



Curriculum Vitae

Personal information **Esther Werner**

Work experience

1. Employer: National Veterinary Institute for Pharmaceuticals and Immunologicals, Berlin
 - Start date: 091986
 - End date: 121990
 - Position: Scientist and assessor in veterinary immunological department
 - Activities: _ Scientific assessment of new applications, variations and renewals of immunological veterinary medicinal products _ Batch testing of virus vaccines and diagnostics _ Clinical research in development of immunologicals
 - Country: Germany
2. Employer: Paul_Ehrlich_Institut (Federal Institute for Vaccines and Biomedicines), Langen,
 - Start date: 011991
 - End date:
 - Position: Acting Head of Vet Division (since 10/2018); Head of section Assessment of IVMPs
 - Activities: Regulatory and scientific work in pre_marketing assessment (assessor for new applications) and post marketing surveillance (variations, renewals, pharmacovigilance) of immunological veterinary medicinal products _ Assessment of quality, safety and efficacy of IVMPs _ Involved in CVMP scientific advices and in centralised, MRP, DCP and national marketing authorisation procedures _ Assessment of monoclonal antibodies, cell based products and other biotechnological products _ Batch testing of vaccines, immunsera and tuberculin _ Adverse reaction and PSUR assessment _ Research projects on alternatives to animal testing in vaccine quality control, development of methods to replace/refine animal experiments and validation of batch potency tests
 - Country: Germany

Education and training

1. Subject: Humboldt_University of Berlin
 - Start date: 091981
 - End date: 071986
 - Qualification: Diploma of Veterinary Medicine
 - Organisation: studies of veterinary medicines
 - Country: Germany
2. Subject: Humboldt_University of Berlin
 - Start date: 121987
 - End date: 121991
 - Qualification: Doctor of Veterinary Medicine (Dr. med. vet.)
 - Organisation: Veterinary Medicine – veterinary virology and microbiology
 - Country: Germany

Additional information

Publications

Jungbaeck C, Werner E, von Messling V. Regulatory aspects of the development, licensing, and availability of immunological veterinary products. *berl. münch. tierärztl. wschr.* 128 (2015), 473_477. Roos K, Werner E, Lössner H. Multicopy integration of mini_Tn7 transposons into selected chromosomal sites of a Salmonella vaccine strain. *Vol. 8, Issue 1. Jan 2015. 177–187.* Balks E, Gyra H, Kobe B, Cussler K, Werner E. Development and validation of a serological potency test for the release of Leptospira vaccines _ Requirements in the European Union. *Biologicals. 2013 Sep;41(5):325_9. doi:10.1016/j.biologicals.2013.06.011. Epub 2013 Aug 1.* Balks E, Wolf C, Loessner H, Werner E. Towards in vitro potency testing of inactivated erysipelas vaccines. *Dev Biol (Basel).* 2012;134:37_44. Roszkopf, U., Noeske, K., Werner, E. (2005) Efficacy demonstration of tetanus vaccines by double antigen ELISA. *Pharmeuropa Bio 2005.1, S. 31_51* Roszkopf, U., Noeske, K., Werner, E. (2005) Replacement of the in vivo neutralisation test for efficacy demonstration of tetanus vaccines ad us. vet. *ALTEX 2005/3, S. 169_174* Roszkopf_Streicher, U., Volkers, P., Noeske, K., Werner, E. (2004) Quality Assurance of *C. perfringens* Epsilon Toxoid Vaccines _ ELISA Versus Mouse Neutralisation Test. *ALTEX, Suppl. Linz 03/2004: 65_69* Esther Werner Vaccines for Minor Species and Minor Indications _ Current Situation and Concepts in Germany as well as Feasible Approaches for the Future _ Authorities' View _ Proceedings, International Veterinary Meeting on Consideration of Alternative Licensing Procedures for Vaccines for Minor Species, Minor Indications and Autogenous/Autologous Products, 29. – 31. Oktober 2003, Langen Roszkopf_Streicher, U., Volkers, P., Werner, E. (2003) Control of Clostridium perfringens Vaccines using an Indirect Competitive ELISA for the Epsilon Toxin Component. *Pharmeuropa Bio 2003_2: 91_96* A. Hoffmann, E. Werner, A. Mergel and K. Cußler (2003) Unerwünschte Wirkungen nach Applikation immunologischer Arzneimittel beim Tier. *Deutsches Tierärzteblatt. 12: 1246_1251* Cußler, K., Borrmann, E. und Werner, E. (2002) Fortschritte beim Ersatz von Tierversuchen in der Qualitätskontrolle von Clostridien_Impfstoffen. *Dtsch. Tierärztl. Wschr. 109: 172_173* Luick, K., Gottschaldt, J., Schulze, F., Werner, E., Erler, W., Borrmann, E., (2002) Anwendung des Toxin_Bindungs_Inhibitionstests zur Wirksamkeitsprüfung von Clostridium _novyi_Typ_B_Alphatoxoid_Impfstoffen. *Dtsch. Tierärztl. Wschr. 109: Ebert, E.; Öppling, V.; Werner, E.; Cussler, K. (1999) Development and prevalidation of two different ELISA systems for the potency testing of Clostridium perfringens β _ and ϵ _toxoid containing veterinary vaccines. *FEMS Immunology and Medical Microbiology 24: 299_311* Ebert, E.; Öppling, V.; Werner, E.; Cussler, K.; (1999) Ersatz von Tierversuchen bei der Wirksamkeitsprüfung von veterinärmedizinischen Clostridien_Immunpräparaten. *Tierärztliche Umschau 54: 28_33* Elvira Ebert, Volker Öppling, Esther Werner und Klaus Cußler Optimierung und Etablierung von serologischen Methoden für die Wirksamkeitsprüfung von Immunglobulinen gegen Clostridium tetani_Toxid Optimisation and establishing of serological methods for the potency testing of immunglobulins against Clostridium tetani_toxin (*Altex Archiv Suppl. 1/98*) Elvira Ebert, Entwicklung und Prävalidierung von Alternativmethoden zur Wirksamkeitsprüfung*

von Clostridium perfringens_Impfstoffen http://www.zet.or.at/ALTEX/issues/1998/supp/S_98ebert1.htm Elvira Ebert, Manuela Kusch, Volker Öppling, Esther Werner und Klaus Cussler Serologische Wirksamkeitsprüfung von Clostridium perfringens_betatoxidhaltigen Veterinärinpfstoffen _ eine Alternative zum gesetzlich vorgeschriebenen Mäuseneutralisationstest (Altex Archiv Suppl. 2/96)

Projects Research projects on alternatives to animal testing in vaccine quality control, development of methods to replace/refine animal experiments and validation of batch potency tests

Memberships DE CVMP Member or alternate since 12/2011 Chair of CVMP IWP since 12/2013 Member VICH BQM_EWG Member ADVENT group (until 2020) Member OEG Bacteriophages Member of the BSP_SC at EDQM Member CVMP SAWPV DE Alternate CVMP 12/2011 to 01/2020 Chair of CMDv 11/2005 to 09/2014 European Working groups (e.g. CMDv/VMRFG, CTS subgroup, CTS usergroup, Pharmacovigilance WP vet, Variation TF, ESS group)

Other Relevant Information