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VENUE

CRC HANNOVER

Clinical Research Center Hannover
Feodor-Lynen-Strasse 15
30625 Hannover, Germany

For detailed travel instructions to the workshop venue, please refer to the course website.

FEE

€ 490
Includes training, instruction materials, coffee breaks and lunch.

REGISTRATION AND PAYMENT

Registration via the course website will be open until September 25, 2017. Registration will be closed before this date, if the maximum number of participants is reached.

Please note that the registration process is a double opt-in process – make sure you confirm your registration. After successful registration, you will receive a registration confirmation and an invoice. Invoices will be sent once the minimum number of participants is reached.

Cancellations received before August 14, 2017 will be accepted free of charge. Cancellations received between August 14 and September 25, 2017 will be charged € 50 processing fee. For cancellations received after September 25, 2017, 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.

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

https://www.item.fraunhofer.de/eraworkshop

Fraunhofer ITEM

FRAUNHOFER INSTITUTE FOR TOXICOLOGY AND EXPERIMENTAL MEDICINE ITEM

ENVIRONMENTAL RISK ASSESSMENT OF VETERINARY MEDICINAL PRODUCTS

Update, recent developments and implications

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2nd Workshop
November 9, 2017
CRC Hannover

IN COOPERATION WITH

Federal Office of Consumer Protection and Food Safety

OBJECTIVE

This update course aims to inform interested parties on the current state of regulatory requirements of environmental risk assessment (ERA) of veterinary medical products (VMP) as part of their authorization in the European Union. Lectures and presentations will address important legal as well as practical aspects.

COURSE OVERVIEW

The course will give an overview on the concept of environmental risk assessment of VMP as part of the authorization process in the EU including the general legal and ecological background. The general structure of the stepwise Phase I and Phase II approach will be presented. Details on the required studies will be given and discussed with a specific focus on subsequent exposure and risk characterization (based on PEC and PNEC derivation). Recent developments in regulation and upcoming decisions (e.g. on non-standard and higher-tier testing, PBT assessment, RMMs) will be addressed with specific respect to their regulatory and practical implications.

This course is designed for all interested professionals such as representatives of the pharmaceutical industry, consultants and contract researchers involved in the environmental risk assessment of veterinary medicines. Delegates new in this field are welcome.

The course will be held in English language. Participants will receive backup material and a certificate of attendance. Seating is limited to 50 participants.

PROGRAM

Thursday, November 9, 2017

08.30 Registration, welcome coffee

09:00
- Legal framework: ERA as part of the EU authorization of VMP
- Basic requirements: physical-chemical studies, fate and effect studies for aquatic and terrestrial compartment
- Exposure and risk characterization

13.00 Lunch

14.00
- PBT assessment
- Risk mitigation
- Upcoming decisions in the legal framework – what can we expect?
- Discussions

17.00 End of course

SPEAKERS

Dr. Gesine Hahn	Federal Office of Consumer Protection and Food Safety (BVL)
Dr. Monika Herrchen	Fraunhofer IME
Dr. Gustav Könnecker	Fraunhofer ITEM
Dr. Michael Lammers	ERAvet
Dr. Jörg Römbke	ECT Oekotoxikologie GmbH
Dr. Christian Schlechtriem	Fraunhofer IME
Dr. Susanne Schwonbeck	Fraunhofer ITEM
Prof. Dr. Georg von Samson-Himmelstjerna	Freie Universität Berlin

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