"Research on innovative drug with an immunostimulating effect in animals" UDA-POIG.01.03.01-28-108/12-01
Project co-financed by the European Union under the European Regional Development Fund

Ref. 2d/safety studies/potential risks to the environment resulting from the use of VMP

Request for proposal

Please, to submit an offer concerning **conducting environmental studies (environmental risk assessment)** for immunostimulatory pharmaceutical veterinary medicinal product **for pigs and cattle**.

Project title: *Research on innovative drug with an immunostimulating effect in animals*

Environmental risk assessment studies are conducted to determine the effects of a substance on environmental parameters and must be conducted and reported in accordance with Good Laboratory Practice.

Offer concerns studies mentioned below:

Freshwater Algal growth inhibition – OECD 201
Freshwater Fish acute toxicity – OECD 203
Freshwater *Daphnia* immobilization –OECD 202
Earthworms, Chronic/Reproduction toxicity test – OECD 222
Terrestrial plants test Seedling Emergence and Seedling Growth Test – OECD 208 (6 plants representing six different families with four dicotyledonous and two monocotyledonous species,)
Nitrogen Transformation test – OECD 216 (28 days, 2 concentrations)
Soil Adsorption/Desorption (C14) – OECD 106 5 soils
Aerobic Transformation in Soil (C14) – OECD 307, 4 soils with identification of potential degradation products representing each >10% of total radioactivity – hypothesis: 4 compounds to identify-)
Optional: Biodegradation water (C14) – OECD 309
Optional: Biodegradation in cattle and pig manure (C14) – EMA/CVMP/ERA/430327/2009
Physicochemical (Kow, pKa, water solubility) – OECD 107, 112, 105

Requirements:

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Studies must be conducted and reported in compliance with GLP (GLP Certificate is required) and in accordance with OEDC guidelines or other specified guidelines (eg. EMA)

Experience in:

- toxicological investigations for veterinary medicinal products (a few different EU countries veterinary medicinal products applications, especially environmental risk assessment studies)
- preparing study design, protocols, study coordination, study follow-up and monitoring

An offer must contain:

- details of the study outline and the study price, and potential start dates.
- Description of laboratory experience in requested area and general information about laboratory

Please send an offer in 7 days after receiving and offer request to:

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Research, Development and Regulatory Affairs Manager
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Please immediately confirm receipt of this request - e-mail in the form of responses to its content.