

PERSONAL INFORMATION **Esther Werner**

WORK EXPERIENCE

- September 1986-December 1990 **Scientist and assessor in veterinary immunological department**
National Veterinary Institute for Pharmaceuticals and Immunologicals, Berlin (Germany)
- 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
- January 1991- Present **Acting Head of Vet Division (since 10/2018); Head of section Assessment of IVMPs**
Paul-Ehrlich-Institut (Federal Institute for Vaccines and Biomedicines), Langen, (Germany)
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, immunosera 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

EDUCATION AND TRAINING

- September 1981-July 1986 **Diploma of Veterinary Medicine**
Humboldt-University of Berlin (Germany)
studies of veterinary medicines
- December 1987-December 1991 **Doctor of Veterinary Medicine (Dr. med. vet.)**
Humboldt-University of Berlin (Germany)
Veterinary Medicine veterinary virology and microbiology

ADDITIONAL INFORMATION

- Expertise** Regulatory veterinary medicine
Assessment of immunological veterinary medicinal products and other biological products
Laboratory vaccine testing
Clinical trials for veterinary vaccines
Veterinary pharmacovigilance (immunologicals)
- Publications** Jungbaeck C, Werner E, von Messling V.
Regulatory aspects of the development, licensing, and availability of immunological veterinary products. *berl. munch. tierarztl. wschr.* 128 (2015), 473-477.
Roos K, Werner E, Lossner 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.

Roskopf, U., Noeske, K., Werner, E. (2005)

Efficacy demonstration of tetanus vaccines by double antigen ELISA. *Pharmeuropa Bio* 2005.1, S. 31-51

Roskopf, 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

Roskopf-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

Roskopf-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 und K. Cussler (2003)

Unerwünschte Wirkungen nach Applikation immunologischer Arzneimittel beim Tier. *Deutsches Tierarztlebl.* 12: 1246-1251

Cussler, K., Borrmann, E. und Werner, E. (2002)

Fortschritte beim Ersatz von Tierversuchen in der Qualitätskontrolle von Clostridien-Impfstoffen. *Dtsch. Tierarztl. 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-Alpha-toxoid-Impfstoffen. *Dtsch. Tierarztl. Wschr.* 109:

Ebert, E.; Oppling, V.; Werner, E.; Cussler, K. (1999)

Development and prevalidation of two different ELISA systems for the potency testing of *Clostridium perfringens* ss- and -toxoid containing veterinary vaccines. *FEMS Immunology and Medical Microbiology* 24: 299-311

Ebert, E.; Oppling, V.; Werner, E.; Cussler, K.; (1999)

Ersatz von Tierversuchen bei der Wirksamkeitsprüfung von veterinärmedizinischen Clostridien-Immunpräparaten. *Tierärztliche Umschau* 54: 28-33

Elvira Ebert, Volker Oppling, 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 Pravalidierung 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 Oppling, Esther Werner und Klaus Cussler
Serologische Wirksamkeitsprüfung von Clostridium perfringens-beta-toxoidhaltigen
Veterinärinpfstoffen - eine Alternative zum gesetzlich vorgeschriebenen Mausneutralisationstest
(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 since 02/2020
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