA), President 2014-2015.

2007-2015: Member of the Scientific Advisory Board at Faculty of Pharmacy, University of Lisbon, the Research Institute for Medicines and Pharmaceutical Sciences.

Other Relevant Information