BIO-TOX
Toxicologie – Ecotoxicologie
Sécurité Produits et Environnement
www.bio-tox.fr

Environmental Risk Assessment (ERA)

In the framework of a full market approval application of medicinal products

THE EVALUATION OF MEDICINAL PRODUCTS.

Directive 2001/83/EC, amended by Directive 2004/27/EC, requires the taking into account of the environmental impact of drugs when assessing the risk-benefit balance of medicinal products.

An environmental risk assessment is required for the full market approval application for all new medicine.

The environmental risk assessment considers emissions related to the use, storage and disposal of drugs.

Manufacturing is excluded from this assessment.

Directives 2001/83/EC and 2004/27/EC divide the environmental risk assessment into to phases :

- *Phase I : estimation of exposure*
- *Phase II : environmental fate and effects analysis*

Within this frame, Bio-Tox can carry out the Environmental Risk Assessment for the full market approval of your medicinal product (Module 1.6), according to the EMEA's guideline on the environmental risk assessment of medicinal products for human use.

Bio-Tox takes care of :

⇒ *The evaluation of the existing studies and the identification of missing data ;*
⇒ *The monitoring of needed GPL studies (OCDE Guidelines / ISO standards);*
⇒ *The identification the laboratories where to perform the studies ;*
⇒ *The writing of the environmental risk assessment of your full market approval application (module 1.6).*

Bio-Tox can also carry out custom risk assessments.

Contact :

Dr. Marine Saint-Denis
m.saint-denis@bio-tox.fr
+33 557 990 169

BIO-TOX
Toxicologie – Ecotoxicologie
Sécurité Produits et Environnement
18, impasse de la fauvette, 33400 Talence
Tel : +33 557 990 169 – Pble : +33 630 068 065 - : ph.soler@bio-tox.fr