

### Course outline

The technologies for diagnostic testing for infectious and other hazards in live animals, animal products, food and animal feed are rapidly developing and so are mathematical methods used in validation and interpretation of test results. The course will provide insight in and practical knowledge of both the classical and the new emerging statistical methods used for validation and interpretation of diagnostic tests. The course topics will be illustrated using data sets related to animal health and zoonoses, which are representative for a wide range of applications in veterinary sciences, veterinary public health and related areas.

# **Course topics**

- Concepts and international standards of test validation for infectious animal diseases (presented by Dr. Diaz, OIE)
- Concepts and international standards of method validation in toxicology
- Diagnostic performance measures
- Study design, sample size, validation strategies
- Receiver operating characteristic analysis
- Meta-analysis of diagnostic tests
- Selection of cut-off values
- Predictive values and likelihood ratios
- Testing at the herd (aggregate) level and pooled testing
- Multiple tests and testing strategies
- Test validation and interpretation without gold-standard (latent class analysis)

# **Target group**

The course is tailored to address the necessary competencies of professionals dealing with validation or certification of diagnostic methods in veterinary and other sciences. Practitioners from academic, commercial or regulatory institutions and postgraduate students in areas including but not limited to veterinary medicine, microbiology,

laboratory science, risk assessment, epidemiology and statistics will benefit from the presented proven approaches to problem-solving. Basic skills and interest in mathematical methods are assumed.

### Course fee

The course fees are 270 EUR per participant and cover

- three-day course participation
- electronic copy of course materials including slides, software and further reading materials
- refreshments during morning and afternoon coffee breaks
- light lunch on three course days
- course dinner on 14 May 2008

# **Hands-on training**

Computer-based methods will be presented and applied in practical sessions. Note that a PC will NOT be provided for the practical exercises. Participants are invited to bring their own notebooks and will be assisted to implement all methods on their own hardware.

### Software and resources

Please visit <a href="www.bfr.bund.de/cd/3866">www.bfr.bund.de/cd/3866</a> for further information about the course including links to software downloads, back-ground information, etc.

### Course dinner

Enjoy a breathtaking view of the old and new City of Berlin at night. A tour and course dinner will be organised on the evening of the first course day (14 May). The price for guests not registered for the course is 75 EUR per person and includes

- bus transport
- visit and welcome drink at a scenic location in the City of Berlin
- course dinner

# Registration and deadlines

Please register online at www.bfr.bund.de/cd/3866

The registration fee (270 EUR) and an additional fee for the course dinner (75 EUR) for any guest not registered to the course must be paid to the account indicated in the online registration form. Note that the limited number of course places will be allocated in the order of receipt of registration and payment.

The deadline for online course registration, receipt of payment for course fees and reservation of the hotel room is **15 April 2008**.

### Lecturers

Dr. Matthias Greiner is a scientist in the unit of Epidemiology, Biostatistics and Mathematical Modelling at the Federal Institute for Risk Assessment (BfR) in Berlin. As veterinarian and applied statistician he gained his expertise in the area of diagnostic testing as head of a serological laboratory (Freie Universität Berlin), head of the Animal Health Section and the International EpiLab (OIE Collaborative Centre for Research and Training in Population Animal Health Diagnosis and Surveillance Systems, Copenhagen). His current research interest is in quantitative risk assessment. He is also member of the Animal Health and Animal Welfare Panel of the European Food Safety Authority (EFSA).

Dr. Ian Gardner is a Professor of Epidemiology in the School of Veterinary Medicine at the University of California, Davis. His research interests include diagnostic test evaluation, risk analysis for livestock diseases and food safety, development of methods for certification of pathogen

freedom in animal populations, and the epidemiology and transmission of Johne's disease in cattle. His collaborative research on diagnostic testing with Dr. Wes Johnson from the University of California, Irvine involves application of Bayesian methods to the evaluation of test accuracy, prevalence estimation and surveillance problems for animal diseases. He is an author of more than 200 peer-reviewed publications and has served on many national and international committees, panels and review teams.

Dr. Manfred Liebsch is Head of the BfR unit Centre of Alternative Methods to Animal Experiments (ZEBET). By academic training biologist (parasitology, biochemistry, microbiology), he works since 1980 here as a toxicologist. He headed the unit "Pharmacodynamics" in a Contract Research Organisation. At ZEBET, he is mainly responsible for participating in, co-ordinating of, or managing of successful Validation Studies of alternative toxicological testing methods at the national or international level. He is expert in national and international Working Groups performing Peer Reviews of new testing methods and validation studies, e.g. the Scientific Advisory Committee of ECVAM (European Centre for the Validation of Alternative Methods), the OECD Test Guide-lines Programme or ISO TC 194 (Biological Evaluation of Medical Devices).

Dr François Diaz works at the OIE Central Office in the Scientific and Technical Department. He is mainly in charge of the secretariat for the OIE procedure for Validation and Certification of Diagnostic Assays, a position he has held since 2005. A French national, Dr François Diaz was awarded a degree of Doctor of Pharmacy at the University of René Descartes (Paris V) in 2002. He also obtained a Masters degree in International Law and law of International Organizations at the University of Panthéon - la Sorbonne (Paris I) in 2004.

## Venue

Bundesinstitut für Risikobewertung (BfR) Federal Institute for Risk Assessment

Location Marienfelde – Room 146 Diedersdorfer Weg 1, 12277 Berlin www.bfr.bund.de



# Contact

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# OBEWERTUN Щ

# Advanced methods for validation of diagnostic tests



**Short Course** 

Berlin, Germany

14 – 16 May 2008



