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Environmental Risk Assessment (ERA)

An Environmental Risk Assessment (ERA) is an environmental risk evaluation for human medicinal products. It assesses whether and to what extent active substances or their metabolites enter the environment after use – for example, through excretion or improper disposal. Some substances are persistent, bioaccumulative, or toxic and can therefore have long-term effects on aquatic and terrestrial ecosystems.

Target Group

All applicants for a new marketing authorisation for human medicinal products in the EU require an ERA. Since the revised EMA guideline came into force in 2024, there are no longer any exemptions. An ERA may also be required for Type II variations or line extensions.

What does an ERA include?

The assessment follows a stepwise approach:

- **Phase I:**
  The potential environmental risk of the active substance is evaluated. The predicted environmental concentration (PEC) in surface water is calculated. If the PEC is ≥ 0.01 µg/L, a Phase II assessment is required.
- **Phase II:**
  In-depth studies on ecotoxicity, degradation and distribution in surface water, groundwater or sewage treatment plants.

Our Service

We provide ERA assessments conducted in accordance with the **EMA guideline** (EMEA/CHMP/SWP/4447/00 Rev. 1-Corr.) using a two-phase procedure.

The assessments are carried out by **specialised toxicologists** with extensive experience in conducting ERAs in line with current regulatory requirements.

Information required for a non-binding quote

- Name and address of the company
- Name of the medicinal product/active substance
- Name of the country in which the product is intended to be sold
- Maximum daily dose

Your non-binding quote

Request your non-binding quote for one or more Environmental Risk Assessments now!

› get your quote