ORGANIZERS

Dr. Gustav Könnecker,
Fraunhofer ITEM

Dr. Kristin Krome,
Fraunhofer ITEM

Dr. Gerd Maack,
German Federal Environment Agency (UBA)

Dr. Markus Simon,
Fraunhofer IME

CONTACT PERSONS

Dr. Kristin Krome
Phone +49 511 5350-329, Fax -335
kristin.krome@item.fraunhofer.de

Dr. Gustav Könnecker
Phone +49 511 5350-328, Fax -335
gustav.koennecker@item.fraunhofer.de

Fraunhofer Institute for Toxicology and
Experimental Medicine ITEM, Chemical Risk Assessment
Nikolai-Fuchs-Straße 1, 30625 Hannover, Germany

VENUE (workshop and hotel)

Maritim Grand Hotel
Friedrichswall 11
30159 Hannover, Germany

HOW TO GET THERE

For detailed travel instructions to the workshop venue please refer to the website: www.item.fraunhofer.de/workshop

FEES (workshop, accommodation, catering)

€ 950.00
This rate includes workshop attendance, instruction materials, accommodation and catering.

Please register via Internet by August 15, 2013:
www.item.fraunhofer.de/workshop

After receipt of your registration you will receive a registration confirmation/invoice.

Cancellations received until four weeks prior to the registration deadline (August 15, 2013) will be cancelled free of charge. Cancellations received less than four weeks prior to this date will be charged a processing fee of € 50.00. For cancellations received after the deadline, the participant will be required to pay the full registration fee.

All cancellations must be received in writing. Substitute participants can be named without additional costs.

If the course is cancelled by the organizers for whatever reason, paid fees will be refunded in full. Further recourse is excluded.

Fraunhofer
ITEM

FRAUNHOFER INSTITUTE FOR
TOXICOLOGY AND EXPERIMENTAL
MEDICINE ITEM

ENVIRONMENTAL RISK ASSESSMENT OF VETERINARY MEDICINAL PRODUCTS

WORKSHOP
OCT 22-24, 2013
Hannover

IN COOPERATION WITH

Fraunhofer IME

Umwelt Bundes Amt
for our Environment




OBJECTIVES

The aim of this advanced training course is to inform about the legal and regulatory requirements of an Environmental Risk Assessment (ERA) of Veterinary Medicinal Products (VMP) at national and international levels.

TOPICS

The workshop will start with an introduction to the idea of Environmental Risk Assessments for VMP including the general legal and ecological background. The general preparation of a Phase I and Phase II ERA will be presented. Physico-chemical, fate and ecotoxicity studies will be introduced with specific focus on execution and validity criteria. This will be followed by exposure calculations and the determination of risk quotients.

The course will finish with specific group discussions and practical trainings, from more general questions to introducing relevant exposure models such as "FOCUS". Non-standard and higher-tier testing may be discussed. Themes and break-out groups will be tailored according to specific requests of the participants. After the training course, there will be the possibility to deal with individual questions regarding the ERA. Experts from the German Federal Environment Agency (UBA) and two Fraunhofer institutes will be available to help with problems of individual tests and of the ERA.

TARGET GROUPS

Representatives of the pharmaceutical industry, consultants, contract researchers, and any other persons involved in ERA of veterinary medicines. Persons new in this field are welcome.

PREVIOUS KNOWLEDGE

This advanced training course is for all interested persons. The course will start with an introduction to the idea of an ERA, so previous knowledge is not required.

TEACHING METHODS

The individual sessions will start with lectures, followed by general discussions. The second part of the advanced training course will be dominated by exemplary case studies, starting with more general questions, but specific individual questions will also be welcome.

INSTRUCTION MATERIAL

Participants will receive backup materials at the beginning of the course and a certificate at the end.

PARTICIPANTS

Seating is limited to 60 participants.

PROGRAM

Tuesday, October 22, 2013

13.00 Check-in, registration, welcome coffee
14.00 Official welcome, introduction and logistics
14.15 Talks:
- Veterinary medicinal products in Europe
- Regulatory background
- Ecological background
- Phase I assessment
- Phase II assessment

18.30 End of talks
19.30 Dinner

Wednesday, October 23, 2013

08.30 Talks:
- Physico-chemical studies
- Fate studies
- Exposure calculations
- Aquatic studies
- Terrestrial studies
- Risk characterization

12.30 Lunch
14.30 Risk mitigation
PBT assessment
ERA in consortia
15.00 Exemplary case studies I (break-out groups)
18.30 End of talks and sessions
19.30 Dinner

Thursday, October 24, 2013

08.30 Talks
09.00 Exemplary case studies II (break-out groups)
12.00 Closing session / individual questions
13.00 Lunch
14.00 Departure

INVITED SPEAKERS

Dr. Gesine Hahn	German Federal Office of Consumer Protection and Food Safety (BVL)
Dr. Dieter Hennecke	Fraunhofer IME
Prof. Dr. Manfred Kietzmann	University of Veterinary Medicine Hannover, Foundation
Dr. Michael Klein	Fraunhofer IME
Dr. Gustav Könnecker	Fraunhofer ITEM
Dr. Kristin Krome	Fraunhofer ITEM
Dr. Michael Lammers	ERAVET
Dr. Gerd Maack	German Federal Environment Agency
Dr. Jörg Römbke/ Mr. Adam Scheffczyk	ECT Oekotoxikologie GmbH
Dr. Christian Schlechtriem	Fraunhofer IME
Mr. Jens Schönfeld	German Federal Environment Agency
Dr. Susanne Schwonbeck	Fraunhofer ITEM
Dr. Markus Simon	Fraunhofer IME
Dr. Andrea Wenzel	Fraunhofer IME